

An analysis of the government-
industry relationship in the British
pharmaceutical price regulation
scheme

Michael David Sedgley

PhD Thesis

London School of Economics and
Political Science
University of London

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Abstract

This thesis examines the government-industry relationship in the regulation of pharmaceutical prices in the UK, through the pharmaceutical price regulation scheme (PPRS). It takes a broadly institutionalist approach to explaining and understanding the design and persistence of this idiosyncratic form of pharmaceutical cost control. Broad factors such as the global nature of the pharmaceutical industry and its industrial importance in the British economy, as well as the conception of the British state's role, the place of parliament in framing regulation and the organisation of the executive all play a part in underpinning the PPRS as a co-operative policy community between government and industry for the control of medicine costs to the NHS. Key to the dynamics of this sector of policy is the interplay between the industrial policy and health policy concerns of government, in a unique relationship in which government is both the primary sponsor and customer of the industry.

The thesis develops a theoretical framework and five working hypotheses for the study of three cases of policy development in the PPRS during the 1990s. The empirical research is undertaken through interviews with key players across industry, government and parliament, as well as the analysis of government and industry documents and legislation.

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Appendix 1: Interviewees

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Abbreviations

ABPI	Association of the British Pharmaceutical Industry
AFR	Annual Financial Return
APPG	All-Party Parliamentary Group
BMA	British Medical Association
CHI	Commission for Health Improvement
CPA	Committee of Public Accounts
DHSS	Department of Health and Social Security
DOH	Department of Health
DTI	Department of Trade and Industry
EFPIA	European Federation of Pharmaceutical Industry Associations
EGA	European Generic Medicines Association
FDI	Foreign Direct Investment
GDP	Gross Domestic Product
GMS(R)	General Medical Services (Regulations)
GSK	GlaxoSmithKline
GP	General Practitioner
HMT	Her Majesty's Treasury
IID	International and Industry Division
IPB	Indicative Prescribing Budget
M&A	Mergers and Acquisitions
MCA	Medicines Control Agency
MOH	Ministry of Health
MOT	Margin of Tolerance
MPI	Medicines, Pharmacy and Industry Division
MPOG	Medicines Policy Oversight Group
MS	Multiple Sclerosis
MSD	Merck Sharp & Dohme
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NIS	National Innovation Systems
NCE	New Chemical Entity
NME	New Medical Entity
OECD	Organisation for Economic Co-operation and Development
OTC	Over-the-Counter Medicine
PAC	Public Accounts Committee
PACT	Prescribing Analysis and Cost
PCG	Primary Care Group
PCT	Primary Care Trust
PICTF	Pharmaceutical Industry Competitiveness Task Force
POM	Prescription Only Medicine
PPA	Prescription Pricing Authority
PPRS	Pharmaceutical Price Regulation Scheme
R&D	Research and Development
ROC(E)	Return On Capital (Employed)
ROR	Rate of Return
ROS	Return On Sales
SHA	Strategic Health Authority
VPRS	Voluntary Price Regulation Scheme
WDTA	Wholesale Drug Trades Association

Introduction

The core of pharmaceutical price regulation in the UK consists of the Pharmaceutical Price Regulation Scheme (PPRS), which has existed in one form or another since 1957. This is a voluntary scheme that regulates the level of profits that pharmaceutical companies may earn on their business with the National Health Service (NHS). Its terms are negotiated periodically between the Department of Health (DOH) and the Association of the British Pharmaceutical Industry (ABPI).

The PPRS is unique and contrasts sharply with other European systems of price regulation, which between them take one of several different 'off-the-shelf' approaches to pharmaceutical cost control. In all European countries, cost containment in health care has been a major determining factor in the design of pharmaceutical price control. Yet public policy in pharmaceuticals is also driven by industrial policy concerns. The industry is a major 'high-tech' employer and a significant contributor to the science base of many countries. Its investments are highly sought after.¹ The aims of cost containment and those of industrial policy (or industry promotion) pull in opposite directions and the balance between the two has defined the politics of pharmaceutical price regulation in the UK for several decades.

It is the purpose of this thesis to explain the persistence of the PPRS through the 1990s. Structural and institutional factors are identified which underpin the PPRS 'policy community' and which are responsible for its persistence and its change.

This thesis asks why a system so idiosyncratic has persisted in the UK, alone among European countries, which face similar dual policy pressures in this field. It proposes that the structural context of pharmaceutical policy has combined with institutional aspects of the British polity and its bureaucratic and administrative organisation to entrench the PPRS and underpin its

¹ Burstall, M.L. and Dunning, John (1985), p.189.

persistence as a system of supply side regulation. An interplay between industrial policy and the procurement of medicines has defined policy in a way that seeks to balance the two important concerns of the government.

In answering the question as to why a co-operative, non-statutory system of regulation has been at the heart of the economic regulation of the pharmaceutical industry and has represented and enabled the successful co-existence of government and industry aims for so long, the thesis takes a broadly institutionalist approach to analysing the PPRS. It invokes institutionalist and policy-community approaches to the analysis of policy making to create an analytical framework for approaching the question. From this framework five hypotheses are proposed, which arise from the examination of the structural and institutional context of policy making.

A key feature of government-industry relations in the sector, which has been both a cause and an outcome of the PPRS, has been the persistence of a co-operative relationship between government and industry, expressed through a co-operative policy community. As an abiding feature of the government-industry relationship in this sector, the five hypotheses between them suppose that this co-operative relationship is fundamental to the development of policy in the sector and the desire to maintain it a central delimitation of the choices both sides make in their strategies for the development of policy and their negotiations over it with each other.

Three policy developments in the 1990s are examined in order to test the hypotheses: the negotiation of the scheme in 1999; the passage of the Health Bill in 1999, which contained specific clauses related to the PPRS; and the negotiation of the scheme in 1993. The studies are undertaken through interviews with the key individuals in government, industry and parliament who have been responsible for policy development, as well as through the analysis of relevant government, industry and parliamentary documents.

Interviewees were contacted on the basis of their role in the 1999 PPRS negotiations and the passage of the Health Bill. The large majority of those contacted agreed to interview. Some notable exceptions proved not to be critical to the research outcomes and alternative means of on-the-record evidence of their views were sourced. These consisted of one industry participant in particular and two government ministers, Baroness Jay and Baroness Hayman, none of whose roles and positions could not be deduced from the interviews that were undertaken or from on-the-record sources.

Interviews were semi-structured: structured around the five working hypotheses, as well as enabling broader and less structured input from all interviewees on the nature and determinants of policy development.

Chapter 1 analyses the structural context of pharmaceutical policy making: the place of the pharmaceutical industry in the British economy, the UK as a location for global pharmaceutical investment, the changing shape of corporate structure in the sector, the supply and demand sides of the pharmaceutical market and the implications of all these factors for politics and policy.

Chapter 2 analyses the functioning of the PPRS in detail, as well as the administrative architecture of regulation and other mechanisms of cost containment in the health care sector which complement the scheme.

Chapter 3 sets out the theoretical framework and develops an institutionalist and policy community approach with which to examine the PPRS and related policy. The five working hypotheses are developed from both the structural context set out in Chapter 1 and the theoretical analysis undertaken here.

Chapters 4, 5 and 6 analyse in detail the three instances of policy development in the 1990s, against which the hypotheses are judged.

Chapter 7 is the conclusions to the thesis.

Chapter 1

The structural context of pharmaceutical price regulation

- 1.1 The pharmaceutical industry in the UK economy
- 1.2 The UK as a pharmaceutical industry location
- 1.3 Corporate structure and consolidation
- 1.4 Pharmaceutical supply and demand
- 1.5 Political implications and policy
- 1.6 Overview of the UK pharmaceuticals market

This chapter analyses the structural context of pharmaceutical industry regulation: the importance of the industry in the UK economy and the importance of the UK for the global industry, as a research base; how the shifting global corporate structure of the sector interplays with and affects these concerns; and the nature of the supply and demand sides of the sector in the purchase of medicines for the NHS. These factors underpin both the aims and resources of government and industry in arriving at agreement on the PPRS.

The relationship between the UK economy and the pharmaceutical industry is distinctive. For the UK economy the industry is of particular importance and the industry regards the UK as an important location for its operations. These two points are interrelated but the former is also related strongly to the relative position of the pharmaceutical industry among other industries in the British economy.

1.1 The pharmaceutical industry in the UK economy

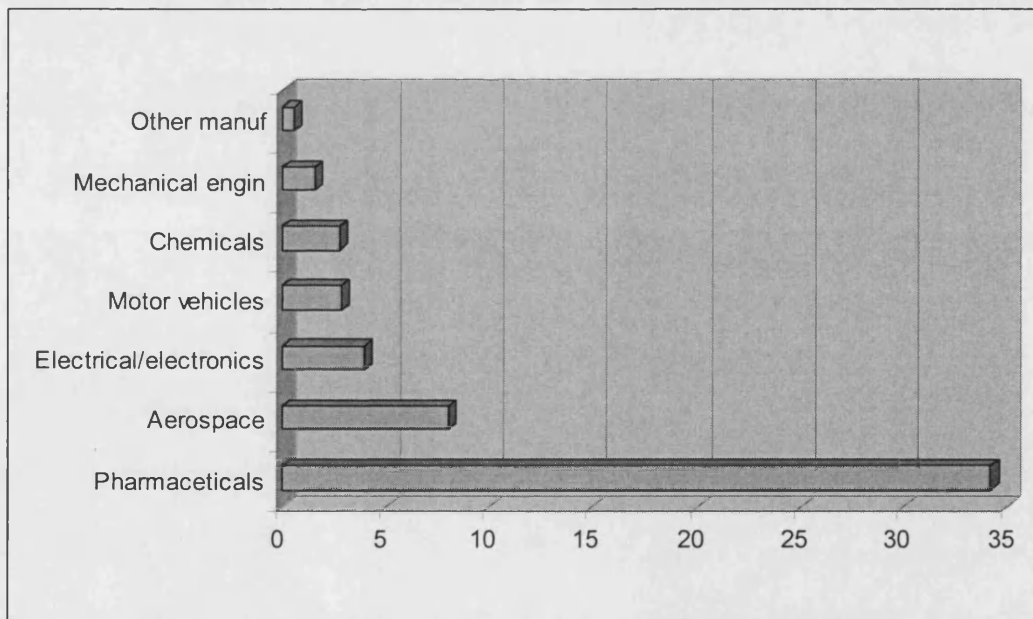
There is a vast array of literature exploring the causes of Britain's economic decline, ostensibly in the post-war era but in reality stretching as far back as the turn of the twentieth century.² The 1980s and 1990s have seen a significant turn-around and gross domestic product (GDP) per capita in the UK was, by 2003, higher than in Italy, France or Germany,³ making the UK the richest large economy in Europe. Nevertheless, industrial decline remains a salient issue for politicians and governments, ingrained in their psyche, and Britain can claim to be a world leader in only a few industrial sectors. Among these industrial sectors is pharmaceuticals. It is a high value, research intensive sector of the UK economy.

The pharmaceutical industry is the leading investor in research and development (R&D) in the UK economy, responsible for 37% of total R&D

² See, for example: Hall, Peter (1986); Coates D. and Hillard J. (eds.) (1986); Wilks, S. (1984), chapter 1.

investment by the manufacturing sector and around a quarter of all industry R&D in the economy, far ahead of any other sector. This has risen consistently from just 5% in the early 1970s.⁴ It now invests over £2.8 billion in R&D per annum, representing 34% of its sales. Other high-tech industries invest less – aerospace, another industry in which the UK is a world leader (the UK has the second largest aerospace industry in the world and is the world's second largest exporter of defence equipment, after the United States), is responsible for £1.5 billion of R&D investment per year; the chemical sector as a whole invests £3.5 billion (although this is a conflation of several sectors within the chemical industry. Most commentators, including HM Customs and Excise, separate the industry into several sub-sectors, parts of which comprise relatively low-tech consumer products). This represents around 2-3% of its sales.⁵ Chart 1.1 shows a comparison of R&D investment in pharmaceuticals, aerospace, electrical machinery/electronics, motor vehicles, mechanical engineering and other manufacturing.

Chart 1.1: R&D as per cent of sales for major industry sectors



Source: ABPI⁶

³ See, for example: *The Economist. The World in 2003*. December 2002.

⁴ Greener, M. (2001), p.22.

⁵ Department of Trade and Industry (2003b), chapter 2.

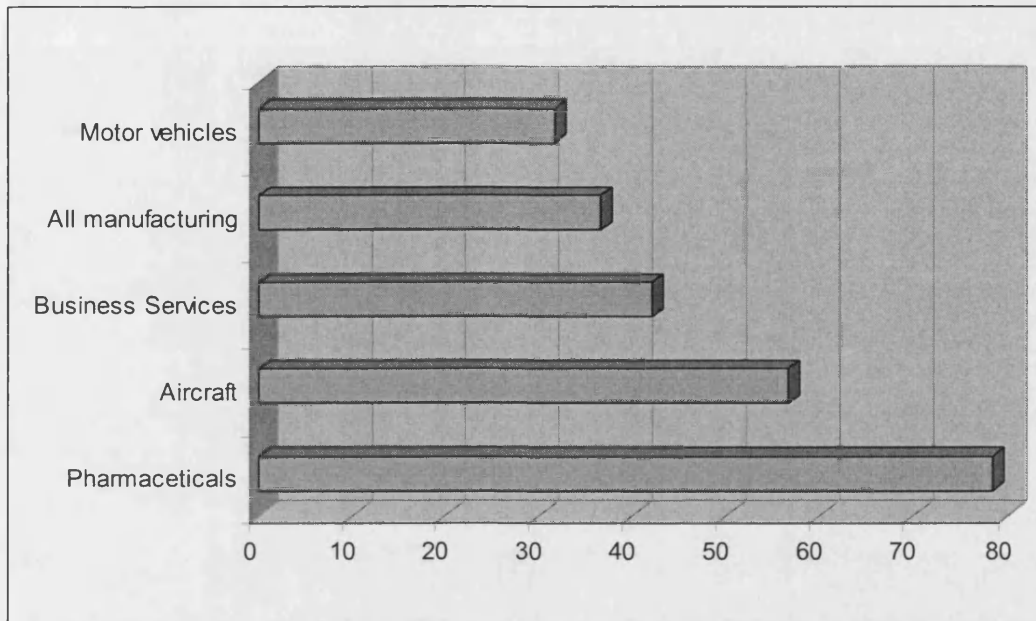
⁶ Association of the British Pharmaceutical (ABPI) (2003).

As a trading sector, the British pharmaceutical industry also makes its mark. It is one of the major exporters among British industries. Its £9.25 billion of exports in 2001 compares with aerospace at £15 billion and chemicals at £29 billion. This puts it among the UK's largest trading sectors. Yet it is the contribution to the balance of trade where the industry really stands out. It contributed £2.9 billion in 2001. Few sectors contribute so much and only two sectors are listed by HM Customs and Excise as contributing more: petroleum and power generating machinery. The chemical industry, where the various sectors are conflated, contributed £4.6 billion in 2001 and the aerospace industry followed pharmaceuticals at £2.8 billion. The pharmaceutical industry is therefore third or fourth (depending on the category split of 'chemicals') in the league table of contributors to the balance of trade.⁷

The pharmaceutical sector is a significant employer. It employs over 65,000 people across the UK. Although this is a large number in itself, the key point is the value of these jobs: other sectors employ far more people – 145,000 in aerospace; 235,000 in chemicals; 715,000 in the automotive industry, 404,000 in banking and 360,000 in insurance.⁸ Yet there is no other manufacturing sector that creates more value-added than pharmaceuticals. Each pharmaceutical employee is responsible for over £76,000 of value-added, compared with £56,000 in the aircraft industry and £37,000 in manufacturing industry as a whole. Pharmaceutical jobs are some of the most productive in the UK economy. Chart 1.2 shows value-added per employee for pharmaceuticals, aircraft, business services, all manufacturing and motor vehicles.

⁷ ABPI (2003); Chemical Industries Association (CIA) (2001); Society of British Aerospace Companies (2001).

⁸ Association of the British Pharmaceutical Industry (ABPI), 2003; Chemical Industries Association (CIA), 2001; Society of British Aerospace Companies (SBAC), 2001; Department of Trade and Industry (2003a); Association of British Insurers (ABI), 2003; British Bankers' Association (BBI), 2003.

Chart 1.2: Value-added per employee by sector, £, 000

Source: ABPI

A further aspect to the value of the industry within the UK economy is the very real success of British-based firms. While the industry includes global firms, the majority of whom are based or have their origins elsewhere, the British firms are themselves important global companies and yet have a tendency still to invest in the UK for their research. Unlike the motor industry, for example, which is dominated by overseas companies, the pharmaceutical industry maintains a strong 'home-grown' element. As the UK is the leading biotechnology centre in Europe⁹ and the two sectors are linked scientifically and financially, ensuring strong British-based firms may also have positive spin-offs in that 'sunrise' sector.

The 'sunrise' nature of the pharmaceutical-biotech sector is a critical issue because of the extent of reliance on emerging scientific discoveries for future wealth creation, as well as the interconnectedness of all forms of 'technological revolution', not least in light of the struggle of successive British governments to encourage the restructuring of traditional British manufacturing sectors.¹⁰ Scientific advances in materials, information

⁹ Ernst & Young's Annual European Life Sciences Reports 1998-2003.

¹⁰ Toterdill, Peter et al. (1990).

technology and biotechnology are highly interrelated and the basis of the knowledge economy of the future. Attention to the science base is an increasingly important part of any government's economic policy in a globalising knowledge economy.¹¹ Just as pharmaceutical R&D investment is in part due to the strength of the UK's science base,¹² so the pharmaceutical-bioscience industries are seen in particular as central to driving these various areas of technological discovery.¹³

The government have seen the pharmaceutical industry as an important base for the development of biotechnology.¹⁴ R&D investments are targeted at countries with a high innovation capacity and strong science base, thereby reinforcing the status quo.¹⁵ Indeed, the countries identified as particularly strong in pharmaceutical innovation two decades ago (US, UK, Switzerland and Germany) have arguably strengthened their position over that period (with the possible exception of Germany).

The UK's traditional strength in pharmaceuticals is an important factor in its more recent success in the biotech area,¹⁶ another reason for government to be wary of its regulation of the pharmaceutical sector.¹⁷ The interconnectedness between the pharmaceutical and biotech sectors gives the industry an important part to play in the mind of government, not least as a 'cash cow' for the more cutting edge research organisations, in providing the non-innovative business support functions that would emulate the positive relationship that has emerged in the sectors in the US,¹⁸ often through European companies exploiting the American academic and research base.¹⁹ For both sectors, the regulatory environment has implications for their operations and, important for governments, for their

¹¹ See, for example: Kaounides, Lakis C. (1999), pp.53-79.

¹² See, for example: Burstall, M.L. and Dunning, John (1985), p.190.

¹³ See, for example: Office of Science and Technology, (1995).

¹⁴ National Economic Development Office (1987), p.1.

¹⁵ Burstall, M.L., Dunning, J.H., and Lake, A. (1981).

¹⁶ Kettler, Hannah E. and Casper, Steven (2000); Ernst & Young's Annual European Life Sciences Reports 1998-2003.

¹⁷ Bartholomew, S. (1997).

¹⁸ Shan, W., Walker, G., Kogut, B. 1994, pp.387-94.

¹⁹ Sharp, Margaret (1995).

innovativeness. Strict controls on pharmaceutical prices have, specifically, been found to affect pharmaceutical company innovation.²⁰

The nature of global capital is also important for government's attitude to the industry. The development of knowledge-based economies is linked to 'clusters' of knowledge, capital, expertise etc., and the generation of innovation which they underpin. The place of any national economy in the global distribution of such clusters is reliant on successful 'national innovation systems' (NIS).²¹ Knowledge-intensive industries are particularly conducive to cluster development and the attention of policy makers has been drawn to how encouraging clusters may improve national innovation.²² Firms' investment decisions are significantly affected by macro conditions in any national economy.²³ There are therefore specific features of the global organisation of firms, of which the pharmaceutical industry is a clear example, for government's industrial policy. It is more important than ever to attract and to keep high value, knowledge-intensive activities for general future economic prosperity.

The pharmaceutical industry occupies a special place in the British economy, to the extent, it is proposed here, that the industrial policy concerns of the British government have been amplified in arriving at a balance of health and industrial policy aims in the economic regulation of the pharmaceutical industry.

1.2 The UK as a pharmaceutical industry location

Not only is the pharmaceutical industry of importance to the UK economy as a highly research intensive, knowledge-based industry, but the industry has found the UK a good place to do business. Although per capita

²⁰ OECD (1997), p.12.

²¹ On national systems of innovation see: Bartholomew, S. (1997), pp. 241-266; Kaounides, Lakis C. (1999), pp. 53-79.

²² OECD, (2001).

²³ OECD, (1995), pp.22-26.

pharmaceutical spending has been low by the standards of most major pharmaceutical producing countries, R&D in the sector has been high and the British-based industry has been remarkably commercially successful.²⁴ It has an unusually international orientation in terms of attracting R&D capital.²⁵ Although only around 3% of the global market, the UK is home to around 9% of global R&D expenditure in the sector.²⁶ It has also spawned some of the most successful pharmaceutical companies: GlaxoSmithKline (GSK) and AstraZeneca are currently the world's second and third largest respectively. British companies are considered to have been competitively very strong relative to European counterparts for at least the past two decades.²⁷

1.2.1 Research and development (R&D)

As a contributor to the science base, the industry provides specialised, high value-added jobs and maintains scientific knowledge and skill within the national economy. It is not only the size of the industry or the cash value of its production that is significant to government, but how much of its investment is in the science base, i.e. in R&D. As Chart 1.3 shows, this is high for the UK.

Key to the UK's position, and successive governments' attitudes to the industry, is this favouring of the UK as an R&D location. The success of the large British firms is an important aspect of this but it is not the sole or even the primary factor in accounting for the scale of UK R&D in the sector. The large American firms have substantial R&D operations in the UK. R&D expenditure by the industry in 2000 was \$23 billion in the US, \$17 billion in Europe and \$7 billion in Japan.²⁸ The UK's share of all European²⁹ R&D in the sector was over one-quarter. The UK's heritage in attracting international R&D investment is deep. In the early 1980s, the UK was clearly second only

²⁴ Taylor, David and Maynard, Alan. 1990, p.15.

²⁵ Burstall, M.L. (1990), p.21.

²⁶ ABPI (2000a).

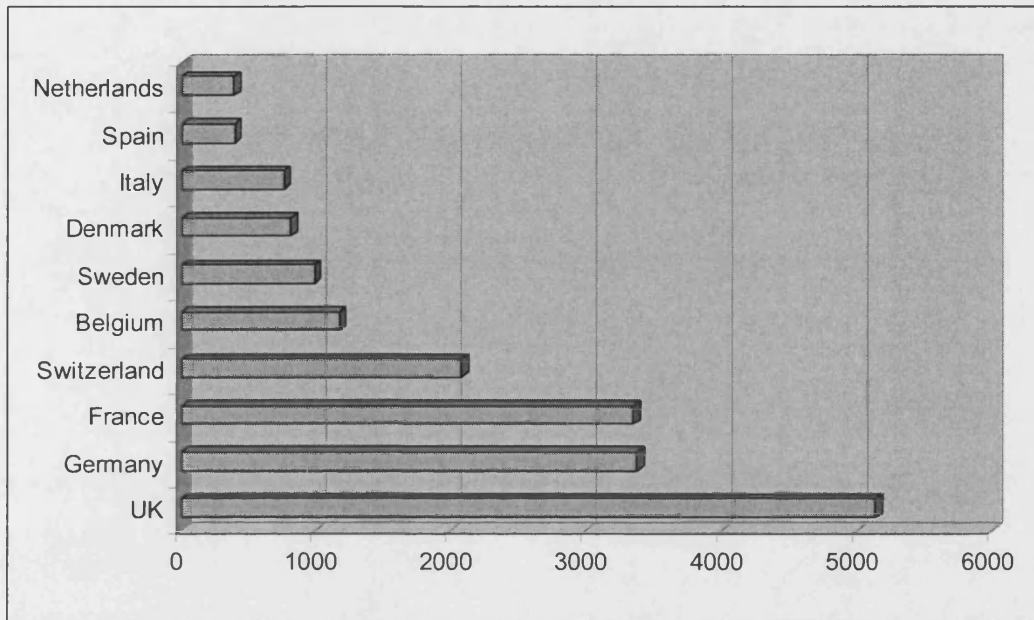
²⁷ Burstall M. (1985).

²⁸ *Scrip's Pharmaceutical R&D Databook: Benchmarks Trends and Analysis*. Vol. 1. (2002). p.24.

²⁹ Where EFPIA statistics are used, 'Europe' refers to the EFPIA European region of the following 17 countries: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, UK

to the US in the number of the top firms with R&D facilities located in the country.³⁰

Chart 1.3: Pharmaceutical R&D investment in national economies (2001 €m)



Source: EFPIA³¹

The UK's position in this regard does not appear to be eroding, certainly within a European context. Following the acquisition of Pharmacia by Pfizer in the spring of 2003, the company announced a rationalisation of its global R&D organisation. For early research it announced that all its efforts would now be focused on six sites globally – four in the US, one in Japan and at its large facility in Sandwich, SE England. Its clinical testing would be rationalised, focusing on six sites, five in the US and its Sandwich facility, while sites in France and Italy would be closed.³² As there may be significant gains and losses from the rationalisations that follow further consolidation in the sector, it is a positive sign for the British government that the first of these has continued the recent pattern of favouring the UK among European locations for the major global corporations.

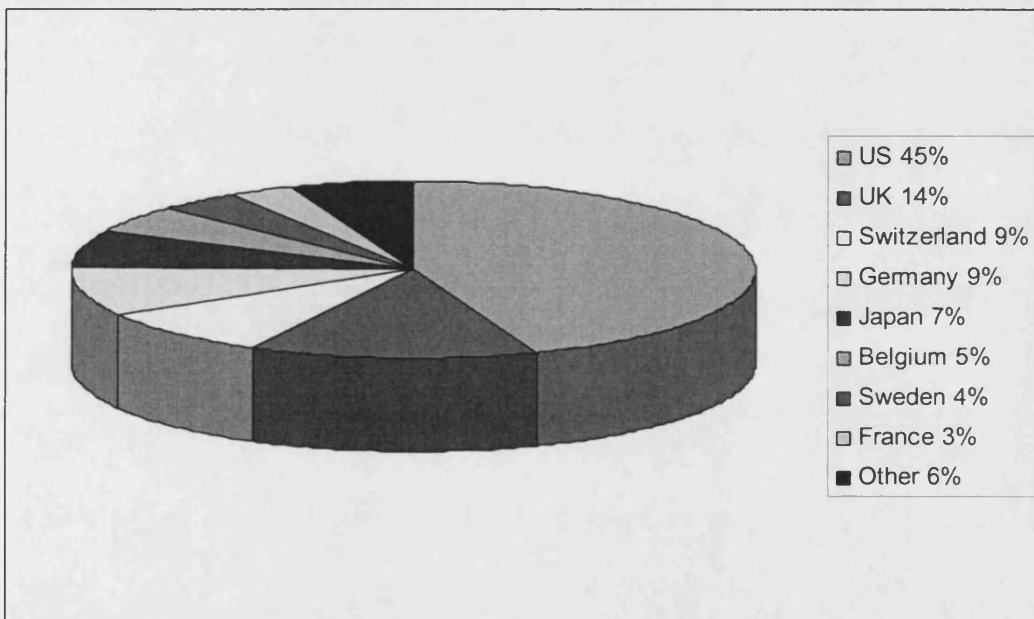
³⁰ Burstall, M.L. and Dunning, John. (1985), p.186.

³¹ European Federation of Pharmaceutical Industry Associations, (2003).

³² *Wall Street Journal Europe*, 30 April 2003.

The R&D investment in the UK has succeeded in producing a consistent line of new drugs. Of the major centres for R&D around the world, the principal innovators are the US, UK and Switzerland, with over two-thirds of 'Category A' (i.e. the most innovative) drugs from the mid-1970s to the mid-1990s between them.³³ Of 152 major global drugs developed between 1975 and 1994, 45% were of US origin, 14% originated in the UK, and 9% were of Swiss origin (see Chart 1.4).³⁴

Chart 1.4: Origin of major global drugs developed 1975-1994 (%)



Source: PhRMA

The British-based industry is seen as highly successful in producing medicines that penetrate world markets. This is in significant contrast to France, where politicians have worried about the weak research base of the French industry for many years.³⁵

³³ OECD, (1997), p.12.

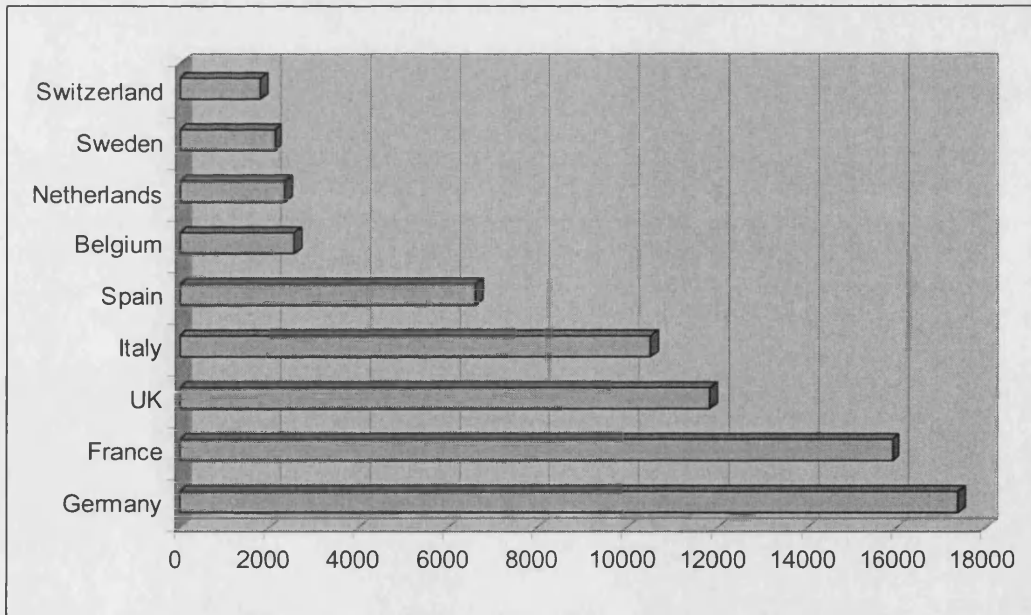
³⁴ See website: <http://www.pharma.org/publications>

³⁵ Bosanquet, Nick (1990), pp.9-11.

1.2.2 The market

The major markets of the pharmaceutical industry are in North America, Europe and Japan. In 2001, North America (largely the US) accounted for 50% of the world pharmaceutical market, at \$182 billion. This compares with 24% for Europe (\$87 billion) and 13% for Japan (\$47 billion). Asia, Africa and Australia accounted for 8% and Latin America for 5%.³⁶ There is not necessarily a direct correlation between the size of the domestic market and the intensity of R&D or the volume of production. Ireland and Switzerland are both large producers but small markets. Yet, again, the two countries are very different: Ireland has become a favoured location for manufacturing owing to its low corporation tax rate; Switzerland is an established giant, with a highly research intensive industry. Both Germany and France continue to be large scale producers and have significant positive balances of trade as well, yet R&D investment and innovation have waned.

Chart 1.5: Size of national pharmaceutical markets (1999, €m)



Source: EFPIA³⁷

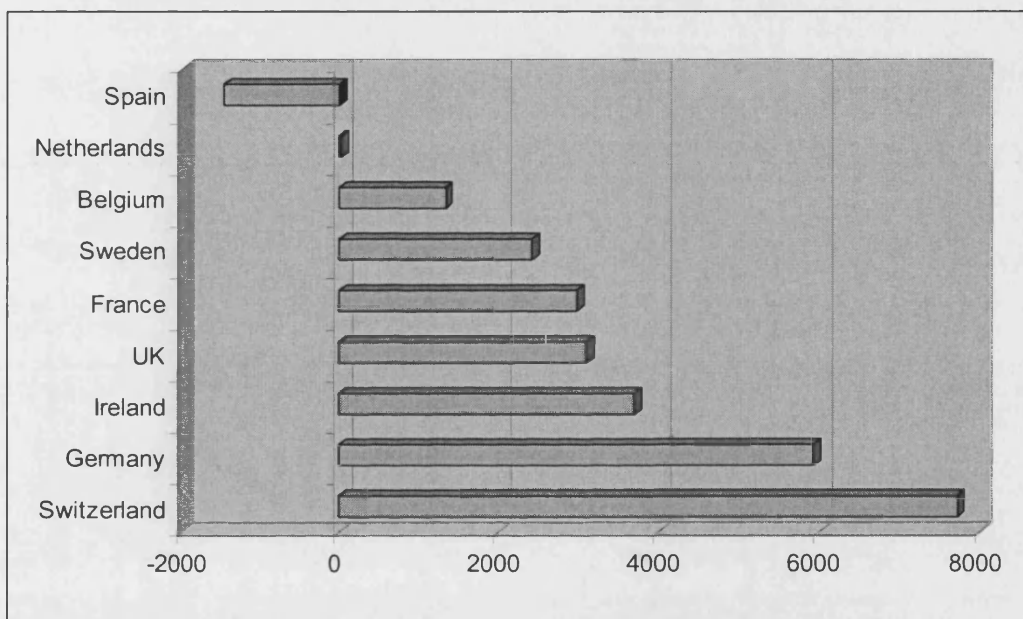
³⁶ *Scrip's Pharmaceutical R&D Databook: Benchmarks Trends and Analysis*. Vol. 1. (2002), pp.54-5.

³⁷ European Federation of Pharmaceutical Industry Associations (2003), p.7.

1.2.3 Relative balance of trade

As stated above, the pharmaceutical balance of trade is high in the UK relative to other sectors of industry. It is also high by comparison with the pharmaceutical balance of trade for other countries. In Europe, only Switzerland and Germany have consistently had greater positive trade balances from the sector, although Ireland has also had large trade surpluses in recent years (see Chart 1.6).

Chart 1.6: Pharmaceutical balance of trade (1999, €m)



Source: EFPIA³⁸

1.3 Corporate structure and consolidation

By its very nature an industry at the cutting edge of science, the pharmaceutical sector is one that has been, and continues to be, profoundly shaped by the dynamics of modern scientific research. The pharmaceutical industry is the most research intensive of all industries.³⁹

³⁸ European Federation of Pharmaceutical Industry Associations (2003), p.10.

Modern medicine discovery began in the 1930s when there was a shift in the basis of pharmaceutical products from natural to synthetic substances. It is therefore a twentieth century industry, albeit with long commercial roots in pharmacy.⁴⁰ The scientific focus of research has changed radically during the past few decades and the research *intensity* of pharmaceutical discovery as it is understood today is a yet more recent phenomenon.⁴¹ The overt commercialisation of the drug discovery process is something that has happened in the post-war years, giving rise to a new *scientific-commercial* organisation of industry's research, in industrial style laboratories.⁴²

It is this process that has underpinned the place of the pharmaceutical process at the heart of both health and industrial policy. The trends in the industry towards bigger, globally mobile firms, with gigantic R&D budgets, producing ever more sophisticated and expensive products will intensify the aims and incentives for government in both industrial and health policy in coming years.

It is, therefore, the industrialisation of the processes of research and development that has transformed the drug discovery process and the place and scope of medicines in health care and, crucially for this study, of the medicine industry in the economy. This process of scientific industrialisation has changed radically the nature of the relationship between government and industry.

It is also a central driver of change for the corporate structure of the research-based industry. The growth in the cost of drug research, discovery and development has driven consolidation among firms as companies seek to share costs and risks.⁴³ Various estimates of the total cost of bringing an NME (new medical entity) to market show a large and sustained increase over the past four decades. Estimates from different sources ranged from 54

³⁹ Danzon, P. (1997), p.5.

⁴⁰ Howells, J and Neary, I. (1995), pp.65-6.

⁴¹ Breckon, W. (1972), pp.43ff.

⁴² Sykes, Sir Richard (2000), p.18.

⁴³ Sharp, Margaret and Patel, Pari (2002).

to 125 million dollars in the 1970s to 450 to 802 million dollars in the 2000's and average development time has lengthened from around 8 years in the 1960s to over 14 years during the 1990s.⁴⁴ This has been a major driving force behind merger activity in the sector. This process of consolidation has become greater in recent years as some of the industry's best known names have merged to become yet bigger companies. The top league of companies dominates the global market. A *Financial Times* survey in 1996 showed that the top ten companies alone accounted for 34% of the global market in pharmaceuticals.⁴⁵

Global R&D in the pharmaceutical sector reached \$45 billion in 2000.⁴⁶ The large global companies now have vast R&D budgets. Latest available comparative statistics show that Pfizer's R&D budget for 2001 was almost \$5 billion, followed by GSK's at around \$3.7 billion (see Chart 1.7). The recent acquisition by Pfizer of Pharmacia is likely to give the new company an R&D budget of around \$7 billion, dwarfing most of the other major corporations, who may now seek further consolidation of their own research and development in order to compete.

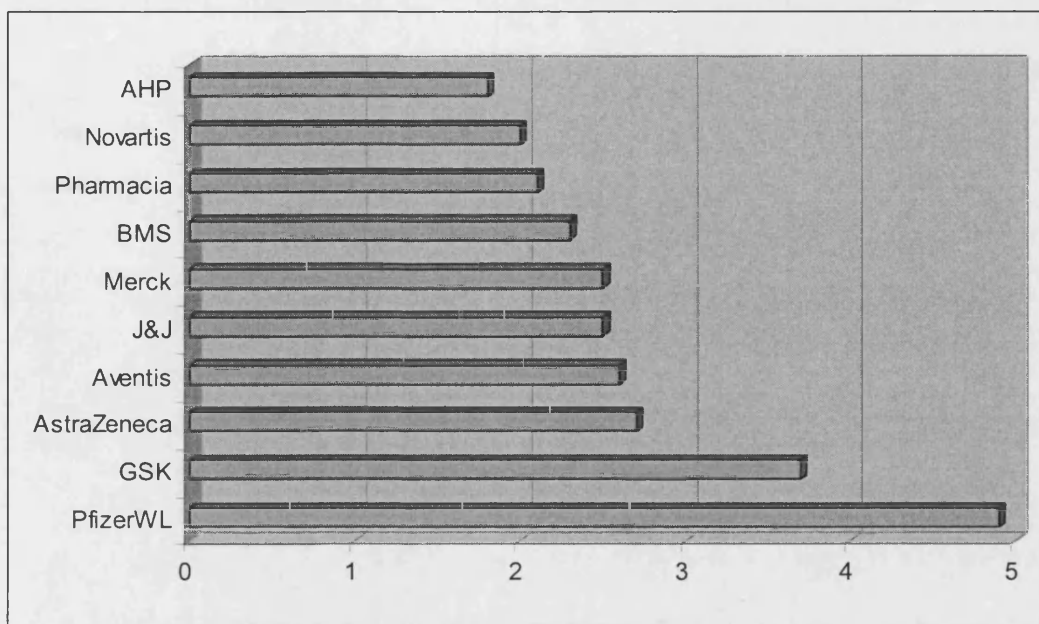
A more traditional and generic form of 'synergy' in corporate consolidation has been the creation of giant sales forces among the top companies. This is one area where traditional economies of scale can be achieved through mergers, as networks of sales personnel can be used to promote additional products at relatively little marginal cost (see Chart 1.8).

⁴⁴ *Scrip's Pharmaceutical R&D Databook: Benchmarks Trends and Analysis*. Vol. 1. (2002), pp.16-18; Association of the British Pharmaceutical Industry. 1999.

⁴⁵ *The Financial Times*. 24 April 1997.

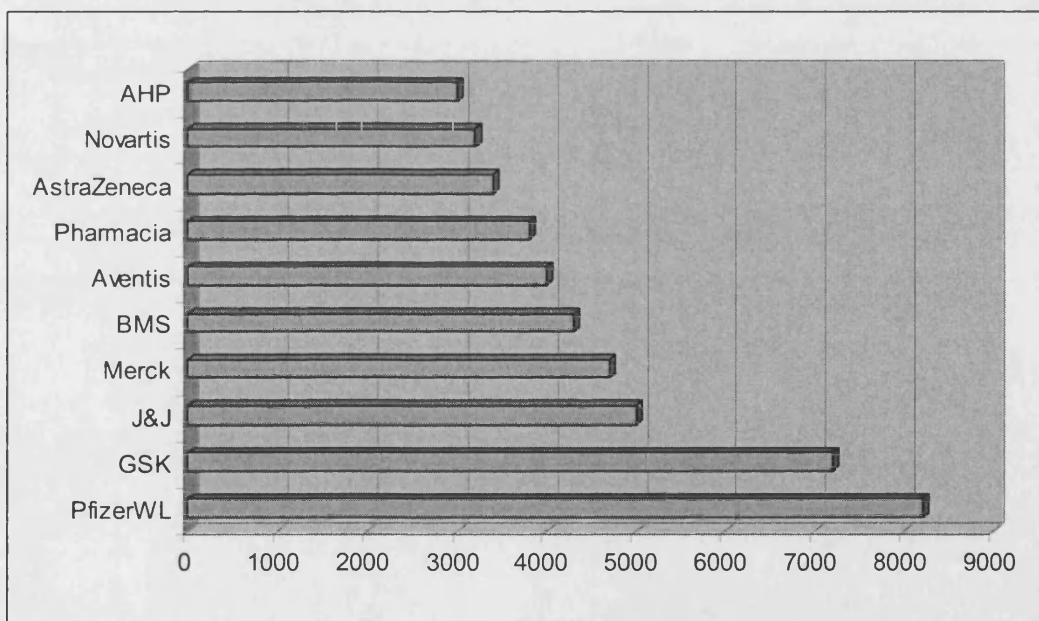
⁴⁶ *Scrip's Pharmaceutical R&D Databook: Benchmarks Trends and Analysis*. Vol. 1. (2002), p.20.

Chart 1.7: R&D budgets of major companies (2002, \$bn)



Source: *Scrip Reports*⁴⁷

Chart 1.8: Sales force personnel of major companies



Source: *Scrip Reports*⁴⁸

⁴⁷ *Scrip's Pharmaceutical R&D Databook: Benchmarks Trends and Analysis*. Vol. 1. (2002), p.68/p.74.

⁴⁸ *Scrip's Pharmaceutical R&D Databook: Benchmarks Trends and Analysis*. Vol. 1. (2002), p.68/p.74.

1.3.1 Shifting geography

In the UK, the commercial structure of the sector has changed greatly and rapidly since the 1950s, when there was a large influx of American and European companies. Their operations tested the ability of smaller British operations to compete, and many failed to do so. The size of British firms increased as companies merged in response to the international competition.⁴⁹ This is not something that has happened to the same extent elsewhere. While American and British firms have consolidated relentlessly, for example, French and German firms have been far slower to do so. In those countries, there persist large numbers of small and family owned firms beneath the few large global corporate players.⁵⁰

Notable from the shape and outcomes of recent merger and acquisition (M&A) activity in the sector is a general shift in the centre of gravity of the industry, in terms of both corporate origin and location of facilities of all companies, from Europe to the US. By 1999 (the year of the most recent negotiation of the PPRS), companies of European origin had begun to constitute a second tier or 'division', with the exception of those originating in the UK and Switzerland, as the analysis from *The Financial Times* in Table 1.1 shows.

⁴⁹ Howells, J and Neary, I. (1995), p.61.

⁵⁰ *The Economist*. 10 April 1999.

Table 1.1: Pharmaceutical companies by market capitalisation (1999, \$bn)

American dominated first division			European dominated second division		
Merck & Co	US	198.0	Zeneca * ¹	UK	38.6
Pfizer	US	179.9	Astra * ¹	Sweden	32.3
Bristol-Myers Squibb	US	126.7	Monsanto	US	27.8
Novartis	Switz	122.9	Pharmacia & Upjohn	US	27.5
Roche	Switz	116.6	Bayer	Germany	24.7
Glaxo Wellcome	UK	114.6	Hoechst * ²	Germany	24.6
Eli Lilly	US	105.0	Sanofi * ³	France	20.8
Schering-Plough	US	82.9	BASF	Germany	19.9
American Home Products	US	82.0	Rhone-Poulenc * ²	France	16.8
SmithKline Beecham	UK	80.7	Synthelabo * ³	France	10.8
Abbott	US	75.4	Akzo Nobel	Netherlands	9.3
Du Pont	US	60.3	Schering	Germany	8.3
Warner-Lambert	US	59.3	Novo Nordisk	Denmark	7.8

*ⁿ merging (at time of publication)
 Bold = European companies
 Source: *The Financial Times*, 13 April 1999.

Since that survey, the top end of the global pharmaceutical industry has metamorphosed, spawning new 'mega-companies' such as Novartis, Aventis, AstraZeneca, GlaxoSmithKline and PfizerWarnerLambert. Many of these have been European, but the American firms have come out more strongly from the process, with the exception of the British firms GSK and AstraZeneca, which have organised themselves globally more than have their continental rivals, and succeeded in gaining substantial global market share.⁵¹ To some extent Glaxo's history and culture of aggressive acquisition has been well suited to this era of consolidation.⁵² Furthermore, the position of the seemingly indomitable Swiss firms appears to have waned to some degree. Arguably, the European corporate situation overall continues to worsen and for the UK the corporate league table does not tell the whole story. The globalising GSK has transferred its research headquarters to the US (though by no means the majority of its research, which remains in the UK) following the completion of its merger.

⁵¹ Hancher, Leigh (1989a), pp.165-66.

⁵² See: Lynn, Matthew. 1992. In particular, part 3.

The following ABPI figures show the league table by sales in 2001, following the most recent round of mergers. The top 11 companies represent over half the world market by sales.

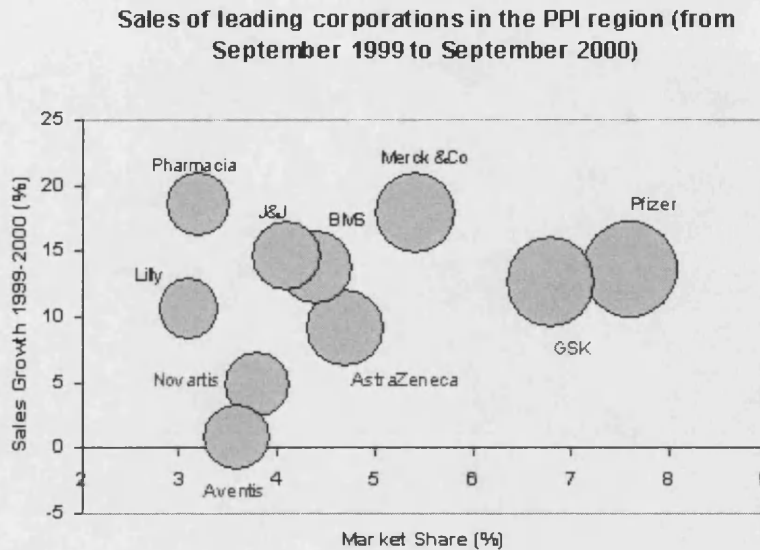
Table 1.2: Leading pharmaceutical corporations, 2001

Company	Country	Sales £	Growth %	Share of world market %
PfizerWarnerLambert	USA	18,275	13	7.5
GlaxoSmithKline	UK	17,066	12	7.0
Merck & Co	USA	12,916	12	5.3
AstraZeneca	UK	11,147	12	4.6
Johnson & Johnson	USA	10,828	21	4.4
Bristol-Myers Squibb	USA	10,422	7	4.3
Novartis	SWI	9,767	9	4.0
Aventis	FRA	8,501	11	3.5
Pharmacia Corp	USA	8,265	15	3.4
Abbott	USA	7,507	10	3.1
American Home Products	USA	7,450	12	3.1
Leading 11		114,694	12	51.1

Source: ABPI⁵³

Statistics also show that the American-based firms are currently more successful at growing their markets than are their European rivals, and in this instance the British firms tend more towards the European camp. As Chart 1.9 shows, the American companies have greater organic growth as well as having merged more rapidly into large corporations.

⁵³ ABPI 2003. Section 1.

Chart 1.9: Sales of leading companies 1999/2000

Note: bubble size is equivalent to market value.

Source: Pharma Prognosis International, 2001-2005⁵⁴

Following a lull of activity during 2001-2002, the merger in March 2003 of Pfizer and Pharmacia in a £57 billion deal, which takes the combined company's global market share to 10%, could herald a new wave of corporate consolidation in the sector.

The picture for the pharmaceutical industry is now being mirrored in the biotechnology sector, though in an exaggerated form. The US is clearly dominant in this new sector, but within a European context the UK's position is strong. Indeed, it is the leading biotechnology economy in Europe, a position of several years standing which it appears to be holding as companies in the sector mature.⁵⁵

R&D investment in biotechnology rose from about \$8 billion dollars in 1997 to about \$14 billion in 2000 in the US; the comparable figures for Europe were about \$2 billion and just under \$5 billion respectively.⁵⁶ This represents a sharp growth rate for the sector in Europe but a continued large gap with its

⁵⁴ The PPI (Pharma Prognosis International) region consists of the top ten markets: US, Japan, Germany, France, UK, Italy, Spain, Canada, Australia and Belgium.

⁵⁵ Ernst & Young's. 1998-2003.

⁵⁶ Ernst & Young's. 1998-2003

American counterpart. American companies are bigger but the growth in the number of companies is now faster in Europe than the US.⁵⁷

1.3.2 Conclusions

The corporate structure of the industry, based in its increasingly industrial-scientific research, is a principal determining factor of the nature of government-industry relations in the sector because it creates large global firms with large R&D budgets. The location strategies of a relatively few firms are responsible for vast amounts of global pharmaceutical R&D. Furthermore, two of the very top few are British-based firms. Yet the sector has undoubtedly begun to shift in its latest phase of consolidation, orientated around the dominant American market. There are mixed signals for the UK: it seems to be maintaining, even strengthening, its attractiveness relative to other European countries; but there are signs that Europe as a whole may be losing out to the US. The industrial policy aspect of the PPRS is arguably more important than ever.

The global corporate dimension of the industry is a key contextual feature of government-industry relations in the PPRS and underpins Hypothesis 2, in Chapter 3 below.

1.4 Pharmaceutical supply and demand

The supply side of the pharmaceutical sector is shaped by several factors. The intensity of R&D in the sector is clearly special, as illustrated from the figures above; the intellectual property generated by this R&D underpins a second distinctive feature: the important effect of patents in the sector; this in turn is reflected in the nature of the brand.

⁵⁷ *Scrip's Pharmaceutical R&D Databook: Benchmarks Trends and Analysis*. Vol. 1. (2002), p.46.

The intensity of R&D creates economies of scale that amount to a significant barrier to entry to the market. The largest firms have a distinct advantage in having vast R&D budgets and broad R&D capabilities, which they can target at the most lucrative areas of the market. Smaller companies focus on particular areas in which they are expert. One result of this is that the therapeutic sub-markets of the sector (in which there is limited therapeutic cross-over)⁵⁸ have less competition than the market as a whole would suggest. Only the largest firms have a presence in all sub-markets and some highly specialised areas may have only a few other, niche, companies.

The concentration of suppliers is further consolidated on the supply side by the presence of patented products that dominate the market, giving a monopoly to a company producing a drug for any particular indication, and creating additional promotional costs to a potential entrant after the patent has expired in order to break brand loyalty built up during the life of the patent.⁵⁹ The patented part of the market is, by value, by far the majority part. Patents reduce competition but this is their intention. Patents are granted by governments to orchestrate a monopoly for the purpose of encouraging innovation. The monopoly status they give to an invention is the mechanism by which R&D funds are drawn into the sector.⁶⁰

Patents allow companies initially to sell their product under exclusive license but this also affords them the opportunity to build brand loyalty among doctors (and patients) which can award them an advantage following patent expiry and the ensuing competition with generic copies. Some cost control initiatives have focused on encouraging doctors to work with the generic (chemical) name of products rather than the brand name to overcome brand loyalty (see below). Nevertheless many doctors and increasingly patients prefer brands they have become accustomed to and brand loyalty built up during the life of the patent therefore acts as a further barrier to entry to other

⁵⁸ Reekie, W Duncan. (1975), p.21

⁵⁹ Reekie, W Duncan (1969), p.5.

⁶⁰ For discussions of the economic purposes of patents, and the relationship between intellectual property protection and R&D investment, see: Danzon, P. (1997); Reekie, W Duncan (1975), pp.84-6.

manufacturers within a particular sub-market and so represents a further limitation on competitive supply.

As a consequence of the barriers to entry – economies of scale, patent protection and brand loyalty – price competition within the research-based industry is low. In markets with competing products, competition centres around the product not the price: if a product is not as good as a rival, lower prices or good advertising are unlikely to have much effect on its market position.⁶¹

Limited price competition is, however, due not only to the nature of the supply side, which would suggest prices are likely to be inflexible, but also to the nature of demand. Demand for pharmaceuticals is inelastic because of the nature of the product. Medicines are not optional purchases (or only at the margins) but essentials for those who use them. The structure of demand in national health services is orientated, in Europe, around large public purchasers.⁶² The nature of demand in health care is therefore different from many other sectors, being similar to other insurance-based markets. Furthermore, health care in most western countries is largely publicly funded.

Health care demand is characterised by third party purchasing, according to principles of insurance markets. In insurance-based markets, the final consumer of a product is not the payer (not directly, at time of use). Hence the marginal cost of the product is zero, a situation which can give rise to 'moral hazard', where there is over consumption because of zero marginal costs.⁶³ Insurance coverage may not be comprehensive and may involve an 'excess' payment, but in the case of the British NHS, this is not so. There is, according to traditional theories of insurance markets such as these, an inherent inducement to consume more health care than if the consumer were paying for it directly.⁶⁴

⁶¹ Reekie, W Duncan (1975), p.34.

⁶² Reekie, W Duncan (1975), p.35.

⁶³ Danzon, P. (1997), pp. 9-11.

In health care, there is a further actor in each act of consumption, complicating the relationship between supply and demand and the dynamics of moral hazard, as monitoring of consumption by insurers is more difficult. Unlike other insurance markets, purchasing decisions are not made by a combination of the consumer and the insurer but by a third party – the medical professional. Hence there are three actors – the payer (government or insurer), the decision maker (doctor), and the consumer (patient).

In the health care market in the UK, the 'insurer' is the government, through the monopsonistic, tax-funded NHS. The government therefore has an opportunity as an economic actor, as well as a legal actor, to regulate the industry. The UK is at the far end of the spectrum among European countries in funding health care through general taxation; only Denmark has a funding formula as concentrated on this single source as the UK (see Table 1.3). Furthermore, the user charges in the British NHS are the lowest of their kind in the EU, making the British government's responsibility for funding pharmaceutical prescriptions the highest as a proportion of the total among EU countries.

Taxation and compulsory social insurance constitute the two principal means of public funding for health care in the EU. Eight EU countries use general national or local taxation as the primary means for funding public health care services (Denmark, Finland, Ireland, Italy, Sweden, Spain, Portugal, UK), in some cases along with small amounts of hypothecated taxation such as National Insurance in the UK. Insurance-based models of funding are used in Austria, France, Germany, Luxembourg, and the Netherlands. Compulsory social insurance contributions overseen by the government but operated by separate social insurance funds is the model used in these countries. Belgium and Greece use a mix of insurance and taxation.⁶⁵

In most countries there is some element of voluntary insurance, such as private insurance, and some element of co-payment by patients within the

⁶⁴ McGuire, Alisatir; Hendersen, John and Mooney, Gavin (1998), pp.169-173.

⁶⁵ Mossialos, E and Le Grand, J. (1999), pp.5-9.

publicly funded services. The table below shows the varying proportions of these sources of funds within EU health care services.

Table 1.3: Sources of health care finance in the EU, 1990s (%)

Member state	Taxation	Social insurance	Voluntary health insurance	User charges (including direct payments)	Other
Denmark (1996)	80.7	–	1.9	17.4	–
UK (1993/4)	78.8	12.3 (NICs)	5.6 (private health insurance)	3.2 (prescription charges)	–
Sweden (1993)	69.7	13.4	–	16.9	–
Ireland (1993)	68.1	7.3	8.6	13.9	2.1
Italy (1995)	64.6	–	2.6	31.2	2.4
Finland (1994)	62.2	13.0	2.2	20.8	1.8
Spain (1995)	59.3	15.3	7.0	16.3	1.7
Portugal (1995)	55.2	6.0	1.4	37.4	–
Belgium (1994)	38.0	36.0	–	17.0	9.0
Greece (1992)	33.3	24.1	2.1	40.4	–
Luxembourg (1992)	30.0	49.8	2.0	7.9	2.8
Austria (1992)	24.0	54.0	7.5	14.0	–
Germany (1995)	11.0	64.8	7.1	7.3	9.8
Netherlands (1996)	10.0	68.0	15.0	7.1	–
France (1994)	3.6	71.6	7.0	16.5	1.3

Source: Mossialos and Le Grand⁶⁶

⁶⁶ Mossialos, E and Le Grand, J. (1999), p.6.

Outside of Europe, the United States has a predominantly private insurance model, though with two major schemes of public provision for the poor (Medicaid) and the elderly (Medicare). Fifteen per cent of the population is not covered by any sort of health insurance in the US. Canada has a universal tax funded system and Japan a social insurance system similar to the German model of compulsory employer contributions.⁶⁷

It is not only in the financing of services that governments are involved in health care but also in many cases in their direct provision, through the ownership and administration of hospitals and so on. Of hospital beds, over 90% are publicly owned in the UK and Scandinavian countries, while in Germany about half are owned by non-profit hospitals and in the Netherlands and Belgium most acute hospitals are private. Doctors are also paid differently in different systems, including fee-for-service payments to salaried employees of the public system. Hence across Europe, while funding of health care is largely public, both the particular type of public funding and the involvement of government in actual health care delivery vary widely between countries.⁶⁸

All these systems have in common, through the 1990s to the present, the new pressures of rising costs. The interest of governments in the cost of pharmaceuticals has in the past decade become more acute owing to the exploding costs of health care services and the arrival of the politics of 'cost containment'.⁶⁹ Public expenditure on health care has risen dramatically in the past three decades across European countries, from 3.5% of GDP in 1971 to 6.1% of GDP in 1996. For the UK, over the same period, the rise has been less marked but significant still, from 4% to 5.8%.⁷⁰ By 2003 the EU average was over 8% and the UK around 7.2%. In North America, health care consumes an even larger spending commitment, whether from public or

⁶⁷ Nedde, Ellen (1995), Section II.

⁶⁸ Nedde, Ellen (1995), Section II.

⁶⁹ Abel-Smith B. (1984); Mossialos E, Ranos C, Abel-Smith B (eds) (1994); Le Grand J, Mossialos E (eds) (1999).

⁷⁰ Mossialos, E and Le Grand, J. (1999), p.48.

private sources, reaching 14% of GDP in the US and 10% in Canada by the 1990s.⁷¹

Two key factors impinge on health care costs and underpin this explosion: first, demographic change and an ageing society; and second, advancing medical technology, including pharmaceuticals. First, longer life expectancy and a diminishing birth rate are changing the age structure of western countries. There is a rising number of elderly people and a smaller workforce to provide tax income with which health care services can be funded. Estimates suggest that by 2011 there will be an additional half million people over 80 years of age in the UK.⁷² The precise resource implications of an older population in itself are not clear. It may be that the onset of degenerative diseases will be delayed and the period of dependent old age no greater than at present, even where people are living longer. The effects on costs of longer term degenerative diseases and the ability to treat them are unclear and research evidence is mixed. It is unclear to what extent longer life spans affect health care costs, as most health care expenditure (for those without chronic diseases) occurs in the final year of life, at whatever age that is.⁷³

Second, technology is both a separate and a related factor. Technological advances are the key element in the increasing costs of health care over a long period of time – in the UK, almost from the outset of the NHS. New treatments have meant that 'health' is a moving target. There are now treatments available where previously there were none and there is an increasing technological component of previously existing treatments. Technology, not least in the pharmaceutical context, can also be cost reducing, as new treatments prevent or reduce hospital stays, for example.⁷⁴ Many of the most 'cutting edge' technologies on the horizon can be expected to reduce health care costs, as Diagram 1 below illustrates. High-tech (and relatively high cost) drugs are likely to have some of the greatest cost saving

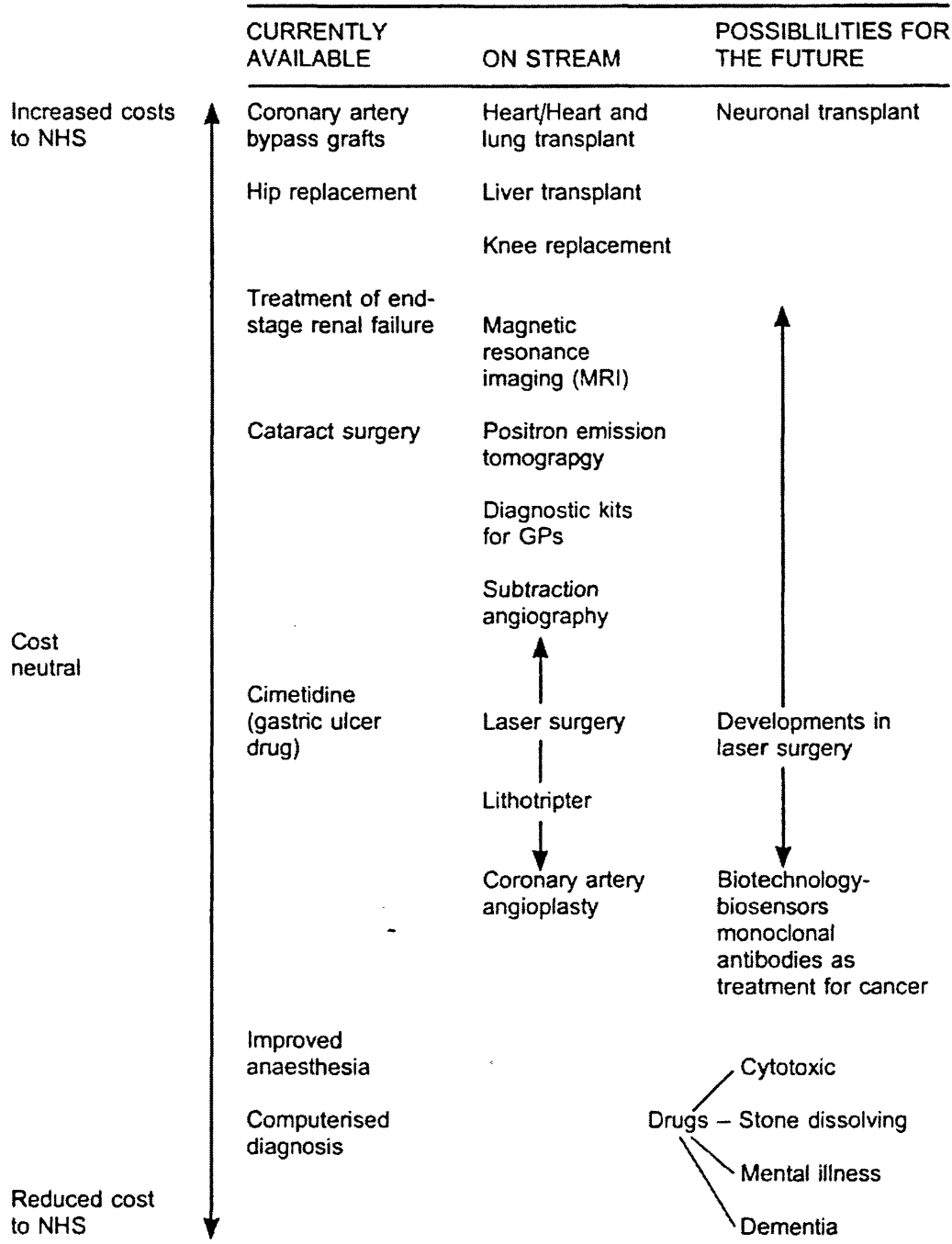
⁷¹ Nedde, Ellen (1995), p.4

⁷² Ham, Christopher (1992), p.245.

⁷³ Mossialos E, and Le Grand J. (1999), pp.55-6.

potential of any technologies. During the post-war period evidence has suggested that new medicines have significant economic benefits to the NHS in reducing other forms of treatment.⁷⁵

Chart 1.10: Summary of resource implications of medical technology⁷⁶



⁷⁴ Mossialos, E and Le Grand, J. (1999), p.58.

⁷⁵ National Economic Development Office (1987), p.5.

⁷⁶ Ham, Christopher (1992), p.250.

Crucially, it is the interaction of demographic change and new technologies that will have the greatest resource implications. Some new treatments are specifically aimed at older people, such as hip replacements and coronary bypass surgery. The key question for health care resources is therefore how many more treatable people there will be than there are today, a calculation that combines both demographic and technology elements.

There is also a political dimension: the increasing wealth of western societies is likely to render health care an increasingly important political priority, along the dynamics of “hierarchy of needs”.⁷⁷ Whatever the effects of individual technologies at the micro (patient) level, at the macro (system) level, new technologies increase costs because there are more treatments than there once were; again, whatever the effect at the patient level of longer life, a higher proportion of aged to young people in itself will serve, in the medium term at least, to increase the relative costs of health care in the economy as a whole. This is notwithstanding the lack of evidence for the constantly rising cost of health care in line with national wealth and the possibility that at some point a limit will be reached.⁷⁸

Cost containment in health care has included a variety of measures. This has led to the introduction of many mechanisms of ‘rationing’ health care across western countries.⁷⁹ In the area of pharmaceuticals, both the supply and demand sides have been targeted. The extension of co-payment has been widely used, where patients pay a larger proportion of their health care costs or pay a fee for some services; the restriction of services provided publicly may also be used, pushing costs into the private sector; and health care budgets – either actual or indicative – have been used to limit the activities of health care practitioners. Other measures can be used to affect costs, such

⁷⁷ Abraham Maslow’s Hierarchy of Needs was a theory that supposed that for human beings lower order needs (physiological) had to be satisfied before higher order needs (self-actualisation) could be satisfied. In this case the point is that as societies develop, health care becomes a higher priority – it is higher up the pyramid of needs than food, housing and so on.

⁷⁸ See, for example: Kanavos P. and Mossialos E. (1999).

⁷⁹ See, for example: Coulter A. and Ham C. (eds). (2000).

as restricting the supply of medical personnel or controlling the costs of drugs.⁸⁰

Through the PPRS, the British government, among the most directly involved in the provision of health services of any developed country, has chosen a very particular means of achieving the latter.

1.5 Political implications and policy

As the pharmaceutical market is dominated on the demand side by public purchasing, the pharmaceutical market is highly political. The economic context of the industry extends into the heart of politics.⁸¹

In the health policy arena, the government as the primary purchaser of medicines, regulates the pharmaceutical industry for several reasons:⁸²

- There is a perceived flaw in the operation of the market on the supply side – a lack of competition which gives producers undue power in the marketplace.
- There is nevertheless the intention to produce a lack of competition through the patent system in order to bring research and development funds into the sector.
- The demand side operates under conditions of moral hazard, where excessive demand can be expected.
- There is also an idiosyncrasy in the market based on lack of expertise by the final consumer (the patient), which means that purchasing decisions are made by a third party professional (the doctor).
- Government, as a funder of health care, has obligations to the tax payer to seek cost controls. This role also gives it the *ability* to exercise its

⁸⁰ Mossialos, E and Le Grand, J. (1999); pp.62-71.

⁸¹ Macmillan, K. and Turner, I. (1987), p.124.

⁸² For discussion of why governments regulate see the following: Peacock, A. (1984); Baldwin, R. and Cave, M. (1999), chapter 2; Breyer, S. (1998); Breyer, S. (1982), chapter 1.

power in the marketplace as a monopsony buyer, adding economic power to its legal authority in relation to the industry.

The government therefore exercises a 'double power' in relation to the industry, as both a regulator and a purchaser.⁸³ Not only is the market one which government may in any case seek to regulate but it is one in which the government has decisive market power. These two facts would lend themselves to a strict form of regulation against which industry would have few '*bargaining resources*'. The PPRS on the other hand has been described as 'light-touch.'⁸⁴ The difference, it is proposed here, lies in the industrial policy concerns of the government, which lend to the industry significant bargaining power and also unify the aims of industry and government to some degree. Both wish to see a favourable environment for pharmaceutical business in the UK, in international terms. The PPRS is therefore the outcome of a clash between two policy aims that are, at face value, in conflict.

1.6 Overview of the UK pharmaceuticals market

An important feature of the PPRS is its claimed ability to balance cost containment with support for the research-based British pharmaceutical industry and one of the claims of this thesis is that the nature of the UK pharmaceuticals market is a central factor in its ability to do so. The UK market itself has several characteristics that distinguish it, arising from the structure of supply and demand and, more idiosyncratically, policy responses to them.

1.6.1 Features of the British pharmaceuticals market

1. It is relatively small in terms of total value.
2. There is a significant degree of therapeutic conservatism among doctors.

⁸³ Teeling-Smith, G. (1969), pp.86-87.

3. There is a large generics market.
4. There is a relatively large over-the-counter (OTC) market.
5. Higher prices are concentrated at the 'top end' of the product range.
6. New medicines are launched quickly following licensing.

Market size

Overall expenditure on medicines is among the lowest of any major western country and around half as much per capita as in France, Japan or the US.⁸⁵ Within Europe, the larger markets are historically those of France, Italy and Spain.⁸⁶ The overall health budget is also lower as a proportion of GDP than in most developed countries,⁸⁷ but it remains that the actual cost of drugs to the public purse is less than in similar countries because consumption is less, and higher prices in some drugs are therefore more easily tolerated (see Table 1.5).

Therapeutic conservatism

The UK is known as a conservative market. New products may reach the market quickly but their uptake is generally quite slow. British doctors, for a variety of institutional and cultural reasons, do not take up new products quickly or use them widely. Their attitude tends to be one of waiting to see how the use of a product by others turns out in practice. The Second Report of the House of Commons Health Select Committee, Session 1993-4, says, "The impact of medical culture should not be underestimated in international comparisons of medicine consumption."⁸⁸ It has also been noted that "cultural differences between European countries' prescribing patterns are

⁸⁴ Interviews, DOH civil servant 5; industry executives 11 & 13.

⁸⁵ Tucker, A. and Taylor, D. (2000), p.21.

⁸⁶ Burstall, M.L. (1990), p.21.

⁸⁷ UK Health spending as a proportion of GDP in 1995 was 6.9%. This compares with 10.4% in Germany, 9.9% in France, 7.7% in Italy and 14.2% in the US. Source: Department of Health & Human Services (2000), Appendix 4.

⁸⁸ See, for example: House of Commons Health Committee, Session 1993-4. HC Papers 80-1, 7 July 1994, paragraph 30 and paragraphs 28-29.

based on deep rooted variations in medical culture and training rather than just the effects of contrasting price and profit controls for medicines.”⁸⁹

It is a fact recognised by the Department of Health. A senior civil servant there commented, “This country has got a history of relatively slow introduction of new medicines into the NHS because our GPs are conservative in terms of prescribing new medicines.”⁹⁰ Therapeutic conservatism was also recognised as a feature of the UK market in the final report of the PICTF: “Existing UK market conditions, including the traditional conservatism of many UK prescribers, mean that sales of new products are limited in the years immediately following launch...”⁹¹

While this is not a fact that the research-based industry would or does like in itself, it is something that acts as an informal brake on the potential shock to the health budget of the introduction of new products, potentially reducing the perceived need by government officials to devise some sort of formal mechanism for achieving this.

Large generics market

The UK generics market has been promoted vigorously so that today it represents over 50% of total prescription volumes. As a senior politician involved in the 1999 PPRS negotiations noted, “a huge proportion of the drugs that people get are now generic and we have one of the highest proportions in the world.”⁹² Generics need to overcome the goodwill built up by branded products during their patent life, and hence tend to be priced significantly lower than the original product. Generics volumes tend to be higher where prices are higher, such as the UK, and this can be seen in comparing European markets.⁹³ The largest generics markets in Europe are the UK, Germany, the Netherlands and Denmark, which also have the higher

⁸⁹ David Taylor (1992).

⁹⁰ Interview, DOH civil servant 5

⁹¹ Department of Health (2001), paragraph 2.14

⁹² Government minister 7

⁹³ Burstall, M.L. (1997), p.78.

prices.⁹⁴ Hence the UK market is characterised by relatively low prices for a large proportion of its volume (the generics) alongside the higher prices commanded by branded products.

Large over-the-counter (OTC) market

In addition, although the NHS accounts for the vast majority of medicine purchases, relative to other European markets the British OTC market is large. This factor further relieves pressure on the public purse (see Table 1.5, Column 4). Only Italy has a comparable (and slightly larger) proportion of OTC sales. OTC medicines transfer the budgetary burden for most sales from the NHS to the patient.⁹⁵ As well as the actual cost of the medicines, OTCs also avoid the considerable cost of a medical consultation. An eight minute meeting with a General Practitioner (GP) is estimated to cost the NHS about £18;⁹⁶ and GP consultations that could be dealt with by pharmacists are estimated to cost the NHS £380 million per year.⁹⁷

Higher price 'top-end' products

Although representing less than 50% of the total prescription market by numbers of prescriptions, in-patent brand name products account for 78% of prescription costs.⁹⁸ The highest selling drugs by value contain very few generics, with only three generic products in the top thirty drugs in the UK market (see Table 1.4). Prices are heavily weighted to the brand name, in-patent end of the market. It is possible to have higher prices at this end of the market yet pursue cost containment objectives only because of the volume of generics. Furthermore, the restriction on price increases in the PPRS means that launch prices are higher than they would otherwise be, because prices tend to be fixed for the longer term (see 3.4).

⁹⁴ Lewis, Graham (2001).

⁹⁵ OTC medicines can be obtained on prescription for financial reasons if a patient chooses, but the vast majority are paid for directly by the consumer.

⁹⁶ BBC News, 22 August 2000.

⁹⁷ BBC News, 29 August 2000.

⁹⁸ European Commission (2001).

Table 1.4: Top UK pharmaceutical products, 2000

	Product	Manufacturer	Date of marketing authorisation	Total sales £m
1	Losec	AstraZeneca	Jun 89	247.17
2	Zocor	MSD	May 89	172.58
3	Zoton	Wyeth	Apr 94	146.81
4	Istin	Pfizer	Jan 90	139.85
5	Lipitor	Pfizer	Jan 97	123.48
6	Seroxat	GlaxoSmithKline	Feb 91	104.80
7	Serevent	GlaxoSmithKline	Dec 90	95.62
8	Flixotide	GlaxoSmithKline	Mar 93	83.74
9	Zestril	AstraZeneca	Jun 88	77.01
10	Cardora	Pfizer	Jan 89	74.64
11	Pulmicort	AstraZeneca	Jan 83	68.24
12	Zyprexa	Lilly	Oct 96	66.79
13	Becotide	GlaxoSmithKline	Oct 72	66.71
14	Ventolin	GlaxoSmithKline	Jan 69	63.05
15	Zoladex	AstraZeneca	Mar 87	57.71
16	Lipostat	BMS	Sep 90	56.25
17	Fluxotine	<i>Generic</i>	n/a	54.50
18	Efexor	Wyeth	Jan 95	54.33
19	Adalat	Bayer	Oct 77	53.40
20	Cipramil	Lundbeck	Jun 95	50.42
21	Enalapril	<i>Generic</i>	n/a	49.51
22	Neoral	Novartis	Apr 95	47.18
23	Ranitidine	<i>Generic</i>	n/a	46.25
24	Imigran	GlaxoSmithKline	Sep 91	42.00
25	Lamictal	GlaxoSmithKline	Nov 91	41.92
26	Tenormin	AstraZeneca	Jun 76	41.58
27	Mixtard Human	Novo Nordisk	Mar 85	41.14
28	Tritace	Aventis	Mar 90	40.75
29	Cozaar	MSD	Feb 95	40.42
30	Becloforte	GlaxoSmithKline	Oct 82	39.23

Comparing pharmaceutical product prices across markets is notoriously difficult because bases of comparison can limit the studies undertaken, such as availability from the same manufacturer and difference in dosage forms, strengths and pack sizes of drugs in different countries. Studies can yield remarkably distinct results according to the criteria used for measurement.⁹⁹ As with any international price comparisons, exchange rate fluctuations also cause difficulties of measurement. Nevertheless, assembled data show the UK to be in the middle- to higher-end range of prices across-the-board in the EU, a position that has changed slightly over recent years, with relative aggregate prices for the UK coming down somewhat. A decade ago, they were towards, or at, the very top of the European league table.¹⁰⁰

Quick launch

Products are launched early in the UK relative to other European countries. The PPRS allows companies to price newly launched products as they wish. Because, in addition, it also effectively prevents actual price increases from that point on, prices are likely to be set higher at launch than they would be in a free market. Freedom of pricing at launch is therefore the means by which branded products are priced higher than in other European markets.

Freedom of pricing at launch it is a key feature of the market insofar as it allows products to be launched immediately following the issue of a license. This is because the price regulation system does not require any process of assessment for reimbursement purposes, as is the case in many other regimes. The PPRS enables this one, important, aspect of a free market to remain. It is one that is regarded by industry as vitally important in enabling them to recoup their large R&D investments – something that is generally recognised in government: “For industry, it’s about getting things onto the market in the UK,” commented a DTI civil servant.¹⁰¹ The attractiveness to

⁹⁹ Danzon, Patricia M. and Kim, Jeong D. (1998).

¹⁰⁰ Burstall, M.L. (1990), pp.31-32.

¹⁰¹ Interview, DTI civil servant 1

industry of the UK market relative to other European markets is based in large part on this one feature of it (see Chapters 4 and 5).

The importance of the quick launch following licensing approval has been recognised by the government during the deliberations of the Pharmaceutical Industry Competitiveness Task Force (PICTF), set up between government and industry as part of the 1999 PPRS negotiations, to study the competitiveness of the pharmaceutical industry and market.¹⁰²

Table 1.5: Non-hospital pharmaceutical consumption in European countries

Pharmaceutical consumption per person in various countries, 1997 (Column 1) and expenditure on prescription medicines per person in various European countries, 1995/96 (Column 2). Column 3 shows the pounds per person spent on OTC medicines and Column 4, what this represents as a percentage of the total market, per person.

	Column 1 Total £	Column 2 POM £ (%total)	Column 3 difference £	Column 4 % OTC
France	239	170 (71%)	69	29%
Germany	205	169 (82%)	36	18%
Italy	179	79 (44%)	100	56%
Sweden	172	145 (84%)	27	16%
UK	154	87 (56%)	67	44%

Notes. Column 1:

£ per person; Pharmaceutical consumption includes prescription medicines, OTCs, sales tax/VAT and pharmacists' remuneration; Hospital medicines are excluded.
Source: Health Data 1998 (OECD)

Notes. Column 2:

£ per person .
Sources: The Pharmaceutical Industry in Europe – Key Data (EFPIA); Tal Og (MEFA); Compendium of Health Statistics 1999 (OHE); SCRIP Magazine; Statistics '99 (VFA); Health Data (OECD)

1.6.2 Conclusions

The British pharmaceutical market displays a particular configuration of features that separates it in many ways from other European markets. There are greater similarities with some markets and price analyses show a basic correlation between broadly 'northern' European markets, on the one hand, and 'southern' European ones, including France, on the other. Relative

¹⁰² Department of Health (2001), paragraphs 2.8, 9.2 and 9.3.

average prices across Europe show the higher price countries being Germany, Belgium, UK, Denmark, Ireland and the Netherlands, while lower price countries are Italy, Spain, Greece, Portugal and (cheapest of all) France.¹⁰³ However, as Table 1.5 shows, there are cross cutting features which create a more complicated picture, and which mark out the British market as distinct.

There is also a complex interaction between the market and regulation, and identifying those aspects that are independent from regulation and those caused by it is an inexact science. The modern pharmaceutical industry has grown up within the PPRS framework for over four decades. Some features of the market can be seen as independent from, and prior to, the regulatory regime and therefore as ones which form the context within which the regulatory regime has been devised. Others can be seen more as having been created by regulation, in particular higher 'top-end' prices and a quick launch that characterise the PPRS.

In relation to government-industry relations in the PPRS, the market first provides opportunities for the government to achieve its key aims: its relatively small size and other features enable the government's procurement aims to be achieved without stringent regulation. Meanwhile, the PPRS yields key benefits (or '*regulatory goods*' – see Chapter 3) for industry. These features of the market, as a contextual feature of government-industry relations, underpin Hypothesis 1 in Chapter 3 below.

¹⁰³ Burstall, M.L. (1997), p.91; Garattini, L. and Tediosi, F. (2000); Mrazek, M. (200), p.459.

Chapter 2

UK pharmaceuticals regulation

2.1 The administrative architecture of regulation

2.2 Institutional organisation of industry

2.3 Supply side regulation: The PPRS

2.4 Other supply side controls

2.5 Demand side controls

This Chapter sets out the administrative architecture of regulation: the organisation of government and industry for negotiating and administering the PPRS. Through this architecture, both sides are concentrated into a small group of individuals charged with the responsibility to negotiate the PPRS on behalf of the government and the industry as a whole. The structure of supply and demand in the sector has therefore yielded small competent groups with decisive political resources and as a result a small and focused policy community to devise and administer the PPRS.

The market is dominated by a single buyer, the Department of Health (DOH), with overwhelming market power. The low elasticity of demand for medicines and the corporate structure of the industry also mean that there is significant concentration and market power on the supply side. Consolidation has created a small number of very large global firms, creating another important feature of the landscape in which government-industry relations are formed.

The dual aims of the government in both health (cost containment) and industrial policy mean that the market for medicines is shaped by politics.

In 1998, the NHS accounted for £6,056m of the total UK pharmaceutical market of £7,481m.¹⁰⁴ The vast majority of medicines in the UK market are prescription medicines funded by the NHS. The dynamics of the market are shaped by two basic facts:

- That the customer of products (i.e. the doctor) does not purchase (pay for) the product, as would a service provider in a normal market structure. This is the role of the government or taxpayer.
- Nor is the doctor the consumer of the product, which is the role of the patient.

¹⁰⁴ ABPI (2000a) p.20.

So the patient neither chooses the product s/he is to consume, and neither s/he nor the doctor pays for it: the purchasing transaction is a “dinner for three”.¹⁰⁵ There are additional factors including the role of the pharmacist and the various codes of conduct of professional organisations to which doctors and pharmacists are subject, as well as the complicating factor of the status of consumers: ill people in a position of particular need.¹⁰⁶ This has implications for some types of drugs in particular, such as psychotropic drugs. The nature of the demand side is peculiar and this is one of the reasons for the economic regulation of pharmaceuticals, on both the supply and demand sides.

As Chapter 1 explains, the demand side of the market is not the only basis of the perceived need for regulation. The supply of pharmaceuticals is seen as non-competitive because of the patent system, which institutionalises (purposely) product monopolies for a set period of time in order to encourage expensive research and development into new products.

The government therefore believe there is a need for price (or purchasing) regulation to ensure that the purchaser (i.e. government, or taxpayer) is not unfairly treated under the conditions of monopoly that are created by patent protection, exacerbated by the lack of normal purchasing sensitivities on the demand side.¹⁰⁷

This chapter sets out the various regulatory measures that have been developed to control pharmaceutical prices, on both the supply and demand sides, including a detailed and comprehensive analysis of the PPRS. First, it analyses the organisation of government and industry for the purpose of regulating pharmaceutical costs.

¹⁰⁵ Management Forum (2001); Jim Furniss.

¹⁰⁶ Taylor, David (1983), pp.15-18.

¹⁰⁷ Interviews, DOH civil servants 5 and 10.

2.1 The administrative architecture of regulation

The Department of Health is responsible for medicines and the pharmaceutical industry. There are three branches that deal with the industry and with procurement, all of which are part of the Medicines, Pharmacy and Industry Division (MPI).¹⁰⁸ The Branches are:

1. The Sponsorship Branch – aims to ensure that the views of industry are expressed within the Department and that its interests are promoted.
2. The Pharmacy and Prescribing Branch – deals with the consumption side of pharmaceuticals and demand side issues.
3. The Pricing and Supply Branch (formerly the PPRS Branch) – negotiates and operates the PPRS.

The structure of the Department vis-à-vis pharmaceuticals changed in 2000, when the sponsorship and PPRS functions were split into two branches, where previously the sponsorship function had been the responsibility of the PPRS Branch. This was contained within the International and Industry Division (the IID), along with an international function that is now no longer part of the pharmaceuticals-focused MPI Division.¹⁰⁹ It is this structure that was in place during the negotiation of the 1999 scheme. There has been a minor change in 2002, amounting to little more than a change in the name of the PPRS Branch to the Pricing and Supply Branch.¹¹⁰

2.1.1 Varying perspectives within the DOH

The change was in response to the 1994 Health Select Committee Report, which had criticised the presence of the sponsorship function within the PPRS Branch. It had said, "... it is essential that the individual Department of

¹⁰⁸ For the 1993 and 1999 negotiations, the Division of the DOH was the International and Industry Division (IID). It became the MPI, following the loss of the International section, in 2000. It will therefore generally be referred to as the IID throughout, unless the MPI is being referred to specifically.

¹⁰⁹ Interviews, DOH civil servants 4 and 5.

¹¹⁰ Civil Service Year Book 2002.

Health officials who negotiate with the ABPI over the PPRS ... should have *no responsibility* for promoting the industry ..."¹¹¹

Within the Department there are now three perspectives on medicines and the pharmaceutical industry:

- A specifically industry-focused perspective which provides a direct line of communication into the Department from, and for, industry; it also has good working contacts with the relevant part of the DTI.
- A specifically demand side perspective which focuses on issues of prescribing.
- A procurement perspective in the Pricing and Supply (PPRS) Branch.

The splitting of the sponsorship and PPRS functions has not rigidly split policy into two branches because the PPRS itself specifically aims to represent the dual role of government, as a purchaser and a sponsor, but the overt sponsorship function has been removed from those officials responsible for the PPRS. Prior to this, the official responsible for the PPRS also had the formal responsibility for sponsoring the industry, as was the case during the 1999 PPRS negotiations.

Broader pharmaceutical interests within the Department are also taken into account through 'MPOG', the Medicines Policy Oversight Group. This committee is serviced by the Sponsorship Branch and chaired by the Permanent Secretary. It includes representatives from most of the Divisions or Directorates within the Department who have an interest in medicines, including the Medicines Control Agency (MCA)¹¹², responsible for the licensing of medicines, on both the supply and demand sides. Its purpose is to ensure that there is a proper overview of policies that affect medicines.¹¹³

¹¹¹ House of Commons Health Committee. HC Papers 80-1, 7 July 1994, paragraph 93.

¹¹² Since 2003, called the Medicines and Healthcare Products Regulatory Agency (MHRA).

¹¹³ Interview, DOH civil servants 4 and 15.

2.1.2 The three departments

Beyond the Department of Health, formal regulatory architecture gives the DTI an important but limited role. There is a line of communication between industry and government, through the Bioscience Directorate (formerly the Biotechnology Directorate, during the 1999 negotiations). The DTI offers an alternative perspective (to the procurement perspective) that enables industry to communicate its concerns and to have its commercial interests represented. This perspective links in with the sponsorship function of the DOH. A DTI official explained: “The Department of Health Sponsorship Branch and the DTI Biotechnology Directorate look at the health service as a market – how it’s pulling through new technology, and how it operates to encourage, or not, the pharmaceutical companies and biotechnology companies that have got at least some base in the UK. We have the same kind of concerns.”¹⁴

The PPRS Branch of the DOH is concerned with procurement, but the context that shapes the articulation and expression of this concern is the PPRS itself – a scheme that has a broader purpose in defining the relationship between the industry and the NHS.

There are therefore three parts of the bureaucracy with some overt concern for the commercial and industrial interests of the pharmaceutical companies.

In addition, the Treasury has a significant impact on the PPRS. Its interest in the scheme is very significant and considerable time and resources are devoted to it prior to its renegotiation in order to arrive at the government’s negotiating position. In the end, the Treasury must also agree to any ‘deal’ that is agreed by the Department of Health, by formally ‘signing-off’ the agreement, along with the DTI. The Treasury therefore examines the PPRS as a separate framework within which a significant amount of public spending is arranged (over 10% of the total health budget), and does not simply confine its interest to the overall budget, leaving its disposal to the NHS. The

Treasury has a Health Team of several people specifically charged with health department issues and in the run up to a PPRS renegotiation its main task is to examine the scheme.¹¹⁵

2.1.3 The Pricing and Supply (PPRS) Branch

The Pricing and Supply Branch (PPRS Branch) of the MPI (formerly IID) is responsible for conducting the annual round of negotiations and discussions with each supplier to the NHS that the PPRS entails. It is also responsible, along with the division head, for negotiating the PPRS every five years or so and developing and executing the government's negotiating position (for details of the annual and five yearly processes, see 2.3.5). The role of the division head in the five yearly process is to ensure that the balance that the division represents, and whose task it is to achieve, is reflected in the PPRS agreement.

The Branch contains only 15 people including clerical and administrative staff. The Branch consists of two teams, each of three people including an accountant. Each team deals with its own portfolio of companies.¹¹⁶

In addition to the teams dealing with the annual cycle, there is another team including a pharmacist that is responsible for policy issues. Hence a separation has been made within the branch between the annual round of discussions and decisions based on the Annual Financial Returns (AFRs) of companies,¹¹⁷ on the one hand, and the development of policy, on the other.¹¹⁸ There is also a branch head, a supporting pharmaceutical officer and a small general office. At the five-yearly negotiation, the Head of Division is also centrally involved, and took a leading role along with the Branch Head in the 1999 negotiations.

¹¹⁴ Interview, DTI civil servant 1.

¹¹⁵ Interview, Treasury civil servants 24 and 25.

¹¹⁶ Interview, DOH civil servant 5.

¹¹⁷ Annual Financial Returns are submitted by companies to the Department to assess their NHS business (see 2.3.6).

The Department of Health and the Association of the British Pharmaceutical Industry (ABPI), the trade association for the industry, sign the PPRS. The DOH does so on behalf of the government and the ABPI on behalf of the industry. This entails that industry too has a formalised organisation and procedure for representing its diverse interests at these key negotiations.

2.2 Institutional organisation of industry

The ABPI's signature has always been taken as being on behalf of the whole industry. Although not all companies are members of the Association, all companies are expected to comply with the scheme. In fact, less than half of the companies selling to the NHS are members, although 80% of pharmaceutical sales by value to the NHS are from ABPI members.¹¹⁹

This gives the ABPI a highly political role. Indeed, during the negotiation of the 1999 agreement compliance by companies with the scheme was a major issue for the government and the ability of the ABPI to represent all of the industry was therefore an open question – more so because some firms not complying with the scheme were members of the Association.

2.2.1 Negotiating the PPRS

For negotiations of the scheme, the ABPI has set up negotiating teams of about seven people, including an ABPI secretariat and a spectrum of representatives of the industry. A balance has been struck along the two main axes or fault lines of ABPI membership – firm nationality (British, American, European) and firm size (large and small). The negotiating teams on the PPRS are organised to reflect both these size and nationality dimensions.¹²⁰ Throughout the history of the PPRS, the ABPI has modified its internal procedures in order to suit the demand made upon it by the

¹¹⁸ Department of Health (1999b).

¹¹⁹ Earl-Slater, A. (1997), p.39.

¹²⁰ Interview, industry executive 6.

scheme.¹²¹ The PPRS is a significant part of the Association's work and a central focus of its activity on an on-going basis. Even the preparation for the five-yearly negotiations can occupy it two-years in advance, as it did for the 1999 negotiations (see Chapter 4).

Typically, each company will begin a process of defining its position regarding the PPRS at least several months prior to the beginning of the ABPI process. The task of the ABPI is then to agree enough of a blueprint for negotiations to enable the relatively small team of industry negotiators to act with authority when they meet the departmental officials.¹²² In 1999, for example, a flexible negotiating remit was defined in advance for the negotiating group, within which they were not required to refer back to the full membership of the ABPI for approval. This is more effective in allowing the industry negotiators to face the government on reasonably equal terms, but it also requires a great degree of acceptance by the membership as a whole that the team of negotiators is representative and that their brief carries their authority.

2.3 Supply side regulation: The PPRS

The PPRS is the key mechanism of supply side regulation of the pharmaceutical industry in the UK, for the purpose of controlling costs in the purchase of medicines for the NHS.

The PPRS is the descendant of the Voluntary Price Regulation Scheme (VPRS), which dates from 1957. From this early time the government was worried about the rising costs of medicines within the NHS budget and in 1949 and 1956 standing committees had suggested the introduction of some sort of price control of medicines, based on the principle that tax payers had some right to have their interests represented in the public purchase of medicines.

¹²¹ Sargent, J.A. (1985), p.123.

The PPRS regulates the costs of medicines to the NHS by capping the profits on the NHS business of companies selling products to it. The scheme is intended to strike a balance between the health policy aims of cost containment and the broader industrial policy aims of maintaining and encouraging a world class pharmaceutical industry in the UK, contributing positively to the balance of trade.¹²³ Through this, it represents a compromise between the interests of the consumers and producers of pharmaceuticals. This creates a government-industry arrangement very different from other European systems in overtly attempting both cost containment objectives and the promotion of the UK pharmaceutical industry.¹²⁴

The purposes of the scheme have evolved slightly over the years but remain similar – focused on achieving a balance between these two policy aims. The stated purposes of the PPRS, as written in the 1999 scheme but scarcely altered in any scheme since 1978, are to:

- Secure the provision of safe and effective medicines for the NHS at reasonable prices.
- Promote a strong and profitable pharmaceutical industry capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines.
- Encourage the efficient and competitive supply of medicines to pharmaceutical markets in this and other countries.¹²⁵

2.3.1 The early history of the PPRS

The ABPI was formed from the Wholesale Drug Trades Association (WDTA) in 1948 – the change of name reflecting the new role given to it as representing more than the trade in drugs.¹²⁶ The objectives of the WDTA

¹²² Interview, industry executive 2.

¹²³ Earl-Slater, A. and Bradley, C. (1996), p.399.

¹²⁴ Borrell, Joan-Ramon (1999), p.292.

¹²⁵ Department of Health (1999a), paragraph 1.1.

¹²⁶ Lang, Ronald W. (1974), p.64.

were, from its outset in 1930, political. One of its four objectives was to: “promote or oppose or assist in promoting or opposing departmental or parliamentary legislation affecting the trade.” Involvement in policy was a principal aim and the relationship with government during the war years put the industry in good stead to command some influence over policy after the war.¹²⁷

During the war the WDTA had ensured the compliance of its members with the wartime emergency measures of the Central Pharmaceutical War Committee, part of the Ministry of Supply. The purpose of the measures was to ensure the integrity of supply to the public, but the framework of co-operation provided a basis for later strategies of regulation.¹²⁸

It also provided a possible blueprint for detailed administrative control of the industry, within the NHS framework, which industry wished to avoid.¹²⁹ In 1941 a National War Formulary was set up, listing useful and essential drugs dispensed under the National Health Insurance System. In 1945 the Ministry of Health (MOH) published a comparative list of products for inclusion in the formulary. Such powers were not subsequently included in the National Health Services Act. Immediately following the war the government was concerned to restore the balance of trade, and it recognised the place of the pharmaceutical industry in contributing to this.¹³⁰

Rising costs of health care

Following the war years, the British system of regulation developed in the decade after the setting up of the NHS, and was a response on the part of government to the unexpectedly high, and rising, costs of a health care

¹²⁷ Lang, Ronald W. (1974), p.60.

¹²⁸ In fact, as will be seen later on, the emergency wartime measures exist in the background of later regulation as emergency powers held by the Secretary of State for Health to set prices of medicines directly. These powers, though never used, remained in existence until the Health Act 1999. Their legislative incarnation was during the first world war, through the wide ranging Defence of the Realm Act ('DORA'), which aimed to secure the supplies of all types of goods in the wartime economy. Parts of the act exist today.

¹²⁹ Hancher, Leigh (1990), p.74.

¹³⁰ Hancher, Leigh (1990), p.75.

system which was designed with the expectation of an eventual levelling off of overall costs.¹³¹ In 1949 the government passed legislation allowing it to introduce a prescription charge, with the aim of not only raising revenue but, as Aneurin Bevan put it, to reduce the “cascades of medicine pouring down British throats”.¹³² As such, concerns about costs were the central motivation on the part of government in seeking some sort of regulatory framework for the purchase of medicines for the NHS. Several parliamentary committees examined medicine costs.

In 1949 the Standing Joint Committee on the Classification of Proprietary Medicines, *the Cohen Committee*, recommended to the Committee of Public Accounts (CPA) that price regulation of some sort be introduced. It recommended that doctors be discouraged from prescribing expensive branded products which were not sufficiently advantageous over generic equivalents (some sort of demand side control), and that prices for branded equivalents of standard products should have prices agreed in advance by the MOH and the manufacturer (some sort of supply side control). The idea of a negotiated agreement between the MOH and the industry already had the precedent of war time co-operation. The MOH had some experience of such a system while this presented the industry with an opportunity to negotiate to protect its interests.¹³³

A paper submitted to the CPA in 1952 reiterated the concern over the costs of pharmaceuticals, and stated that the rising drugs bill was attributable to the increase in branded prescriptions, which had grown from 7% of total prescriptions in 1947 to 23% in 1951, while overall per capita consumption had not grown so quickly.¹³⁴

Following this, *the Guillebaud Committee* was established in 1953 to examine the increasing expenditure on the NHS and, within it, on medicines. The Guillebaud Report recommended that the tax payer should have some

¹³¹ Macmillan K and Turner I. (1987), p.119.

¹³² Klein, R. (1995), p.31.

¹³³ Hancher, Leigh (1990), pp.77-8.

say in the prices of medicines bought by the NHS, and that at the same time the pharmaceutical industry should be able to develop properly.¹³⁵ Also in 1955-6 discussions with the industry as a whole were undertaken, leading to the establishment of the first VPRS.

An interim report of *the Hinchcliffe Committee on Effective Prescribing* revealed in 1957 that the MOH lacked basic statistical information on levels of drug consumption and use of branded products. This was a conclusion of the Guillebaud Committee as well, which had said that the lack of statistical information made it difficult to make recommendations concerning what to do about the drift towards more expensive branded products.¹³⁶

Government-industry co-operation

The wartime relationship and the setting up of the NHS had left the roles of the ABPI and the government intertwined. As Lang says, "From 1950 on, the fortunes of the ABPI were tied in very closely with the activities of the Ministry of Health, the Treasury and the Committee of Public Accounts."¹³⁷ It was through this relationship and this 'institutional dependency' that the ABPI was so heavily involved in the design of the VPRS when it was first introduced in 1957. Its organisational development was also defined by the relationship with government through the VPRS. But the co-operative relationship between government and industry is something that formed the context of the first scheme, rather than something created by it.

The reports of the successive committees suggest that the prior relationship of the industry with government as well as the inability of government to obtain independently the information it would need for strict regulation have underpinned the particular form of regulation in the VPRS and later PPRS. Indeed, in the years leading up to the first VPRS, the ABPI set up a negotiating committee in order to conduct business with government more

¹³⁴ Hancher, Leigh (1990), p.77.

¹³⁵ Hancher, Leigh (1990), chapter 3.

¹³⁶ Hancher, Leigh (1990), p.78.

efficiently and respond to the increasing pressure for some sort of regulation of pharmaceutical costs. The association therefore became integral to policy making and its role here became a significant part of its purpose and objectives.¹³⁸ It was helped in this aim by the economic situation in the UK at the time: persistent balance of payments problems made the industrial policy side of the case far stronger, and this was something the ABPI was able to argue for successfully.¹³⁹

In determining the relationship between government and industry, the limits to the ability of government to implement a regulatory regime was judged by successive studies to constitute a significant limitation on policy choices. Furthermore, the government was politically weak owing to various battles with the medical profession over the setting up of the NHS and this fostered a desire to avoid confrontation.¹⁴⁰

2.3.2 The 1957 VPRS

The first Scheme of 1957 was based on two assumptions about the pharmaceuticals market: that prices in export markets were competitive and could therefore be used as benchmarks for UK price levels; and that most medicines in the UK were reasonably priced, but that some form of regulation was needed for those that were not. The first assumption was later criticised by the *Sainsbury Report* of 1967, which drew attention to the effects of patents on the world market. The report judged that the nature of the pharmaceuticals market is one operating on the basis of product, rather than price, competition. Hence, where competition between products is reduced, which is the intended effect of the patent system, there ceases to be a market mechanism for a check on prices. It recommended that some types of branded medicine be placed in special categories and doctors prescribing them obliged to justify their decisions. Generally, it suggested far more scrutiny of costs, profits and prices in the sector. Particular attention was paid

¹³⁷ Lang, Ronald W. (1974), p.65.

¹³⁸ Lang, Ronald W. (1974), p.66.

¹³⁹ Hancher, Leigh (1989), p.87.

¹⁴⁰ Wright, Maurice (1991), pp.505-7.

to the extent of promotional expenditure by companies, and this became a key aim for the Ministry of Health in the VPRS.¹⁴¹

The first VPRS used three formulae for arriving at prices, and an option for direct negotiation if these were not applicable or if the manufacturer desired.

- The first formula was the 'export criterion' which was applied where more than 20% of a medicine was exported. In this case the maximum UK price would be the weighted average export price – the international market's competitiveness was assumed here.
- The second formula was the 'standard equivalent criterion', which applied to a narrow range of drugs. The branded product was to be priced no higher than the retail price of the unbranded equivalent.
- The third formula was the 'trade price formula criterion', which consisted of an addition of accepted costs such as the ingredients, an 'Oncost' of 12½%, allowances for processing, packaging and a wholesale discount.¹⁴²

The early development of the VPRS implied recognition that the first scheme needed to be strengthened if prices were to be affected greatly. The ABPI recognised that prices reached under the scheme's formulae would often be higher than those already charged.¹⁴³

2.3.3 Subsequent schemes

In 1961 the principle of negotiations with reference to costs and profits was introduced into the scheme, with the Ministry taking into account the profitability of a company's overall business with the NHS. In 1964, a new scheme tightened regulation further. First, the scope of medicines subject to regulation was extended beyond the branded equivalent of standard products, as defined by the Cohen Committee,¹⁴⁴ to include all medical

¹⁴¹ Taylor, David and Maynard, Alan (1990), p.10.

¹⁴² Ministry of Health (1957).

¹⁴³ Martin, S. (1996), p.5.

¹⁴⁴ Hancher, Leigh (1990), chapter 3.

specialities prescribed by GPs. Unbranded medicines remained excluded.¹⁴⁵ Second, the level of sales of a medicine to the NHS required for it to be subject to direct negotiation was reduced. Hence the thrust of the early schemes was to control prices.

It was in the fourth VPRS, in 1969, that direct reference to the sponsorship role of government was first made. The scheme referred to the importance of a “strong, efficient and profitable” industry, and continued: “As sponsor for the industry the Department of Health and Social Security recognises the industry’s contribution to the economy of the United Kingdom as a whole and wishes further to encourage its competitive efficiency both at home and abroad.”¹⁴⁶

In this scheme, a company’s sales of products to the NHS, rather than the export criterion or costs, formed the basis of negotiations. Companies were for the first time required to submit AFRs to the Department (then, the DHSS),¹⁴⁷ and factors taken into account included the company’s advertising expenditure, transfer costs between affiliated concerns, and research and other such expenditures.¹⁴⁸ It also took into account the ‘reasonableness’ of companies’ profits, as well as drug prices, and in this sense was an important shift towards the later PPRS.

However, this VPRS, in going further down the road of regulation, and in attempting to control both prices and profits, suffered from “the immensity of the administrative task to be undertaken and from its sheer complexity.”¹⁴⁹ Following this, the fifth VPRS, of 1972, incorporated a vaguer notion of ‘reasonable’ profit, and restricted comprehensive regulation to firms with large sales to the NHS, over £750,000, and those with sales of less than £150,000 no longer had to justify any price rises at all.¹⁵⁰ The 1972 VPRS is therefore one that modified the regulatory system in favour of the industry,

¹⁴⁵ Department of Health (1961), paragraph 3.

¹⁴⁶ Department of Health (1969).

¹⁴⁷ Taylor, David and Maynard, Alan (1990), p.11.

¹⁴⁸ Martin, S. (1996), p.6.

¹⁴⁹ Martin, S. (1996), pp.6-7.

which it did in recognition of the complexity of the previous regulatory regime, and the government's inability to implement it properly.

2.3.4 The first PPRS

The first PPRS came into operation in 1978, at a time when the government was concerned about the industry and that earnings and profits had fallen to an unduly low point.¹⁵¹ The scheme represented a further simplification of the regulatory system. It focused on the control of profits on aggregate business, moving away from the more direct control of prices under the preceding VPRSs.¹⁵² Since the NHS was effectively the sole buyer of prescription drugs, it incorporated the principle that *overall* costs and profits was the important factor, and that prices of individual medicines was not relevant.¹⁵³ Hence, uniquely in pharmaceutical price regulation in Europe, the regulation of company *profits* is the basis of the scheme. A target figure for profits earned from NHS business was set. The target for 1978/9 was 25%. The figure was based on a recommendation of the Review Board for Non-Competitive Government Contracts, and was similar to that for defence contracts, but with a slight addition for risk, to reflect the government's role as a sponsor of the industry.¹⁵⁴

The principles of the present PPRS therefore date from the 1978 scheme. The structure of that scheme was far simpler than its predecessors and allowed the DHSS to administer it with very few personnel and remarkably little administration.

The Public Accounts Committee (PAC) in 1983 was not satisfied that this PPRS was achieving reasonable prices for drugs. This criticism of successive schemes has continued, though changes in the schemes since

¹⁵⁰ Martin, S. (1996), p.7.

¹⁵¹ Taylor, David and Maynard, Alan (1990), p.12.

¹⁵² Sargent, J.A. (1985), pp.105-27; Hancher, Leigh (1990), pp.67-106; Earl-Slater, A. and Bradley, C. (1996), p.398.

¹⁵³ HMSO (July 1980), paragraphs 14-15.

¹⁵⁴ Martin, S. (1996), p.7.

then are considered to have made it more severe.¹⁵⁵ This was during a time of particularly strained relations between government and industry, as pharmaceutical costs rose while company incomes fell, partly owing to the strength of sterling and an increase in imports.¹⁵⁶ In the run up to the next PPRS, government-industry relations reached crisis point, with bitter public arguments over the introduction of the limited list in 1984-5.¹⁵⁷

The return on capital for pharmaceutical companies was considerably higher than for UK industry in general, by 5% or more. From 1984, the target rate was reduced from 25% to 21%, and the 'grey area', in which companies' profits were allowed to rise above this, was reduced from 10% to one third of the company's target profit. The target rate was again reduced in 1985. The figure was not made public but it was "consistent with the risk rate recommended by the Review Board in its report of 1984."¹⁵⁸ As the PPRS had given the pharmaceutical industry a 2% increment over these recommendations on non-competitive contracts in the past, 19% has been suggested as a likely figure.¹⁵⁹

The 1986 PPRS used a range for the target rate of return, within which companies negotiated with government. From 1987 this was 17-21%. It also increased the grey area from 33% to 50% above a company's target. The range, rather than a specific target, was to remain in the scheme until its renegotiation in 1999.

2.3.5 The five-yearly and annual processes

The PPRS operates at two distinct levels. First there is the periodic renegotiation of the scheme. This takes place roughly every five years. Each scheme has stated that the terms can be renegotiated (and a new scheme signed) after five years if either party wishes. This has to some degree been

¹⁵⁵ Burstall, M.L. (1997), p.S35.

¹⁵⁶ Taylor, David and Maynard, Alan (1990), p.13.

¹⁵⁷ Letter from Kenneth Clarke QC MP, Minister of Health 1984-5, 23 May 2000.

¹⁵⁸ House of Commons Papers . HC 280 (1985), p.7.

¹⁵⁹ Martin, S. (1996), p.9.

influenced by the electoral cycle. The longest running scheme was the 1978 PPRS, which ran for eight years. There have been eight schemes since 1957:

- VPRS 1957
- VPRS 1961
- VPRS 1969
- VPRS 1972
- PPRS 1978
- PPRS 1986
- PPRS 1993
- PPRS 1999

The five-yearly process sets the terms of the scheme. The various provisions themselves are agreed, as are the various thresholds within each part of the scheme. The scheme then forms the structure and framework for the annual cycle of negotiations between the DOH and each individual company that does business with the NHS. This second part of the scheme – the annual cycle – is where each company discusses its AFR with the DOH.

The negotiation and agreement of the PPRS and its implementation are thus the outcome of two separate negotiating processes, one of which is collective and the other individual, on the industry side.¹⁶⁰

2.3.6 Operation of the scheme: The annual cycle

The annual cycle takes place between the PPRS Branch and each individual company.¹⁶¹ There is no role here for the ABPI. Each company negotiates with the PPRS Branch a global return on capital based on their sales to the NHS in the previous year.¹⁶² Costs are examined following the submission of AFRs by the major companies (with over £25m of sales to the NHS) to the Department. The PPRS Branch only requires copies of audited accounts from companies selling between £1m and £25m to the NHS, and nothing

¹⁶⁰ Sargent, J.A. (1985), p.106.

¹⁶¹ Although the relevant branch is now called Pricing and Supply, it was for many years known simply as the PPRS Branch, including at the times of the 1993 and 1999 negotiations, which are the subject of subsequent chapters here. It will therefore generally be referred to as the PPRS Branch throughout, unless the point being made is specifically related to 2002 and later, and notwithstanding the fact that the annual cycle is described here in general rather than 'time-specific' terms.

¹⁶² Department of Health (1993 & 1999a); Burstall, M.L. (1990). p.30.

from companies selling less than £1m, unless specifically requested.¹⁶³ The distribution of these types of companies, following 1999, within the scheme is as follows:¹⁶⁴

Table 2.1: Categories of PPRS companies by sales

Total number PPRS companies	156
NHS sales in excess of £25m	35
NHS sales between £1m and £25m	71
NHS sales below £1m	50

The PPRS Branch uses the AFRs to ensure that the products listed are correct – that is, that they do in fact come under the auspices of the scheme – and that there is consistency between companies in their representations; they are also used to calculate allowable expenditure under the R&D formula and under the sales promotion formula.¹⁶⁵

There are three stages to the annual cycle. First, the companies submit their Annual Financial Returns, several months after the completion of the company financial year,¹⁶⁶ with provisions for agreed delays in certain circumstances. So the system works retrospectively.

The second stage consists of the DOH examining the returns and possibly seeking additional information, if it sees this as necessary (paragraph 8.5). Here the DOH examines the AFRs to ensure that they yield a permitted level of profit for the company on its NHS business. The accounting process for each company is therefore a key part of the operation of the scheme.

The third stage (paragraph 8.6) is the process of negotiation to reach agreement on the level of profitability achieved by the company, after which the Department issues an assessment, which may indicate a payment due

¹⁶³ Interview, DOH Civil Servant 5; Earl-Slater, A. (1997), p.45; Department of Health (1999a).

¹⁶⁴ Interview, DOH Civil Servant 5.

¹⁶⁵ Department of Health (1999a), paragraph 8.9.

¹⁶⁶ There are three groups, according to alphabetical listing, who submit AFRs 6, 9 and 11 months after the financial year, respectively. See Department of Health (1999a), paragraph 8.2.

from the company. Discussions with each company about its AFR are confidential.

Historically, the timetable is has not always been kept. The 1996 Report to Parliament¹⁶⁷ said that action on 19 of the 50 AFRs for 1993 had not been completed by 1996, though some progress was reported in the 1997 Report to Parliament. Still, the latter Report states that by September 1997 only 23 of the 45 AFRs relating to 1995 had been cleared by the DOH.¹⁶⁸ The 2000 Report to Parliament reported a significant improvement in the clearance of case work by the Department – up to 98% of those AFRs received within the past two years. There was also an improvement in the submission rate, with only a quarter of AFRs not received one year after the end of the financial year by 1998, compared with almost half in 1997.¹⁶⁹ There has been, then, a considerable delay in the application of the scheme to many companies in each year.

While the rate of allowable profit is set at 21%, factors entered on each company's AFR are discussed in the annual round of negotiations to ensure that they are allowable and to calculate what aspects of capital can be attributed to NHS business.

Much criticism of the PPRS stems from the behind-closed-doors negotiations, where each company sits down with government to discuss its capital employed and how much of it can be offset against NHS business. The scheme itself has improved in transparency in recent years – not least in the 1999 scheme – but the annual cycle of discussions is by its very nature not transparent, as it consists of discussions about commercially confidential data.

¹⁶⁷ These are intermittent reports produced by the PPRS Branch, at the request of Parliament in its 1994 Select Committee Report. They give details of the functioning of the PPRS and of the progress in the assessment of company accounts by the Branch.

¹⁶⁸ Department of Health (1996 & 1997).

¹⁶⁹ Department of Health (2000a), Table 1, p.8.

2.3.7 Details of the scheme

In assessing the amount of profit that companies can earn on their NHS sales, there are restrictions on the amount that can be attributed to various activities in calculating capital employed. The basic principle of the scheme is that companies should earn profits roughly in line with those of British industry in general. 'Reasonable' is not defined in the introduction of the scheme,¹⁷⁰ but so far as any explanation of the term is given, it is in this linking of profits to other sectors of industry.

The scheme does two key things. As well as limiting the profits that can be earned on NHS business for branded products, the scheme also obliges companies to apply for any price increase on any branded medicine sold to the NHS. So although companies must regulate the prices of their portfolio as a whole, they cannot do this by increasing individual product prices. They can only increase their overall profitability by either volume increases (where declining marginal costs of production would increase profitability¹⁷¹) or by new product launches, where the company is free to set any price it wishes. Indeed the scheme is designed to push companies to launch new products in order to regain their rate of profit on NHS sales – it is by this mechanism that the scheme encourages R&D investment.

a) *Calculating allowable profits*

Since the 1999 scheme, a rate of return on capital employed (ROC) has been set for the industry as a whole at 21%. The first step in the annual cycle of the AFR assessments is to calculate capital employed by the company – which includes fixed assets, such as buildings and equipment, and working capital, such as debtors and stocks less creditors and tax. Profits are then

¹⁷⁰ Sargent, J.A. (1985), p.105.

¹⁷¹ It seems unlikely that the *rate* of profit could be increased easily through increases in sales volume within the UK market at a constant price, given that production is in any case organised on a global basis and any available economies of scale are likely already to have been achieved for most products. Increases in volume would therefore be to increase overall profit rather than the rate of profit.

calculated by deducting allowable costs from total sales. Costs that are included in this calculation are as follows:¹⁷²

- Costs of goods (direct costs of producing medicines or the cost of importing them or purchasing them from another company).
- Distribution costs.
- R&D costs.
- General administrative costs, which are usually about 12% of sales.
- Costs related to the provision of information on products (i.e. data sheets) and non-promotional expenditure.
- Promotion, which includes the cost of marketing to the NHS.

There is also a fixed costs allocation, through which 7.5% of total net UK-based NHS medicines fixed assets can be allocated to the NHS, before the PPRS allocations take place. This is because, to quote the PPRS itself, “the Department acknowledges that a straight apportionment on the basis of the value of NHS and export would not take full account of the cost and asset base required in the UK to supply branded medicines to the NHS.”¹⁷³ This marks a significant increase in the basic fixed cost allocation, which was 2.4% in the 1993 Scheme.¹⁷⁴

Hence, 7.5% of all fixed assets employed to produce branded, prescription medicines is ‘allocated’ to UK production. The remaining 92.5% is then divided between exports and NHS business proportionately, with some minor differences in the criteria used for apportionment in the two cases.¹⁷⁵ There is therefore a slight weighting of fixed assets in favour of UK production over export production.

The purpose of this mechanism is to offset the widely reported ‘export disincentive’ attributed to the PPRS.¹⁷⁶ The export disincentive arises

¹⁷² Mossialos, E. (1997), p.54.

¹⁷³ Department of Health (1999a), paragraph 15.1.

¹⁷⁴ Department of Health (1999b), paragraph 2.14

¹⁷⁵ Interview, DOH Civil Servant 5.

¹⁷⁶ See, for example: Mossialos, E. (1997), p.68.

because increases in capital do not need to be as proportionately large as increases in export sales, so the capital base of NHS business appears to reduce as exports increase. The figures below serve as a hypothetical example of how profitability on NHS business can be reduced as exports rise. They also show how the 7.5% basic allocation to UK costs might offset this to some degree:¹⁷⁷

Table 2.2: Effects of the PPRS ‘fixed costs allocation’

	<u>Home</u>	<u>Export</u>	<u>Total</u>
<u>Yr.1</u>			
Sales	200	0	200
Capital	100		100
π 21%	21%		
<u>Yr2. with no initial UK allocation</u>			
Sales	200	100	300
Capital	80	40	120
π 21%	16.8%*		
<u>Yr.2 with 7.5% allocation</u>			
Sales	200	100	300
Capital	83†	37‡	120
π 21%	17.4%**		
* 80% of yr.1			
** 83% of yr.1			
† $7.5\% \times 120 = 9$; $120 - 9 = 111$; $2/3 \times 111 = 74$; $74 + 9 = 83$			
‡ $1/3 \times 111 = 37$			
π = target profit			

In addition to specifying a rate of profit allowable, the PPRS also sets limits, or allowances, to some aspects of capital employed. Principal among these are limits on R&D and on promotional expenditure, which includes marketing to the NHS.

¹⁷⁷ Interview, industry executive 13.

The R&D 'allowance' is up to 20% of the value of NHS sales. This is taken to ensure that sufficient research and development investment is undertaken (or available to be undertaken) by companies to support an innovative industry. There is also a variable rate of R&D allowance, which is further intended to encourage innovation: "an additional 0.25% of NHS home sales for each in-patent molecule above a threshold of £0.5 million of NHS home sales per annum up to a limit of 12 molecules. This is available on top of the ... allowances ... The amount allowed reflects both a contribution to the worldwide cost of R&D undertaken by companies developing human medicines and a desire to reward and provide an incentive for success in R&D."¹⁷⁸ The purpose of this is to *recognise* rather than *reward* innovation, as it allows extra money for a diverse product portfolio.¹⁷⁹

Allowable sales promotion expenditure consists of three components. There is a 'standard' element of 6% of home sales of NHS medicines, plus a 'fixed' element of £464,000 per company.¹⁸⁰ In addition, there is a 'product servicing allowance' for each active substance with NHS sales of £100,000 or above in the year to which the AFR refers. These are higher for the limited number of eligible products, reducing gradually. The 1999 scheme allows £58,000 for each of the first three eligible products, £46,000 for each of the next three, £35,000 for each of the next three, and £23,000 for each of the rest. The scheme also sets out what particular activities are regarded as qualifying as 'sales promotion'.¹⁸¹

Sales promotion allowances do not restrict sales promotion expenditure over all. They limit the amount that may be offset for PPRS purposes. In reality, companies may spend more than this (as they may with R&D allowances). This means that 'PPRS profit' may be lower than 'real' profit, as money spent for sales or R&D registers as profit for PPRS purposes.¹⁸² This may be seen

¹⁷⁸ Department of Health (1999a), paragraph 14.1.

¹⁷⁹ Interview, DOH Civil Servant 5.

¹⁸⁰ Interview, industry executive 13.

¹⁸¹ Department of Health (1999a), paragraph 16.1.

¹⁸² Interview, industry executive 13.

to disadvantage small companies, for whom a new drug may form a very large part of their hopes for success. Their ability to 'add' promotional expenditure above that which can be counted in PPRS calculations maybe more limited than for very large companies. The allowance per company is intended to offset this to some degree.

If a company is calculated to earn more than 21% profit on capital employed, using the specified allowances for some types of expenditure, then it must pay back the excess profit to the Department of Health, subject to the operation of the 'margin of tolerance' (see below).

b) Levels of allowances and price increases

Key to the dynamics of the PPRS is that prices of individual products continually fall in real terms. Rises in price of individual products have to be applied for to the Department and in practice they are rare.¹⁸³ As this decline in prices happens, company profits are recovered by the launch of new products, over which they have complete freedom of pricing. The PPRS therefore also specifies rules for price increase applications.

For the rate of allowable profit, allowable R&D costs and allowable promotional expenditure, the PPRS specifies two 'levels'. Level 1 allowances apply for price increase applications. Level 2 allowances – i.e. the figures described above – apply for AFR analysis in the annual cycle.

Level 1 allowances are 17% for the ROC, 17% for R&D and 3% for promotional expenditure. In other words, the AFR is effectively recalculated using the less generous figures to see if the allowable ROC (now 17%) has been reached. Only if a company's profits fall below 17%, subject to the application of the other level 1 allowances and to the operation of the margin of tolerance, will a price increase be granted.

¹⁸³ Interviews, industry executives 9 and 13.

There are further restrictions on price increases. No increase will be granted within 12 months of a preceding authorised price increase (paragraph 19.6); and a price increase will not be granted where a company's 'AFR business' is not up to date (paragraph 19.1).

c) The margin of tolerance

The PPRS is in practice both far more generous in its analysis of AFRs and far more stringent in its consideration of price increase applications than these two levels of allowances suggest. This is because of the operation of a mechanism known as the 'margin of tolerance' (MOT).

The MOT operates in order to allow for rises and falls in profits either side of the target rate, before any price increases need be considered or any profits repaid or price reductions implemented by companies. The MOT is set at 140% above level 2 profit and 50% below level 1 profit. Profits can therefore be kept up to 29.4% of capital employed (21×1.4) before the Department will require money to be paid back. Furthermore, companies can fall significantly below the 17% target profit, that is, 8.5% profit (17×0.5), before a price increase is considered.

This therefore operates as another restriction on price increases. Where a price increase is allowed for a particular company, profits above the *level 1* allowance (17%) in that year must be repaid to the Department. A 'return' to level 2 profit (21%) can therefore only be achieved by means other than price increases – effectively through new product launches. The scheme states: "The MOT will not be available to a scheme member for any year in which it has had a price increase agreed by the Department." Furthermore: "Where a scheme member exceeds its level 1 target profit for a year in which it has received a price increase, all profits above the level 1 target will be repayable."¹⁸⁴

¹⁸⁴ Department of Health (1999a), paragraph 12.2.

In summary, profits must fall below the bottom of the target range, plus the MOT, for price increases to be considered. Price increases are then considered, but on the basis that they will be granted in order to return profits to level 1 target only. No action is taken to reduce profits until they exceed the upper limit of the range, plus the MOT.

d) Return on sales companies

Companies with little capital investment in the UK have their profits based on sales. These are known within the PPRS as 'ROS' (Return on Sales) companies. If a company's sales exceed its capital employed, sales are taken as the basis of calculating allowable profits. The allowable profit target is divided by a factor of 3.5 for this purpose – i.e. 6% profit is allowable on sales to the NHS. This happens if a company's annual sales are more than 3.75 times its capital invested. There were 7 such companies in 1993, out of a total of 43 selling to the NHS,¹⁸⁵ and in 1999 there were 9 such companies.¹⁸⁶

e) Free pricing

A central feature of the PPRS is that it allows companies to set prices for new products. This is a key dynamic of the PPRS 'system', as it is intended to encourage innovation because product launches are the only means of re-attaining allowable profits. Such product launches also enable companies to offset the effects of the overall price reduction that has been part of each five-yearly agreement (see below).

There are qualifications about free pricing related to the launch of potential 'blockbuster' drugs. There is a clause that requires companies to inform the government of the launch on the UK market of any such drug – defined as those that might exceed £20m of sales in any one year of the first five years of sales. This, Earl-Slater suggests (of the 1993 scheme) stems in part "from

¹⁸⁵ Mossialos, E. (1997), p.55.

¹⁸⁶ Department of Health (1999b), paragraph 2.8.

a political fear of 'blockbuster' products rupturing control and growth of the NHS drugs bill."¹⁸⁷ The PPRS does not contain any provision to include such products, which, as new products, would be exempt from individual inclusion in the scheme for the first five years of sales, providing that overall profits do not exceed the MOT.¹⁸⁸ This mechanism shows the government's need to be able to plan adequately for 'blockbuster' products. The term 'blockbuster' for the Department refers to levels of sales, rather than to any therapeutic advance or the extent of medical need, emphasising the nature of their importance from the Department's perspective.¹⁸⁹

f) Price reductions

PPRS agreements have historically been an opportunity for the government to achieve an across-the-board price reduction in the total NHS pharmaceutical bill. The 1993 scheme imposed a reduction of 2.5% on all products covered by it, from companies with NHS sales over £1m, for the period 1st October 1993 to 30 September 1996. The 1999 scheme imposed a reduction of 4.5% from 1 October 1999, to remain unchanged until 1 January 2001, after which companies will be able to apply for price increases. The 1999 scheme includes a mechanism of 'modulation', in which the DOH will accept reductions that in sum (across a company's portfolio of NHS products) amounts to the same as a 4.5% reduction for each product. This is a significant 'one-off' cut and it is possible in theory that some companies would have fallen below maximum allowed profits for some time.

2.3.8 Dynamics of the scheme: What it does and doesn't do

The PPRS has several functions. As is described above in detail, the principal mechanism of cost control within it is the regulation of the profits earned by companies on their business with the NHS. There are, though, numerous other features of the scheme that also control costs. These include

¹⁸⁷ Earl-Slater, A. (1997), p.45.

¹⁸⁸ Department of Health (1999a), paragraph 20.1.

¹⁸⁹ Earl-Slater, A. (1997), p.46.

the prevention of price increases, which have to be approved by the Department in accordance with rules laid out in the scheme; and the one-off price reduction across all NHS medicines, which can reduce the drugs bill significantly over the short-term and therefore stem the rate of its longer term rise.

In summary, the main components of the PPRS are as follows:¹⁹⁰

- The statement of objectives
- Control on profits
- Control on price rises
- Control on research and development expenditure
- Control on advertising expenditure
- Advance warning to government of 'blockbuster' products

The scheme aims to fulfil simultaneously health and industrial policy goals. It aims to achieve the health policy goal of cost containment and the industrial policy goal of a successful and internationally competitive pharmaceutical industry.¹⁹¹ As has been noted by several commentators, "These dual objectives of cost containment and industrial innovation, are not necessarily wholly compatible."¹⁹²

The scheme aims to achieve 'reasonable prices' for NHS medicines. As prices are not themselves regulated, what it in fact does is effect to some degree the amount, in aggregate, that government pays for NHS medicines. High prices in one part of a company's portfolio must be offset by lower prices elsewhere. It *regulates* prices but does not set them directly, in so far as they cannot easily be raised once they have been set by companies. In real terms prices of individual medicines continually fall.

Only if company profits fall significantly below the allowable ROC is a rise in price of an individual medicine considered by the Department of Health. The

¹⁹⁰ Earl-Slater, A. (1997).

¹⁹¹ Sedgley, M. (2001).

¹⁹² Martin, S. (1996), p.3.

basic 'dynamic' of the PPRS is therefore that as real prices of products are eroded by inflation, pharmaceutical firms must release new medicines into the marketplace in order to maintain their allowable profit level. Free pricing at launch is a key feature of the system and such releases enable companies to move back up to their allowable rate of return if they have fallen back from it. Through this, the scheme aims to encourage innovation.

The value of free pricing for industry extends beyond its function in assisting in a rise in the rate of profit. Crucially, it enables a quick launch. Reimbursement systems, where a price has to be fixed in advance of sales, can delay launch by many months. The UK has one of the quickest launch times following market approval of any major market. Germany, Switzerland and Sweden are similar and only the US is quicker.¹⁹³

The launch price is also important in relation to other markets – the UK is referred to overtly by other European countries to fix their (reimbursement) prices. Countries that include the UK as one of the countries for fixing prices include Italy, the Netherlands and Ireland; several other countries use an average of all EU country prices. However, the extent of cross referencing (where countries base their prices on countries that have already based them on prices elsewhere) mean that only three EU countries actually price their pharmaceuticals completely independently: Germany, France and the UK. All other 12 member states of the EU have prices based in some way or other on the UK.¹⁹⁴

The scheme exercises no control over volumes of consumption and therefore cannot *determine* the overall NHS drugs bill. The release of new medicines into the marketplace could, in theory, have a significant effect on NHS costs if demand for them proved to be very high. The effect of the scheme is therefore quite limited: it helps, where a company is already at its profit ceiling, to ensure that the effect on the NHS's costs of the release of new

¹⁹³ See, for example: Department of Health (2002c), p.41.

¹⁹⁴ Management Forum (2001); Jim Furniss.

drugs under patent protection are *to some degree* compensated for by price reductions on other, older products.

Through the across-the-board price reduction on all business with the NHS, the scheme provides an occasional opportunity for government to keep in check the growth in the NHS drugs bill. Given the near impossibility of then achieving a price increase on a particular product, only products that are released following such a reduction remain unaffected by it – a further incentive for the development of new medicines.

In summary, the PPRS interacts with and affects the market for medicines in several ways:

- It allows free pricing at launch.
- It encourages new product launches.
- It prevents product price increases.
- By capping company profits it can potentially reduce the effect of new product launches on the NHS budget.
- By capping various aspects of company expenditure as legitimate components of capital employed it can affect company behaviour.
- It provides a five-yearly opportunity for renegotiation of details and a one-off price reduction.
- It provides a context and an arena for a close working relationship between government and industry.
- It provides some insurance against a 'budgetary shock' from a 'blockbuster' product.

2.3.9 Significant developments in the 1999 scheme

The first significant change in the 1999 scheme was the introduction of the two 'levels' of allowances – i.e. the introduction of a separate set of allowances for price increases. Previously, there had been stated 'ranges' of allowances, and the way in which these were implemented vis-à-vis each company were not transparent. The ROC was a range of 17-21%. Where

each company fell within this range was a confidential matter between the Department of Health and each company.¹⁹⁵

The R&D allowance was stated in very vague terms in the 1993 scheme, and subject to discussion between the DOH and each company. The type and level of investment in the UK was one factor used to decide upon a “level of support” for R&D.¹⁹⁶ In the 1999 scheme, the range was replaced by two fixed amounts of 17% and 21% for the two levels. The 1993 scheme stated that research allowances will be maintained “in total for the industry at the existing level”, without saying what that was.¹⁹⁷ The previous scheme of 1986 does not state a level either but rather says, “The level of support will be negotiated individually with each company.”¹⁹⁸ This was an area of flexibility, where the annual cycle determined the figures on a company by company basis.

The sales promotion allowance remained unchanged except for the introduction of the level 1 allowance of 3%.

The other significant change between the 1993 and 1999 schemes was the extension of the MOT. In the 1993 scheme the MOT was 25% either side of the target profit range. Price increases would therefore be looked at if profits fell more than 25% below the lower end of the target profit range, and excess profits would have been made when they rose 25% above the target profit range. The 1999 scheme saw these increased to 50% below the fixed 17% for price increases and to 140% above the 21% for normal AFR business. The additional restriction on profits for a year in which a price increase had been granted was also introduced in the 1999 scheme.

¹⁹⁵ Trumbull, J. Gunnar (2000), p.30.

¹⁹⁶ Department of Health (1993), paragraphs 12.1-12.4.

¹⁹⁷ Department of Health (1993), paragraph 12.1.

¹⁹⁸ Department of Health (1993), paragraph 12.1

Both industry and government commentators see this extension of the MOT in the 1999 scheme as essential to a system that they regard as having (to a greater or lesser degree) penalised success and rewarded inefficiency.¹⁹⁹

Other changes include:

- The 1993 scheme had a restriction on price increases in any one year to a maximum of 10%, but this has been dropped from the 1999 agreement.
- ROS allowances were increased from 4.5% return on sales in 1993 to 6% in 1999.
- In order to improve compliance (and get AFR business up to date), which was a key aim of the new scheme,²⁰⁰ the 1999 scheme was accompanied by a provision in the 1999 Health Act for a 'statutory scheme' to be applied to any company that did not sign up to the voluntary scheme (see Chapters 5 & 6).²⁰¹

In addition, there was the setting up of a Pharmaceutical Industry Competitiveness Task Force (PICTF) to examine all aspects of the industry's regulation and other factors affecting its competitiveness, including contextual features that affect pharmaceutical investment, such as the science base (see above and Chapter 4).

2.4 Other supply side controls

2.4.1 Statutes

a) *The Health Act 1999*

The 1999 Health Act introduced provisions for the Secretary of State for Health to impose a 'statutory scheme', which 'shadowed the PPRS in its structure, on any company that did not sign up to the 'voluntary scheme'. As

¹⁹⁹ Interviews, DOH civil servant 5; industry executive 13.

²⁰⁰ Department of Health (1999b), paragraph 4.1.

²⁰¹ HMSO (1999), paragraphs 33-38.

is explained in Chapters 5 and 6, this was a highly significant development in the politics of government-industry relations in the pharmaceutical sector. The government now has statutory powers to control the prices of medicines directly if it so wishes. Furthermore, there now exists a legislative framework that effectively gives added force to the negotiating competence of the ABPI over all the industry, because if companies do not sign the scheme negotiated by it, they may be subject to statutory control.

The scheme can be applied immediately to any company that does not sign up to the voluntary PPRS. Nevertheless, to prevent the flouting of the PPRS by companies that have signed up to it, there is also provision within the Health Act for direct powers to control the prices of medicines. The Secretary of State can “prohibit any manufacturer or supplier to whom a voluntary scheme applies from increasing any price charged by him for the supply of any health service medicine covered by the scheme without the approval of the Secretary of State.”²⁰² The Secretary of State can also, after consultation with the ABPI, “limit any price which may be charged by any manufacturer or supplier for the supply of any health service medicine.”²⁰³

b) The National Health Service Act 1977

The government has had direct power to control prices since the First World War. More specifically, the National Health Service Act 1977 gave the Secretary of State the right to impose prices on individual medical products. Section 57 of the Act states: “The Secretary of State may by order provide for controlling maximum prices to be charged for any medical supplies required for the purposes of this act.”²⁰⁴

The 1977 Act was passed in an atmosphere of suspicion between the industry and the Labour government, which had mooted the idea of nationalising the industry (as was to happen to parts of the French

²⁰² HMSO (1999), paragraph 33 (8)(a).

²⁰³ HMSO (1999), paragraph 34 (1)(a).

²⁰⁴ HMSO (1977), Section 57.

pharmaceutical industry in the early years of the Mitterrand presidency, when one quarter of the industry was transferred to the legal ownership of the state²⁰⁵). The Act was a decisive shift in the government's approach to the industry because it effectively put the force of law underneath the negotiating table. Trumbull notes that it "changed the nature of government-industry relations."²⁰⁶ He also notes that agreements subsequent to the 1977 Act were renamed PPRS in place of the Voluntary Price Regulation Scheme (VPRS) that it had previously been.

Although the power to control prices directly is restated in the 1999 Act, the 1977 provisions have been regarded as not providing for a 'variable response' and rather being a 'nuclear option' that could never in practice be used without scarring relations between government and the industry, possible irreparably.²⁰⁷ The 1999 Act, while allowing for direct price controls, also enables a scheme shadowing the PPRS to be imposed – i.e. it allows for the statutory control of profits as a more measured, and therefore realistic, response to non-compliance by companies.

2.4.2 The General Medical Services (GMS) Regulations

Supply of some medicines to the NHS has been restricted through provisions set out in the National Health Service Act 1977. As part of the National Health Service (General Medical Services) Regulations, which are the terms of service for GPs in the NHS, two schedules restrict the right of GPs to prescribe some drugs on the NHS. Schedule 10 is a 'blacklist', which completely bans the prescription of those medicines that appear on it. Schedule 11 is a 'greylist' that restricts the use of a named drug to particular groups of patients or specified indications or severity of indication.

²⁰⁵ Hancher Leigh. (1990), p.238.

²⁰⁶ Trumbull, J. Gunnar (2000), p. 30.

²⁰⁷ Interviews, DOH civil servants 5 and 10; industry executives 3 and 13.

a) Schedule 10, the Selected or Limited List

Schedule 10 is otherwise known as the Selected List or Limited List, first introduced in 1984, and extended in 1993. It is titled “Drugs and other substances not to be prescribed for supply under pharmaceutical sales.”²⁰⁸ Its introduction was controversial and soured relations between the government and industry.

The 1984 list was one of the most politically controversial acts taken by the Department of Health (then DHSS) and marked a low point in the government’s relationship with industry. It forbids the prescribing of brand name products in certain therapeutic categories, which must be replaced by generic prescribing. Overall, in 1984/5, 600 products in seven therapeutic classes were banned from prescription under the NHS.²⁰⁹ The list was extended significantly in 1993. Now there are about 3000 products listed on it.

The drugs that are listed in Schedule 10 can be prescribed to patients privately but may not be prescribed at the cost of the NHS. The medical law firm Lockharts, in its brief on the subject,²¹⁰ notes that the Limited List is recognised to have both an impact on the pharmaceutical companies’ targets and on the direction in which they use their resources to develop new pharmaceutical products.

b) Schedule 11

Schedule 11 contains a small range of specialised drugs which may only be used on certain occasions. The schedule is titled “Drugs to be prescribed under pharmaceutical services only in certain circumstances.”²¹¹ In its original form the schedule was not controversial and specified uses of certain drugs for certain purposes, with medical justifications at the basis of such

²⁰⁸ Statutory Instruments, 1992 No.635, National Health Service, England and Wales; p.222.

²⁰⁹ Earl-Slater, A. & Bradley, C. (1996), p.400.

²¹⁰ See information from Medical Law Firm, Lockharts: www.lockharts.co.uk

decisions. Schedule 11 has, however, become more noteworthy and certainly controversial in recent years as it appears to have been used for 'cost-effectiveness' type decisions by the Department of Health, in cases where the nature of medical need is not clear. The most notable example recently is that of the sexual dysfunction drug Viagra, produced by Pfizer; another significant one is Propecia, a drug to alleviate baldness produced by Merck Sharp & Dohme (MSD), which again falls outside what the NHS considers to be appropriate for public funding.

The inclusion of Viagra in Schedule 11 has caused very considerable concern and the British Medical Association continues to press the government to remove the prescribing restrictions on the grounds that the conditions for which the drug may be prescribed are not the only conditions for which the drug has a proper clinical purpose.

2.4.3 The risk-sharing scheme

In May 2002, a novel attempt to overcome one of the principal fears of government – that of a shock to the medicines budget from so-called 'blockbuster' drugs – was introduced. It was an experiment in risk-sharing between the NHS and the pharmaceutical industry and was introduced for multiple sclerosis (MS) drugs in May 2002 (announced in February), following controversy about cost-effectiveness appraisals for MS drugs by the National Institute for Clinical Excellence (NICE). The risk-sharing scheme is in its early stages, in part because of delayed NICE assessments of the drugs concerned – beta interferon and glatiramer – and also because of a lack of available specialist staff.²¹²

The scheme is based on the principle of 'payment by results'. Costs to the NHS of the drugs will be gradually reduced unless evidence of their effectiveness is shown. Performance of the drugs will be assessed according to target outcomes set between the government and the manufacturers of

²¹¹ Statutory Instruments, 1992 No.635, National Health Service, England and Wales; p.2239.

²¹² *Scrip* No. 2763, 12 July 2002, p.6

each of the four drugs involved. If performance targets are met in full, the drugs will be considered to be cost-effective for the NHS. The department estimates that adjustments in costs according to the performance criteria, are likely to continue for about 10 years.²¹³

Strategic health authorities (SHAs) and primary care trusts (PCTs) are obliged to fund MS drugs under the scheme. Patients are put on the scheme following assessment of their suitability for it by consultant neurologists at special MS centres.

The scheme may form a model for the funding of expensive innovative drugs in the future. Though initially billed as a scheme confined to MS drugs, an extension to other areas has not been ruled out by the Department of Health. It has said that it would depend on such a suggestion being made by NICE. However, there is the potential for the risk-sharing approach to be seen as an alternative to the NICE appraisal process, even though NICE itself is the means by which any future schemes would be introduced.²¹⁴

2.5 Demand side controls

Until the NHS reforms of the Thatcher governments, and the subsequent reforms introduced by the Major and Blair governments, pharmaceutical expenditure was controlled chiefly by supply side measures – mainly the Pharmaceutical Price Regulation Scheme (PPRS), as well as Schedules 10 and 11 of the GMS regulations.

From 1948 onwards, pharmaceutical expenditure in the NHS had been 'demand-led' – that is determined by the activities of GPs (who have accounted for about 75% of all NHS pharmaceutical expenditure) and their assessment of need. There had been attempts to control indirectly the activities of GPs, but these, in the 1950s, centred on getting good prices from

²¹³ Polak, M. (2002); pp.153-54.

the industry for 'expensive' products – in other words, formed the basis of supply side controls later instituted in the VPRS.²¹⁵

There are now various demand side controls in the area pharmaceutical purchasers and the extent of this has been recognised in the PICTF report. The report states that the extent of these marks out the British market as distinct from all other European markets.²¹⁶

2.5.1 Co-payment and cost-sharing

The longest running demand side control on pharmaceutical consumption has been the prescription charge. This is one of the few co-payment systems in operation in the NHS, where patients contribute to the cost of treatments. Most other European health care systems make far greater use of co-payment as a demand side control. Nevertheless, the prescription charge, although quite high (in some cases exceeding the total cost of the drug) is charged to only a minority of the population, and those exempt are the heaviest users – only 14% of NHS prescriptions incur the prescription charge.²¹⁷ Today however, there are significant other demand side controls on pharmaceutical consumption.

2.5.2 Prescribing controls and advice

Through the 1980s a Prescribing Analysis and Costs system, known as PACT, was developed. This was given to doctors to show them how much they were spending on pharmaceutical prescribing, and enabling comparison across practices. This was as an informal means of encouraging prescribing efficiency, and the system remains in place today. Each GP practice receives a quarterly Standard PACT Report from the prescription pricing authority

²¹⁴ Polak, M. (2002).

²¹⁵ Glennester M., Matsaganis M., Owens P., Hancock, S. (1994), p.89.

²¹⁶ Department of Health (2001), paragraph 6.3.

²¹⁷ European Observatory on Health Care Systems (1999), p.82.

(PPA) setting out its prescribing data and costs, in a comparative context across its Health Authority and nationally.²¹⁸

The Community Care Act 1990, which introduced the NHS internal market, established GP fundholding.²¹⁹ Prescribing budgets were included within GP fundholding budgets, giving GPs incentives to prescribe efficiently. Indicative prescribing budgets (IPBs) for non-fundholding GPs were also introduced. Independent medical advisers at the local level used these to try to put pressure on high-prescribing GPs, and those practices spending more than the indicative budget were expected to explain why. Non-fundholding GPs could keep some of any savings made from their indicative budget and fundholders, operating within an overall budget, could use all money saved on the drugs bill in other areas of service.²²⁰

The IPB system developed in the mid-90s to include, apart from the freedom to transfer funds across services, the empowerment of health authorities to pay a fee of up to £3000 per GP for meeting agreed prescribing targets. An *additional* cash incentive was therefore instituted for keeping prescribing costs under control.²²¹

From 1999, GPs had their prescribing budgets merged with hospital and community health service budgets, on a cash limited basis, and organised through new Primary Care Groups (PCGs).²²² The NHS Plan of the Labour Government has removed this form of fundholding and developed PCGs into new PCTs of larger numbers of GPs, covering population ranges of between 50,000 to 250,000 people – far larger than the traditional model of primary care practice with a few general practitioners. Larger population coverage will ‘average out’ to some degree differences across sub-populations, providing

²¹⁸ See website: www.ppa.org.uk/

²¹⁹ Tucker, A. and Taylor, D. (2000), p.46; Reekie, W.D. (1996), pp.16-18.

²²⁰ Glennester M., Matsaganis M., Owens P., Hancock, S, (1994), p.89.

²²¹ Tucker, A. and Taylor, D. (2000), p.47

²²² European Observatory on Health Care Systems (1999), p.82-3.

an operating environment in which budgeting will be easier and more effective than the GP fundholding model.²²³

A further innovation has been the development of the computer advice system PRODIGY that is linked into GP surgeries and gives advice to GPs on lowest cost prescribing for particular indications. It is a computerised decision and learning support tool for GPs offering a series of recommendations for the treatment of diagnosed conditions in terms of therapy options, non-specific drug advice or referral on.²²⁴ The system disseminates information to encourage cost-effective prescribing by providing clinical guidance adapted to the patient, including information on diseases, and their management.²²⁵

2.5.3 Pharmacists

There is pressure on pharmacists too. The Drug Tariff limits the amount that pharmacists can be reimbursed by the NHS for generic drugs. Generics are an important exception from the PPRS, not being covered by it on the basis that there is genuine price competition within the generics medicines market. Despite this, the Drug Tariff forms a formal barrier to any escalation of costs to the NHS from this sector.²²⁶

There is currently debate about extending the role of pharmacists to enable them to play a more proactive part in controlling medicines for chronically ill patients. The chronic market represents the lion's share of the prescribing budget. Government policy through the NHS Plan, published in 2000, aims to enhance significantly the role of community pharmacy, including the aim that by 2004 repeat dispensing will be the function of pharmacists and will mean that patients can get repeat prescriptions from a pharmacy, without having to

²²³ European Observatory on Health Care Systems (1999), p.19.

²²⁴ See www.prodigy.nhs.uk/

²²⁵ See www.doh.gov.uk/ipu/whatnew/itevent/tables/eprescribinginprimarycare.htm

²²⁶ Redwood, H. (1997), p.95.

contact their surgery each time.²²⁷ These plans were finalised in November 2002, to take effect in early 2003.

2.5.4 Generic prescribing

Several measures have been introduced to encourage generic prescribing – and many of those above have a bearing on it. PRODIGY can recommend generics as part of its advice; Schedule 10 of the GMS Regulations prohibits certain brand name drugs from NHS prescription; and the Drug Tariff then limits prices paid for generics to pharmacists. In addition, the PPA provides Health Authorities with information, as part of PACT, on how each practice may make more use of generics in order to cut prescribing costs.

Large increases in the costs of some generics through 1998/9 resulted in the government setting up a statutory maximum price scheme for generic drugs. “The scheme will set statutory maximum prices for the main generics supplied for NHS use in primary care.”²²⁸ The Scheme took effect from 3 August 2000.

2.5.5 OTCs

Another demand side feature of the UK market is the relatively large amount of drugs sold over-the-counter (OTC) without a prescription. The removal of the need for a prescription immediately moves a drug, in large part, from the NHS to the private market. Although OTC medicines can still be gained through a prescription by a patient for financial reasons, most OTC medicines are sold by direct consumer purchase. Re-categorising borderline drugs in this way is therefore a significant cost containment measure. The government’s 2000 NHS Plan includes the aim of enabling patients to obtain a “growing range of medicines over-the-counter”.²²⁹

²²⁷ Department of Health (2002a).

²²⁸ Department of Health (2000c).

²²⁹ Department of Health (2000b).

Nevertheless, the UK OTC market remains a minority of the total market, and is limited by the nature of medicines available – ‘borderline’ drugs are a very small group of products, with most medicines, and particularly the most expensive, innovative medicines being prescription only. There are likely to be only a few candidates from this ‘borderline’ group that could be given OTC status in order to reduce the total public medicines bill.

2.5.6 Quality control and cost-effectiveness

Apart from direct budgetary constraints that aim to emulate a more ‘normal’ market by limiting demand, there are several more indirect mechanisms on the demand side to control the market. Most notable, and politically sensitive, is the creation of the National Institute for Clinical Excellence (NICE) in 1999. The institute’s purpose is to assess individual health technologies, which include pharmaceutical products, medical devices, diagnostic techniques, and procedures, as well as the clinical management of specific conditions, and to issue advice to health care managers. The advice is intended “to provide patients, health professionals and the public with authoritative, robust and reliable guidance on current best practice.”²³⁰ Assessments are based on, among other criteria, judgements of ‘cost-effectiveness’, which inevitably implies some element of economic evaluation of products and procedures, which entails their comparison within the overall context of NHS health care provision, therefore “implicitly, if not explicitly, setting rationing criteria”.²³¹

Other quality focused arrangements have also been established to raise standards and attempt to meet the challenge of ‘postcode prescribing’. A Commission for Health Improvement (CHI) has been established under the Health Act 1999 to monitor service standards including prescribing and dispensing standards.²³²

²³⁰ See website: www.nice.org.uk/

²³¹ Tucker, A. and Taylor, D. (2000), p.49

²³² Tucker, A. and Taylor, D. (2000), p.48

As with NICE, its focus is on giving national leadership to quality standards and disseminate best practice. It will develop and disseminate clinical governance principles through the scrutiny of local clinical governance in NHS Trusts, Primary Care Trusts and Health Authorities. Clinical governance covers areas of professional training and professional-patient interaction, and CHI therefore aims to ensure the high quality treatment of and communication with patients as well as ensuring professionals have up to date knowledge of best practice. It is also linked to NICE in that it is responsible for monitoring local implementation of NICE guidelines.²³³

²³³ www.doh.gov.uk/chi

Chapter 3

Theoretical framework and working hypotheses

3.1 The state-level

3.2 The policy community

3.3 Negotiating resources

3.4 Institutions and policy continuity

3.5 Structural and institutional context of the PPRS

3.6 The PPRS: Five structural and institutional variables

3.7 The pharmaceuticals market

3.8 The global context

3.9 The co-operative state

3.10 The role of Parliament

3.11 Role of the Department of Health

This chapter builds a theoretical framework for the analysis of policy making in the PPRS. It reviews the theoretical literature and deduces five hypotheses for the analysis of the PPRS and the government-industry relationship which underpins it. It draws on a variety of approaches from “*the tool box of policy analysis*”,²³⁴ in order to identify and analyse those factors that explain the Pharmaceutical Price Regulation Scheme (PPRS) as a form of industrial and market regulation, which has persisted in one form or another for almost half a century.

The theoretical framework here first examines the policy community that the PPRS constitutes and then analyses the structural and institutional context within which it is set, in order to explain the PPRS as a regulatory framework for the control of pharmaceutical prices. It draws on the policy community approach to policy analysis in order to understand the nature, structure and operation of the PPRS policy community; and on institutional approaches in order to analyse the causes of its existence and persistence.

3.1 The state-level

A generic ‘state-level’ approach to explaining the policy process in the PPRS is not appropriate. Policy areas can be quite isolated from each other: “If each policy area develops into a semi-watertight compartment, ruled by its own ‘policy elite’, then quite different policy styles may develop within the same political system.”²³⁵ For this reason, pluralist and corporatist approaches are of limited usefulness for the study of the policy process in an area of industrial regulation and procurement. Different sectors and subsectors are likely to be operating simultaneously according to different principles and procedures. State-level theories are abstracts and imperfect as complete explanations of policy.²³⁶

²³⁴ Parsons, W. (1995), p.188.

²³⁵ Richardson and Jordan (1983) p.249

²³⁶ See Ham, C and Hill, M. (1993), pp.45-47.

At first examination, features of the PPRS may lend themselves to 'state-level' pluralist and corporatist description but this does not identify, a priori, features specific to a policy 'subsystem' such as the PPRS. The policy community may exhibit – as do so many policy arenas – corporatist features but the approach is specific and cannot be extrapolated easily to complex relationships between actors.²³⁷

Similarly, a pluralist type theory used for analysis of government-industry relations, capture theory, is a state-level one, which posits at the generic level a view of regulation as being 'captured' by the regulated.²³⁸ In capture theory, the organisation of producer groups means that their lobbying is far stronger than that of dissipated and disorganised consumers and regulation is likely to get made in the producers' favour.²³⁹ Regulation is acquired by the industry and is designed and operated primarily for its benefit. In this rendering of power distribution, the government stands as a more or less neutral agency, lobbied by competing industrial and consumer interests – clearly not the position in the PPRS, where the government *is* the consumer, and where the government seeks the promotion of the industry through its industrial policy.

That 'generic' state-level theories are not appropriate tools for this case is not to say that the 'state' is irrelevant – some features of the state will likely be significant in determining the form of the policy community and how it operates, and these are identified below in the hypotheses. In this vein, Atkinson and Coleman note that the state-level will ordinarily influence the structure of the sub- state-level, but that in some cases particular factors may prevent this from happening: "... it is also reasonable to expect that the relative frequency of different types of policy communities will vary systematically across democratic polities depending on the state-level

²³⁷ Rhodes notes how the term 'corporatism' has been used in many ways, appearing to be altered to make it fit the empirical situation. See Rhodes, R.A.W. (1985), p.4.

²³⁸ Peacock, A. (1984), pp.13-18.

²³⁹ On capture theory see also: Makkai, T. and Braithwaite, J. (1998), pp. 173-191; Hood, C. (1994), p.21; Grant, W. (1990).

political institutions."²⁴⁰ Which institutional factors are significant for policy in one subsystem may be different from those that are significant in others: the interplay of institutional factors is what is important.

3.2 The policy community

Analysing particular areas of policy making – ‘sub- state-level’ analysis – is in general a response to the perceived failure of traditional state-level theories to get to the ‘nitty-gritty’ of policy making – the need, in the words of Wilks and Wright, to “break away from system-level macro-generalisations and move towards empirically-based analysis.”²⁴¹

Policy community analysis can focus on the sectoral level.²⁴² It allows that different policy *subsystems* may be present within a state. Different areas of policy making can display markedly different features.²⁴³ Freeman in 1955 was an early advocate of this approach²⁴⁴ but it was Rhodes who developed the idea most fully as a way of examining the relationship between political institutions,²⁴⁵ while Wilks and Wright applied the terminology to government-industry relations and took a more individual-centred view.²⁴⁶ Wright defines the members of a policy community as actors who “share a common identity or interest,” and who will ‘transact’ with each other, exchanging resources in order to balance and ‘*optimise*’ their mutual relationships.²⁴⁷

This approach highlights another feature of policy making that has been widely identified: its pragmatic and ‘political’ nature. For actors at all levels of the policy process, Wright notes, policy is not about *optimising* so much as it is about *balancing* the various aims and interests of the different parties

²⁴⁰ Atkinson and Coleman (1989), pp.66-7.

²⁴¹ Wilks, S. and Wright, M. (1987), p.275.

²⁴² For further description of policy communities see: Marsh and Rhodes (1992) chapter 1; Atkinson and Coleman (1989); Parsons, W. (1995), pp.184-92.

²⁴³ See: Allison, G. and Zelikov, P. (1971), chapter 5; Marsh & Rhodes (1992), chapter 1.

²⁴⁴ Freeman (1955).

²⁴⁵ Marsh and Rhodes (1992) p.9.

²⁴⁶ Wilks, S. and Wright, M. (1987), pp.294-305.

involved.²⁴⁸ Optimising is probably over optimistic, according to Simon: the limited scope of analysis as well as the circumstances of the political process lead to '*satisficing*', where courses of action are taken because they are 'good enough'.²⁴⁹

The mergers and takeovers policy community in the City is, according to Wright,²⁵⁰ comparable in many respects to that operating in the pharmaceutical sector. In particular, he states of the parties to the community: "Collectively, they prefer the '*satisficing*' outcomes of their network interdependence, to win/lose outcomes. Above all, they prefer voluntary self-regulation through predictable and stable network relationships to statutory control."²⁵¹

Policy in this sense is the outcome of an overtly political process rather than of objective, 'rational' analysis. A system of bargaining between the major interested groups has the advantage that the rationality of any policy is defined by those most interested in it. For example, Schilling argued this point of view, suggesting that there was no 'right answer' to many policy questions, such as what is the right budget for a government department.²⁵²

Bargaining over policy is the means by which policy changes are made. A 'bargaining model' of policy making in general had been developed by Neustadt in 1960, to apply to the American system of "separated institutions sharing powers." His model of the US presidency, though not directly applicable to the UK, was an important step in developing notions of bargaining that would inform the policy community discussion.²⁵³

As described in Chapter 2, the PPRS is a regulatory regime that is devised and run by a small group of civil servants in the Department of Health (DOH)

²⁴⁷ Wilks, S. and Wright, M. (1987), pp.298-9.

²⁴⁸ Wright, M. (1991), p.513.

²⁴⁹ Simon (1957) pp.204ff; March and Simon (1958), pp.48ff.

²⁵⁰ Wright (1988b).

²⁵¹ Wright (1988b), p.402.

²⁵² Schilling (1962), pp.295-337.

²⁵³ Neustadt (1960).

in co-operation with the representative body of the industry, the Association of the British Pharmaceutical Industry (ABPI), as well as, in its implementation, the individual firms. Other actors have a role to play and can be seen as part of the extended community – influential if not present: principally the Treasury but also the DTI and other parts of the DOH, along with the wider industry to which the ABPI negotiators are accountable. During the operation of the scheme, the community consists only of the PPRS branch of the DOH and the individual company negotiator. The policy community is therefore small and discrete.

While the policy community approach here provides a language and a means of describing the actors involved in making policy, and identifies features of policy making appropriate to the PPRS as an instance of government-industry bargaining, it is not in itself an adequate basis of analysis and explanation of why decisions are made in the way they are in the PPRS arena, and of what has caused this co-operative form of bargaining to come into being and to persist. Indeed, the behaviour of policy communities is dependent on the structural and institutional position in which they are located. This is clearly the case with the highly structured and formalised PPRS.

3.3 Negotiating resources

Central to the make up of the PPRS policy network is the nature of the 'resources' held by each side. The dynamics of the PPRS are in part defined by the high (though not absolute) level of competence each side possesses to negotiate. This is intensified for the DOH by its dual role, something hypothesised here to have been very influential in maintaining the scheme; and for the ABPI in its representation of the whole industry.

The initial phase of negotiations in the 1950s between government and industry and its outcome in the VPRS (the forerunner of the PPRS – see

Chapter 2) can be seen as one in which the role of the ABPI and the extent of its 'authority' to act are established.²⁵⁴ The organisation of the industry and the overall competence of the Department of Health were, according to Wright, both important factors in shaping the policy community that emerged for the regulation of drug prices.²⁵⁵ The state here has a strong 'mission' and clearly defined objectives, and the 'agency' involved appears to have a high degree of autonomy from other parts of government. Crucial to the evolution of a policy community was the dual role of the DOH with respect to the industry.²⁵⁶ The authority of relevant units of each of the government and industry sides are important for their ability to bargain successfully.²⁵⁷ The DOH is not completely autonomous in its policy making in the PPRS but it is far more so than in countries where the equivalent department deals only with procurement policy with regard to pharmaceuticals.

Resources that arise from the basic nature of government and industry are also central to the PPRS and to the dynamics of its periodic renegotiation. Each side has the ability to threaten the other with something it specifically aims to avoid in the regulatory arena. For industry, the government can threaten legislation in place of the voluntary agreement; while industry can threaten disinvestment, undermining the key purposes of the government's industrial policy. These 'bargaining resources' constitute the 'ultimate sanctions' of each side, which can be seen to keep the equilibrium of the government-industry relationship intact.

Information is another important resource. This too can be seen to shape the PPRS in that the DOH appears, a priori, to be reliant on the information supplied by the industry through the PPRS; information is also important in inter-departmental discussions, through which the DOH can be expected to value its relationship with industry.²⁵⁸ The 'liberal' nature of the British state as one in which commercial freedom is sought-after, may also in part be a

²⁵⁴ Sargent, J.A. (1985), p.109ff.

²⁵⁵ Wright M. (1991), p.513

²⁵⁶ Wright M. (1991), p.513

²⁵⁷ Scharpf, Fritz W. (1993).

²⁵⁸ Grant, Wyn (1993a), p.47.

weakness in the state's armoury owing to a lack of independent information resources. Alternative forms of regulation would require a greater level of independent information gathering by the DOH than does the PPRS.

Structural and institutional factors therefore define the nature and dynamics of the PPRS policy community: they define the '*resources*' of each party to the community, their *competence to act* in their field, the *terms of co-operation*, their *policy aims* and, in consequence, *the range of policy possibilities* that will satisfy both sides and enable *optimal and balanced policy outcomes*.

3.4 Institutions and policy continuity

Institutions are the context within which actors in the policy making process make decisions: "The institutionalist focus means that the analysis of policy making involves taking account of the way in which the configuration of interests and ideas within an institutional context shapes and determines the conduct of policy."²⁵⁹ This is partly because policy makers make decisions according to their institutional role. Their institutional position will define the scope of their powers and their judgement of success.²⁶⁰ As Olsen notes, "An institutional perspective assumes that political life is patterned."²⁶¹

Institutions structure the relationships between policy actors and they determine who the actors are: "Because policy making in the modern state is always a collective process, the configuration of the institutions that aggregate the opinions of individual contributors into a set of policies can have its own effect on policy outputs."²⁶² Individuals and groups in a policy subsystem don't simply interact but are structured by procedure and practice.²⁶³ This does not deny the central role of individuals: "institutions

²⁵⁹ Parsons, W. (1995), p.334.

²⁶⁰ Vickers, G. (1965), p.135ff.

²⁶¹ Olsen, J. P. (1996), p.250.

²⁶² Hall, Peter A. (1986), p.19.

²⁶³ Hall, Peter A. (1986), p.19; Vickers, G. (1965), p.135ff.

constrain and refract politics but they are never the sole 'cause' of outcomes."²⁶⁴

History itself can be a factor in the choices that policy makers make, as well (again) as their expectations of policy outcomes: the PPRS has continued with modifications and reforms, for almost half a century. Political relationships can become 'frozen' and continue long after the set of purposes for which they were initially designed.²⁶⁵

An existing policy path in can determine future policy. This 'path dependency' hems in policy makers and channels their decisions along well trodden routes.²⁶⁶ In the absence of some sort of crisis or external shock, to shift decisively the path of policy, policy change is likely to maintain its existing dynamics and basic principles.²⁶⁷ 'Path-dependency', as Wilsford describes, is where political changes are "tied to previous decisions and existing institutions."²⁶⁸ In path dependency, structural forces dominate, therefore policy movement is most likely to be incremental.

Policy communities that bind actors into formalised relationships can emerge, acting as a conservative force on policy. This is Katzenstein's contention regarding foreign policy in Western countries, where he claims 'policy communities' have underpinned the persistence of some policy positions.²⁶⁹

The conservative institutional straightjacket identified as a form of path dependency can in some cases restrict the scope of policy analysis and narrow the choices seen as available to policy actors. Policy change can become a step-by-step, trial-and-error process: a characterisation of policy making described (and advocated) by Lindblom in the 1960s. He contended that only a change in the basic purpose or the context of policy is likely to

²⁶⁴ Thelen K. and Steinmo S. (1992), p.3.

²⁶⁵ Olsen, J. P. (1996), p.249.

²⁶⁶ Wilsford, David (1994), pp.256-258.

²⁶⁷ Knill, Christoph. (2001), p.22.

²⁶⁸ Wilsford, David (1994).

²⁶⁹ Katzenstein, Peter (1978).

lead to radical policy change.²⁷⁰ Lindblom developed this idea not simply as a description of policy making but as a formula for actively assessing policy change that recognises the limitations on people, in both time and ability, to understand complex problems. The choice of policies is deliberately limited to those that can be understood and achieved and, if necessary, reversed.²⁷¹ The group element to this idea is developed in 'partisan mutual adjustment', in which the different group interests in a policy arena affect the decisions of each other: a structured, 'bargaining' model of the policy making process.²⁷²

These approaches reiterate the importance of a stable institutional environment for the nature of policy. They posit the idea that a 'shock' to the structural context of policy making as the principal (perhaps only) way in which any substantial policy change will take place. They therefore attempt to describe the nature of policy but not to analyse its structure, the latter being the particular configuration of structural factors that underlies a particular policy arena. The idea of a policy 'path' is not explanatory and may indeed be tautologous: if structural factors shape policy, then their change will be necessary for its reform.

3.5 Structural and institutional context of the PPRS

The focus of the approach taken here is to examine and analyse the structural context of the PPRS. Because the policy making process is in part 'determined' by its structural context, policy is not simply a process in which individuals make rational decisions. Rather, while actors in any bargaining process may indeed act rationally, what is rational and what is not is strongly determined by structural factors.

The development of particular national institutions (at the state-level) is important for understanding how types of policy and policy making structures

²⁷⁰ On incrementalism as a form a method of policy making, see: Lindblom, Charles E. (1959); Lindblom, Charles E. (1979); Braybrooke, David and Lindblom, Charles E. (1963); Gregory (1989).

²⁷¹ Weiss, Andrew and Woodhouse, Edward. *Policy Sciences* 25(3): 255-73.

come about. Electoral and legislative systems affect the nature of policy as they determine the organisation and power of the executive and the breadth and makeup of the interests that have influence over the policy process.²⁷³

What actors in the policy community represent, what they seek from policy outcomes and from the regulatory framework or regime – i.e. their '*regulatory goods*'²⁷⁴ – where external pressures on them arise from and where there are '*veto points*' on their decisions are all structural features that affect the decisions they make. Immergut, in her analysis of health insurance policy in Switzerland, France and Sweden, argues that the number of veto points is essential in understanding policy outcomes,²⁷⁵ showing that the strength of parliament in the French Fourth Republic enabled interest groups to veto policy easily, owing to the fragmented nature of party alliances – something not open to interest groups in Sweden, where executive dominance in this policy area reduced the veto points available.

Government-industry relations in the PPRS are underpinned by structural and institutional factors that sustain this community in a way that has caused it to follow a consistent path for over four decades. For government to overturn the PPRS policy community and legislate in this area would entail a loss of co-operation, and would likely be precipitated by some sort of crisis in the relationship between government and industry.

3.6 The PPRS: Five structural and institutional variables

It is hypothesised here that the co-operative framework for policy making is determined by various factors that underpin the '*goods*' that each side aims to achieve from policy (i.e. their policy aims) and the various '*resources*' they each have to enable them to do this: neither side has sufficient '*resources*' to

²⁷² Lindblom, Charles E. (1979), pp.522-3; Lindblom, Charles E. (1965).

²⁷³ Steinmo, S. (1993), chapter 3.

²⁷⁴ Wilks, S. and Wright, M. (1987), p.298.

²⁷⁵ Immergut, Ellen M. (1992).

achieve its 'goods' without co-operation. Co-operation is a 'core-value'²⁷⁶ of the policy community and policy outcomes will find a balance sufficient to maintain it. Changes in the structural and institutional factors identified here will be the basis of any 'crisis' in the policy community. These structural and institutional factors form the independent variables that shape bargaining resources, the extent of the policy community and the policy and regulatory aims within it.

The structure of the market defines the opportunities available to both sides in the PPRS. It affects the kinds of compromises that are possible: the lower volumes of the UK market mean that some pricing freedom has less of an impact than it would in a market of very high volumes; and this in turn has created regulatory goods for industry in the PPRS that they are keen to maintain, such as freedom of pricing of new products.

The global structure of the industry means that it is mobile and can tailor its investment decisions according to the regulatory and economic circumstances of any particular country. This draws the attention of government to its industrial policy and broadens out their policy aims from narrow procurement concerns.

The 'liberal' nature of the British state is an important institutional feature that appears, a priori, to underpin the PPRS. The limited conception of the state's role by its own executive actors and its historically liberal approach to the economy have limited the range of policy possibilities. This structures the 'balance of forces' between government and industry in the policy community in a way that enables a co-operative relationship to operate.

A lack of parliamentary influence over the design and operation of the PPRS means that there is the absence of a parliamentary 'veto point' and of the ability of Parliament to administer any external 'shock' to the stability of policy

²⁷⁶ Wright M. (1991), pp.510-11.

and precipitate its reform. The policy community is small, self contained and to some extent informal, and characterised by executive dominance.

The concentration of executive competencies within a single department of state (the DOH) is an unusual institutional feature of British pharmaceutical supply side regulation. The department has an official '*sponsorship*' function for the industry as well as the responsibility for negotiating prices as a *customer*. This enables it to balance policy aims at the departmental level, lending it greater authority in its dealings with the Treasury.

All these factors will be tested for their validity as key factors underpinning the continuing form and content of the PPRS by the use of five related working hypotheses, elaborated below and analysed in empirical studies of the 1993 and 1999 PPRS negotiations and agreements and the passage of the 1999 Health Bill.

3.6.1 Summary: Assumptions about key structural and institutional factors

Assumption 1: The market for pharmaceuticals in the UK underpins the PPRS by enabling sufficient rewards for both government and industry within the scheme, and enabling policy aims to be balanced.

Assumption 2: The global organisation of industry lends it bargaining resources it would not otherwise have and makes government more alive to the need for an active industrial policy.

Assumption 3: The 'liberal' nature of the British state means there is the desire by government for 'light-touch' and co-operative regulation using limited administrative, technical and legal resources.

Assumption 4: Parliament has a peripheral role in this policy field and does not constitute a veto point or external influence on the policy community.

Assumption 5: The siting of an industrial policy function within the Department of Health gives DOH authority and competence to act and highlights the government's industrial policy aims, enabling a co-operative regime.

3.6.2 The working hypotheses

In answering the question as to why a co-operative, non-statutory system of regulation has been at the heart of the economic regulation of the pharmaceutical industry and has represented and enabled the successful co-existence of government and industry aims for so long, five hypotheses are proposed, which arise from the examination of the structural and institutional context of policy making, as set out above. The hypotheses will be analysed through an examination of two successive re-negotiations of the PPRS and the passage of the 1999 Health Bill.

The five assumptions above underpin five working hypotheses:

Hypothesis 1: Actors on both sides will seek to maintain the current structure of the pharmaceuticals market, and hence the regulatory goods it yields, and will not pursue strategies that would undermine it.

Hypothesis 2: Industry will seek to utilise its global structure as a bargaining resource to counteract the legal monopoly of government, which in turn will pay greater attention to their industrial policy aims.

Hypothesis 3: Policy proposals that require significant technical, administrative and legal resources on the part of government will not be pursued, in particular a legislative approach to regulation. They will seek maintenance of the co-operative regime.

Hypothesis 4: Parliament will not be an influential actor in determining policy outcomes, which in turn will be reflected in the limited direct attention to it by both government and industry.

Hypothesis 5: The dual role of the DOH will prove decisive in defining policy and maintaining the co-operative regime by counteracting the procurement focus of the Treasury.

3.7 The pharmaceuticals market

Assumption 1: The market for pharmaceuticals in the UK underpins the PPRS by enabling sufficient rewards for both government and industry within the scheme, and enabling policy aims to be balanced.

Hypothesis 1: Actors on both sides will seek to maintain the current structure of the pharmaceuticals market, and hence the regulatory goods it yields, and will not pursue strategies that would undermine it.

The British pharmaceuticals market acts as an *'enabler'* of the co-operative policy community. The small size of the market (it's relatively low value by international standards), assisted by the extent of the use of generics and of OTC medicines (paid for direct and not by the NHS) enable certain policy paths to be taken because they limit the potential budgetary implications, a key 'regulatory good' for government. The behaviour of British GPs has a reinforcing influence on these features. In addition, outcomes of the PPRS further shape the market and create regulatory goods for industry, which they are keen to maintain: higher prices for newer products and a quick product launch.

3.7.1 Features of the British pharmaceuticals market²⁷⁷

- Relatively small size by overall value.
- Significant degree of therapeutic conservatism among doctors.
- Relatively large generics market.
- Relatively large OTC market.
- Higher prices are concentrated on new in-patent medicines.
- Quick launch: products reach the market immediately following licensing.

²⁷⁷ See 1.6 for more details.

3.7.2 The market as an 'enabler' of a co-operative policy community

Government's approach to the market must be seen through the prism of its dual policy aims. In terms of procurement policy, its aims are confined to costs and there is an overlap between the Treasury's objectives and those of the DOH. But in its industrial policy aims, the government, both DOH and DTI, seek more complex outcomes. The shape of the market enables them to achieve this balance, and in so doing to deliver regulatory goods to industry within the co-operative regulatory framework, which the government also seeks to maintain (see Hypothesis 3 below).

The concerns of a research-based industry are likely to be focused on new and in-patent medicines, which they will seek to get to market quickly and at a good price. The constraints on drug consumption enable these to be delivered without unsustainable growth in the medicines budget. In turn, the maintenance of a stream of new medicines fulfils not only industrial policy goals but budgetary ones as well, because new medicines may have positive budgetary implications in the broader NHS context by reducing the needs for other health care interventions. Attitudes to the shape of the market will also be influenced by this concern.

Hence because the government's regulatory aims are diverse (they seek cost containment but also support for R&D and encouragement of new medicines), it can best achieve them through a co-operative relationship with the industry.

Key among the regulatory goods that industry will seek in the PPRS is the maintenance of free pricing of new products. Sacrifices in other areas will be seen as worthwhile if this feature of the PPRS – itself linked to the co-operative nature of the scheme – is maintained. Reimbursement procedures can add months to the time lapse between product registration and market introduction, in some cases up to 18 months. This feature of the PPRS – 'free-pricing-at-launch' – is valued by industry and recognised by the

government: "Access to the market is their big issue," said a DTI civil servant.²⁷⁸

The regulatory goods that the two sides seek from the PPRS will shape their strategies and approaches. In essence, the positive balance of advantages for each side that underpin this hypothesis are that both government and industry seek or value things that they see the PPRS as helping them to achieve because of the way it maintains or creates features of the British market. The sacrifices they make in the PPRS are sufficiently minimal for them not to risk its overhaul.

The ability to 'optimise' policy is therefore created by the contextual and structural conditions of the two sides. The importance of industrial policy and the ability to pursue it within the confines of cost containment; this in turn underpins the ability of industry to gain regulatory goods through a co-operative framework. The two sides have a common interest.²⁷⁹

3.7.3 Market size

Perhaps the most important feature of the market as an enabler of the PPRS is its size, in cost terms. The spend per head is low by international comparison. In 1999, per capita spending on pharmaceuticals in the UK was £107 compared with £251 in the US, £183 in France and £140 in Germany.²⁸⁰ This low volume is not directly attributable to the PPRS and is underpinned by various forms of 'rationing' including demand side measures that limit doctors' spending. It is related to the structure of the NHS with its gatekeeper GP system and its implicit rationing of health care services through limited supply and the queuing system. However, it is also partly 'cultural': some countries such as France and Spain are renowned for high prescription rates and others, the UK in particular, for lower ones.

²⁷⁸ Interview, DTI civil servant 1.

²⁷⁹ Wilks, S. and Wright, M. (1987), p.298.

²⁸⁰ ABPI (2000a)

3.7.4 Therapeutic conservatism

One cause of the smaller market in the UK is the prescribing behaviour of GPs. There is documented 'therapeutic conservatism' among British doctors.²⁸¹ In part the structure of the NHS lends itself to this behaviour, reinforced by increasing demand side controls. New medicines take far longer to reach wide usage. This can be seen as a major enabling factor in the PPRS because it reduces the risk to the NHS budget of new 'blockbuster' drugs launched quickly at relatively high prices. With prescription and consumption patterns more akin to France and Spain, this would present the government with considerable budgetary risk.

Shifting to more expensive products was identified as the principal driver of increases in the drugs budget in the late 1980s and early 1990s and the therapeutic conservatism of GPs is therefore a key factor in the containment or otherwise of the drugs budget.²⁸²

3.7.5 Generics and OTCs

The relatively high proportion of generics in the prescription market and the high proportion of OTCs in the market as a whole also take the pressure off the government in the PPRS. The government have encouraged generic prescribing in order to cut pharmaceutical costs and many more products are licensed for OTC sale than in some European markets.²⁸³ Both these factors reinforce the shape of the market that is created by its relatively small size: innovative products can more comfortably command higher prices because other areas of the market are relatively low cost for the taxpayer.

²⁸¹ House of Commons Health Committee, Session 1993-4. HC Papers 80-1, 7 July 1994, paragraph 30; David Taylor (1992); Department of Health (2001), paragraph 2.14.

²⁸² Interview, DOH civil servant 27

²⁸³ See 1.6 and Table 1.5.

3.7.6 Value to industry

The regulatory goods created by the PPRS for industry are a quick launch and free pricing at launch (the latter both a good in itself and a facilitator of the quick launch).

The market is significant for global companies because it enables relatively high prices to be obtained on the products that are most important to the research-based industry: the new, innovative medicines following their launch. The scheme continues to allow free pricing (set by the company) for new patent products and this feature of the market is inseparable from the scheme itself. Within the scheme, this compensates industry for continually falling prices across a company's portfolio of products, while fulfilling a government aim of promoting new medicine discovery.

The other – and, as will be seen in subsequent chapters, related – feature of the market created by the PPRS is the quick launch. The ease of passage to market following licensing approval has great significance for global companies because they create positive spin-offs in other markets. Having a product 'up and running' in a major market has the potential to influence authorities elsewhere and creates pressures and opportunities to make it available there.

3.7.7 Regulatory goods

This hypothesis supposes that these features of the market and the PPRS are the ones that the industry would most seek to defend in the policy process, while the enabling features of the market are those features that allow government to do this because they limit the financial impact of greater freedom.

The assumption of this hypothesis is that sufficient regulatory goods are provided by the PPRS for both sides to defend the broad structure of the market and not to risk its radical change – either because market features

enable the PPRS to continue or where they are explicit features of the PPRS itself. The goods that are provided for each side must be seen in the light of their aims in the policy process and what they see themselves as having to achieve from the co-operative policy community of the PPRS for it to be worth their while continuing in it.

3.8 The global context

Assumption 2: The global organisation of industry lends it bargaining resources it would not otherwise have and makes government more alive to the need for an active industrial policy.

Hypothesis 2: Industry will seek to utilise its global structure as a bargaining resource to counteract the legal monopoly of government, which in turn will pay greater attention to their industrial policy aims.

The salience of industrial policy aims is reinforced by a further structural facet of the sector: the global nature of the industry. It is this that defines industrial policy aims, because it defines the targets of the government's industrial policy attention. The global nature of the industry and the national structure of its markets create special dynamics in the government-industry relationship. They enable the industry to employ its global structure as a counterbalance to the government's legal monopoly in their bargaining over policy and regulation. Government's commanding position as a customer and a legislator is kept in check by the global corporate power of industry, in the context of the government's industrial policy concerns.

The regulatory goods therefore flow both ways. The corporate structure of the industry means that it is footloose to a degree that commands government's attention, a fact which it can use to its advantage, as an important resource in regulatory bargaining.

3.8.1 Organisation of the industry

The concentration on the supply side of the industry arises from its nature. Barriers to entry in the industry are relatively high. There are some absolute cost disadvantages to new market entrants owing to the patenting of existing

products; and companies already in the market possess some economies of scale that may give them an advantage, though this is not clearly the case.

The foremost barrier to entry is through product differentiation, where branding of products creates an uphill task for any new entrant to change the habits of a prescriber.²⁸⁴ This is exacerbated by promotional competition, where creating a large market requires significant resources. Controls on advertising that may have been devised to reduce this can have the effect of entrenching it, as they can (including through the PPRS) be defined as a proportion of turnover, assisting the large, entrenched firm over the new or small firm.²⁸⁵

Therapeutic sub-markets can be more concentrated still, with considerable price inflexibility. As drugs are for the most part essential items, demand is inelastic and price is therefore not a major factor in determining levels of aggregate demand or that for a particular patented product. Indeed, within the patented sector, accounting for the large majority of value in the market in most countries, price competition is effectively precluded.²⁸⁶

These industrial and demand side factors give the large pharmaceutical firms a commanding position. More recent economic developments have tended to further drive consolidation, across all industries, not just pharmaceuticals, and in this sector the dominance of a few firms has accelerated over the 1990s. The sector therefore has consolidation pressures on the supply side. At a time when globalising pressures have also emerged through increased trade and global brands, the large pharmaceutical firms have become giant global entities.

²⁸⁴ Reekie, W.D. (1969), pp.3-5.

²⁸⁵ Reekie, W.D. (1969), p.19.

²⁸⁶ Reekie, W.D. (1969), pp.12-13.

3.8.2 Globalising pressures

The forces of globalisation have created pressures for the consolidation of industries through merger and acquisition activity as well as the organisation of the firm on a more global basis, with an allocation of resources determined by the organisation of the firm's functions across national borders. The growth of world trade, which has been faster than the growth of world GDP for several decades, has driven the globalisation of corporations.²⁸⁷

The pharmaceutical industry can be seen as a 'global' one rather than, in the terms of Michael Porter, a 'multi-domestic' one, because its competitiveness in one country is affected by its behaviour and competitiveness in others.²⁸⁸ Firms organise themselves across space through the use of global finance, global technologies and global customers.²⁸⁹ The nation state is less relevant to their activities.²⁹⁰ Definitions of what constitutes a global firm are not entirely consistent but criteria identified by various writers show clear areas of consensus. On any measures, the globalisation of firms is continuing apace²⁹¹ and pharmaceutical firms are at the forefront of this process.²⁹²

Consolidation in the pharmaceutical sector is driven by the vast scale of R&D now required to produce a new product and the vast sales personnel needed to market it once it is produced. The increasing cost of developing drugs requires firms to have larger markets in which to recover the investment (perhaps leading to a situation of 'natural oligopoly' where the existence of more than a few firms would prevent this recovery of costs from being possible).²⁹³ Despite the large mergers and acquisitions that have changed the corporate shape of the sector through the late 1990s, these two factors

²⁸⁷ Saari, David J. (1999), chapter 2.

²⁸⁸ Porter, M.E. (1986), pp.226-46.

²⁸⁹ Barnett, R.J and Cavanagh, J. (1994), pp.13-22.

²⁹⁰ The extent of attachment to the nation state of origin is a matter for debate: Porter sees global firms as retaining some attachment while Ohmae sees the nation state as unimportant to truly global firms. See Graham, Edward M. (1996), pp. 33-41.

²⁹¹ Saari, David J. (1999), in particular, Appendix B.

²⁹² In research by Roland Berger consultants, GlaxoSmithKline was second only to IBM as a truly global firm, according to its presence in major economies, brand position and supply base. *Spectra* magazine, Summer 2002, pp. 9-11.

²⁹³ OECD (1995), pp.55-61.

are likely to further drive consolidation of the sector over the coming decade.²⁹⁴

3.8.3 Mobile capital

The principal effect on the national policy making arena of this process is that national governments are under pressure to keep and attract globally mobile capital. The industry has to have positive reasons for continuing to invest in the UK. The PPRS and other forms of regulation affect the roll-out of products into the marketplace. As a major, high-tech industry dominated by a small number of large firms, the pharmaceutical industry is in a good position to exploit these pressures and to counteract the economic power of governments on the demand side, by appealing to government's industrial policy concerns.

Large global corporations can locate capital with relative ease. New investments can be located anywhere that public policy – regulatory and fiscal – is most conducive to profitability. National governments must now satisfy the demands of their “supranational capitalist constituents.”²⁹⁵

Capital flight is feared by policy makers, and the threat of it by multinational firms is a powerful influence over policy. Twenty-three US states adopted a new tax to overcome the problem of transfer pricing by multinational firms (where profits subject to tax are understated or eliminated in companies' accounts). Following vehement opposition from a coalition of Japanese and European companies, including Sony, ICI, Unilever and Nestlé, and direct threats to invest elsewhere, all states repealed the tax.²⁹⁶ This illustrates the potential of corporate bargaining resources over policy; and given the industrial importance of a research-based industry such as pharmaceuticals, they can be expected to be substantial.

²⁹⁴ See: interview with Sir Richard Sykes, *Spectra* magazine, Summer 2002, pp.4-7.

²⁹⁵ Scholte, Jan Aart (1997), p.443 & p.446.

²⁹⁶ Barnett, R.J and Cavanagh, J. (1994), pp.345-6.

3.8.4 Corporate concentration

Furthermore, concentration, whether caused by micro economic conditions or the processes of globalisation, brings with it political power. Where government can consider a small number of large firms to represent the interests of an industrial sector, the organisation of co-operation and bargaining between the two is simpler. Very large firms can come to play a key political role under such conditions because governments court them as aggregated points of communication. Within a trade association, they may make its authority and competence over a sector simpler and more complete, hence aiding communication with government and in turn a co-operative regulatory regime.²⁹⁷

3.8.5 A national dimension

However 'global' in their organisation firms become, they may retain some level of attachment to their country, not least in terms of governments' perception of them. Governments still identify firms as national flag carriers even where the firms themselves operate on a global basis. Although the use of national 'flag carriers' for the implementation of national policy objectives (e.g. for strategic industrial or security reasons, such as with ICI)²⁹⁸ has undoubtedly waned, their success globally is still seen as national success.²⁹⁹

There is a complex interaction between the global operations and national identity of firms and the purposes underpinning public policy towards them. Government's may wish to use global economic forces to affect their home industry and attitudes to foreign direct investment (FDI) may be shaped by the particular needs that it sees the national economy or an industry as having.³⁰⁰

²⁹⁷ Grant, W. (1990), pp.149-55.

²⁹⁸ Grant, Wyn. (1993), chapter 7.

²⁹⁹ Graham, Edward M. (1996), pp. 33-41.

³⁰⁰ Doz, Y.L. (1986), pp.226-46; Dunning, J.H. (1993), p.554.

The reasons why firms seek to invest in a particular country are also various. They may include the circumventing of trade barriers (though this ought to diminish as a reason in a more global economy with freer trade), or the acquisition of raw material markets or strategic assets; or for reasons of greater organisational efficiency.³⁰¹ Moreover, public policy in the home country may be of particular importance to a firm and have implications for its global success.³⁰² This latter point may be of particular concern to pharmaceutical companies where national regulations can be compared and some governments may take their leads from others.

3.8.6 Comparison of national regulatory regimes

Governments seek comparative examples of policy, particularly among EU and OECD countries and some pricing systems explicitly base themselves on prices in other countries,³⁰³ so government actions can have implications for industry beyond the borders of the UK (or another country).

The national structure of markets combined with the global organisation of firms, gives an important international dimension to the regulation of prices. The pharmaceutical pricing regulations of different countries overtly follow other systems. Several European countries take their prices from a 'basket' of prices in neighbouring countries – most of them include the UK to some extent; and some Commonwealth countries do the same. There is a direct effect in other markets of what happens in the UK.³⁰⁴

Aside from the direct effect of one regulatory system and market on another, global companies are in a position to compare national systems and may use favourable comparisons in their bargaining with government, again underpinned by their international mobility. Little is as simply effective in bargaining with government as demonstrating positive examples elsewhere. Given the dominance of American-based firms in the global marketplace, the

³⁰¹ Dunning, J.H. (1993), pp.56-63.

³⁰² Procassini, A.A. (1995), p.245..

³⁰³ Mossialos E, Ranos C, Abel-Smith B (eds) (1994).

³⁰⁴ Management Forum (2001); Jim Furniss.

conditions of the American market stand as an example to American executives in Europe and they are the ones most likely to lobby for liberalisation and least accept strict regulation.

3.8.7 Implications for policy

Governments seek inward investment, and seek to prevent outward investment by domestic firms, as part of their industrial policy aims. FDI can contribute to the growth of output in the national economy, as well as to raising productivity,³⁰⁵ as noted for British manufacturing facing American competitors in their home market.³⁰⁶ The UK in particular has been successful in attracting FDI during the 1980s and 1990s, and it has also been a major investor overseas.³⁰⁷

The UK government therefore has to be more aware of the causes of inward and outward investment than do other governments. For more developed economies, although output remains important, a major benefit of FDI is that it can enable technology transfer and boost R&D.³⁰⁸ This is particularly poignant where the industry is a high-tech one, such as in pharmaceuticals, and where the defence of the science base is a central motivator of government concern.³⁰⁹ The use of tax regulations and other policy instruments such as infrastructure development are commonly used by governments to affect the investment decisions of foreign (and domestic) firms.³¹⁰

Owing to the desire of governments to promote home-based companies in the global market, large corporations are further able to encourage favourable policy regimes for their operations in the home country. A dominant position in the national market may be more easily tolerated as a result. "The much discussed 'pressures of global competition' have made

³⁰⁵ Moosa, Imad A. (2002), pp.68-102.

³⁰⁶ Graham, Edward M.(1996), p.36.

³⁰⁷ HM Treasury (1996).

³⁰⁸ Graham, Edward M. (1996), pp.14-15; Moosa, Imad A. (2002), pp.86-87.

³⁰⁹ Sharp, Margaret (1989), pp.119-159.

governments and citizens more ready to allow 'their' corporate flag-carriers to acquire market dominance of a degree an earlier generation would not have countenanced."³¹¹ In promoting home companies overseas, governments must also face the loss of any control they may have had over the strategies of their 'national flag carriers', as they become global companies.³¹²

3.8.8 Designing national regulation

The international organisation of firms complicates the design of national regulatory regimes, which are focused on its national operations. The PPRS is a case in point: detailed financial and operational information underpins the judgements of the Department of Health about how much capital is employed in the production of medicines sold to the NHS. As global organisation becomes more complex, deciphering this will become more difficult. In the 1950s these sorts of problems were faced by the then VPRS, such as the amount of research carried out abroad to be factored into UK sales or the profits due to materials purchased overseas.³¹³

Yet the PPRS has been designed with an international corporate focus. One of the overt aims of the government was to secure a globally successful British pharmaceutical industry through the PPRS. The government has recognised the global context and ambitions of industry and it is exposed to these commercial considerations in its dealings with it.

The global structure of industry therefore provides a powerful dimension to the relationship between government and industry, enabling industry to appeal to government's industrial policy aims and thereby gain important concessions in their cost containment aims. Equally, this negotiating or bargaining 'resource' may be tempered, or bolstered, by events in other markets, through other regulatory systems; and global companies will define

³¹⁰ Lenway, Stephanie Ann and Murtha, Thomas P. (1994), pp.513-36.

³¹¹ Jan Aart Scholte (1997), p.438.

³¹² Doz, Y.L.(1986), p.247.

³¹³ Teeling-Smith, G. (1969), p.88.

limits to the controls governments may impose while they seek industrial policy aims of corporate promotion and sponsorship.

3.9 The co-operative state

Assumption 3: The 'liberal' nature of the British state means there is the desire by government for 'light-touch' and co-operative regulation using limited administrative, technical and legal resources.

Hypothesis 3: Policy proposals that require significant technical, administrative and legal resources on the part of government will not be pursued, in particular a legislative approach to regulation. They will seek maintenance of the co-operative regime.

An important 'state-level' influence on the nature of the PPRS and its persistence appears to be the broadly liberal approach of successive governments to the activities of industry, i.e. the 'liberal' nature of the British state.

3.9.1 Industrial policy and culture

The state has increased its role in the economy significantly over the post-war period, a trend that continued through to the mid-1980s.³¹⁴ Yet it is the nature of the state's role and not only its scale that is significant and which structures the nature of policy communities in the industrial policy field.

The British state did develop close relations with various sectors of industry, quite apart from the widespread nationalisations of the post-war years. But the relationships that operated were co-operative and entailed bargaining between the two sides (or three sides, in the case of tripartite bargaining arrangements between the TUC, the CBI and the government in the National Economic Development Council in the 1960s and 1970s) – what Beer calls 'quasi-corporatism'. Industry was not, for example, directed or forced by the

³¹⁴ See: Cronin, James E. (1991), chapter 1.

state to rationalise its organisation, as was the case in France, in return for a place at the policy making table.³¹⁵ Britain's attempts at an active industrial policy – most notably under the Wilson governments – were largely regarded as failures and eventually abandoned by the Callaghan government in the 1970s.³¹⁶

'Industrial culture' – the perception of the proper role of the state in the economy, and the extent to which intervention by government is acceptable – shapes government-industry relations. British industrial culture can be seen as having a 'liberal' bias, which favours a 'hands-off' approach to the economy and a non-statutory approach to industrial regulation.³¹⁷ Despite the expansion of the state's role in the economy, a concept of a benevolent public power has not emerged in the UK and intervention in industrial decisions is less authoritative as a result.³¹⁸

The less interventionist British state has been characterised as 'weak' and possessing little 'autonomy' in its design and implementation of industrial policy, in contrast to states such as Japan and France, which are seen to have directed private sector activity at the micro level, through the reorganisation of industrial enterprises. A 'strong' state has a greater degree of autonomy from societal actors and can act more strategically and less reactively and incrementally than a 'weak' state with a low degree of autonomy.³¹⁹

3.9.2 'Strong' states

In Japan, the powerful Economic Planning Agency and Ministry of International Trade and Industry (MITI) administered plans and targets for

³¹⁵ Beer, Samuel H. (1965), p.296-7. Hall, Peter A. (1986), p.53.

³¹⁶ Sharp, Margaret & Holmes, Peter (1989), pp.1-18.

³¹⁷ Wilks, S. and Wright, M. (1987), p.278; Wilks, S. (1983), pp.132-137.

³¹⁸ Dyson, K. (1983), pp.31-38.

³¹⁹ Atkinson and Coleman (1989), p.66ff

reconstruction of the economy and its rapid development, including that of the *Kiertsu*, or industrial conglomerates with cross-shareholdings.³²⁰

The French Fifth Republic had in its design an overt aim to subvert the power of sectional (rather than public) interest groups. This approach finds expression in the post-war restructuring of French industry by the state.³²¹ Engagement with, and support from, the state went hand in hand with the requirement to restructure large parts of French industry. The French state's role in the economy had an ideological lineage as well as a pragmatic incentive. It could be traced back to the mercantilist policies of Colbert *contrôleur general* (roughly, minister of finance) under Louis XIV, who sought to counter the economic dominance of England and the Netherlands. The development of the French economy in the Fifth Republic (from 1959) has been driven by the five year planning process and the interventionist directing of private investment across industrial sectors.³²²

The contrast should not be overdone. There is a wealth of literature showing that the Japanese economy exhibits far greater competition and clash of interests than the western 'stereotype',³²³ and the claim that the French state, while more centralised and purposeful, is no more expert or unified in its approach to industry.³²⁴ But the essence of the state's attitude to the economy is different in both Japan and France in that the responsibility of government to intervene in corporate restructuring is a basic given, founded on the particular time and form of industrialisation.³²⁵ Industry and the public both accept and, crucially, *expect* greater public intervention and service provision in France than in Britain.³²⁶

³²⁰ For a summary of post-war Japanese economic planning see: Vestal, James E. (1993), chapter 2; Japanese Economy and Economic Planning Agency (1979).

³²¹ Wright, V. (1989), chapter 11.

³²² See: Sheahan, John (1963).

³²³ See: Boger, Karl (1988).

³²⁴ Sharp, Margaret & Holmes, Peter (1989), pp.1-18.

³²⁵ Sharp, Margaret & Holmes, Peter (1989), pp.1-18; Hall, Peter A. (1986).

³²⁶ Morgan, Kevin (1989), pp.19-55.

3.9.3 The state and regulation

Theories of regulation suggest an objective and interventionist role: the purpose of regulation is to enforce or provide some sort of 'public good' that could not be provided or properly distributed without the intervention of the state, because the economic mechanisms for individuals to acquire these goods do not exist. Regulating industries has been justified by the need to overcome the economic effects of natural monopoly or intervene in markets that do not work for other reasons such as a lack of information for consumers.³²⁷ In the PPRS, the government's position is more complex because it is a customer and not simply a 'guardian of the public good'.

In the regulatory relationship that emerges between government and industry, the regulated might begin to determine the agenda, not least through their superiority of relevant information. The importance of business in general to governments would give added impetus to this basic relationship, and might lead to a situation of *capture*, where normal consumer vs. industrial interests prevailed. A weak state is more likely to succumb to capture than a strong, autonomous state. In the PPRS, the government seeks to represent *itself* as a consumer, through formal mechanisms across departments, including the Treasury. A traditional application of capture theory is not therefore appropriate in this case.

More broadly, the notion of state 'autonomy' is not easily applicable to this case because the government has industrial policy aims, as well as regulatory and procurement concerns, which may in themselves be suited to a co-operative regime.

Identifying strong and weak states at the macro level are of limited usefulness for the same reason as are state-level theories of policy making; what they do achieve is to suggest the sorts of influencing factors that may underpin the types of policy community that emerge within a particular polity.

³²⁷ For theories of regulation and its purpose see: Baldwin, R. and Cave, M. (1999), chapter 2; Breyer, S. (1998); Breyer, S. (1982), chapter 1.

This can only be determined in particular cases such as in the PPRS through empirical investigation. For example, Skocpol notes that autonomous state action can occur in a 'weak' state.³²⁸ She and Finegold studied New Deal agricultural policies in the US, where they concluded that the US Department of Agriculture was "an island of state strength in an ocean of weakness."³²⁹ There may, as in Smith's view, be a trade-off in the power and autonomy to act between different parts or agencies of the state.³³⁰ But the state-level can be assumed, a priori, to *influence* the sub- state-level.

The British state displays features that have direct relevance to the nature of the PPRS as a regulatory regime and would appear, a priori, to naturally underpin a co-operative relationship between government and industry. These include a 'hands-off' and laissez-faire approach to industry in general, suggesting a desire for co-operation with industry as a default position; a relatively 'open' political elite which actively seeks the views of civil society actors and incorporates such consultation within the policy process; and a 'generalist' civil service not historically equipped for complex regulation.

The laissez-faire approach of the state may be more salient a feature than any weak state characteristics – explaining behaviour in terms of motive rather than capacity. Grant et al, for example, point to the considerable resources available to British governments in pursuing particular strategies.³³¹

3.9.4 The liberal and open state

The failure of bureaucracy in dealing with the problems of a larger state derive "from the very success of the boldness of the effort of the Victorian reformer to give Britain an administrative personnel for a Nightwatchman State presiding over the breathtaking expansion of private industrial

³²⁸ Skocpol, Theda (1993), pp.86-109.

³²⁹ Skocpol, Theda (1993), p.XX

³³⁰ Smith, Martin J. (1993) p.54

³³¹ Grant, Wyn, Paterson, William, Whitston, Colin (1987), pp.37-8.

capitalism.”³³² Economic planning required different and specific administrative skills.

The British state has remained limited in its scope and, crucially, its ambition, and attached to liberal, laissez-faire principles,³³³ exercised and developed most through the period of industrialisation in the eighteenth and nineteenth centuries.³³⁴ This has given rise to an industrial culture that gives preference to ‘arm’s-length’ relationships with industry.³³⁵

These attitudes to the role of the state in the economy were articulated by political theorists such as Bentham and Mill, and, earlier, Adam Smith. By contrast, the more communitarian conclusions of philosophers such as Rousseau (while sharing important aspects of broader European and British political thought) underpinned a stronger sense of the possibilities of state action in France.

Such a heritage of political theory was indicative of an understanding the state’s role in favour of the individual, which translated easily into the firm. The nature of British industrialisation, and the Victorian and Georgian values that underpinned it, have had a lasting impact on the relations between government and industry.³³⁶

3.9.5 The Treasury and laissez-faire

The dominant agency in the British bureaucracy and government has historically been the Treasury, which has resisted the expansion of the state’s role in society as a “guiding principle” of its operations.³³⁷ The ‘Treasury view’ was one of a minimalist state, which viewed public expenditure as unproductive, minimising the stock of capital for

³³² Balogh, T. (1959), p.109.

³³³ Balogh, T. (1959), p.111.

³³⁴ Taylor, Arthur J. (1986), pp.226-263.

³³⁵ Dyson, K. (1983), pp.31-38; Grant, W. (1989), pp.85-88.

³³⁶ Grant, W. (1989), p.86.

³³⁷ Cronin, James E. (1991), p.5; Wilks, S. (1983), pp.132-137.

investment.³³⁸ Laissez-faire was an ingrained doctrine of the Treasury and British government through the nineteenth and twentieth centuries.³³⁹ Policy options aimed to solve particular problems, and were narrowly focused. An apparent anomaly arises with this view of the role of the Treasury in a modern state possessing broad responsibilities and a substantial role in society: where taxpayers' money is at stake the Treasury may seek tighter control in an attempt to keep public spending in check.

The mismatch between the nineteenth century design of the British state and its late twentieth century role has been identified as a reason for the failure of much of public policy. "The historic incapacity of the British state persisted into the era of big government and the welfare state."³⁴⁰ The perennial agony of the public expenditure round is the expression of this disjunction between the state's design and its 'welfare' role.

The nature of the bureaucracy, relying on expertise from industry itself, naturally meant that government sought co-operation in any regulation that was introduced and co-operation became a regulatory good in itself for government. British governments attempted to balance various interests rather than develop a strategic position.³⁴¹ This openness has meant that in some areas, the government has bargained with industry in devising its regulation, to the extent that industry interests became "governing institutions, part of the extended state."³⁴² Such openness, at least, suggests that a co-operative solution to regulatory questions is more likely than a command and control solution, more appropriate to an active directorial state.

However, the Thatcher period in British politics may be thought of as limiting to some degree the 'openness' of the state to influence from civil society groups and indeed it was an important facet of Conservative Party politics through the late 1970s and 1980s to suggest that the state had been

³³⁸ Peden, G.C. (1988), p.11.

³³⁹ Wright, Vincent. (1969), pp.329ff.

³⁴⁰ Cronin, James E. (1991), p.16.

³⁴¹ Middlemas, K. (1986), p.348.

³⁴² Middlemas, K. (1986), p.348-9.

'overloaded' by a multiplicity of demands, which would in the end result in ever rising taxation.³⁴³ A new politics had arrived in which the volume of government spending was the central political issue, and this persisted through the 1980s and 1990s.³⁴⁴ It was therefore the unwillingness of the state to accept a broader role, rather than its immediate lack of capacity to do so, that shaped politics in the 1980s.

3.9.6 The civil service

Since the Northcote-Trevelyan Report of 1854,³⁴⁵ which formed the basis of the modern career civil service, the service has been characterised by its professionalism, its permanence and its 'generalism'.³⁴⁶ While the role of government in the economy and society has been transformed in the post-war period, the tradition of the 'talented amateur' has remained with the British civil service and the information handicap is one of the principal barriers to general government intervention in the economy.³⁴⁷

This is in some contrast, for example, to the highly trained civil servants that emerge from France's *École Nationale d'Administration* (ENA), which trains would-be civil servants in finance, management and law.³⁴⁸ British attempts to adapt the non-interventionist state to the tasks of economic intervention in the 1960s by creating new departments and reallocating tasks among them generally ended in institutional confusion and failure.³⁴⁹

As early as the beginning of the 20th century the civil service had been criticised for facing growing responsibilities "with increasing insistence on a lack of expert knowledge."³⁵⁰ This kind of service would surely be one that would find it very difficult to devise legally enforceable regulation in areas of

³⁴³ See Ham, C and Hill, M.(1993), pp.29-30, for a discussion of Public Choice theory.

³⁴⁴ See Mullard, M. (1993), chapters 8 & 10.

³⁴⁵ For a summary of the development of the British Civil Service, see: Griffith, Wyn (1954); Pyper, Robert (1995).

³⁴⁶ Hennessy, P. (1990); in particular, p.31 ff.

³⁴⁷ Young, Stephen. (1974), chapter 16.

³⁴⁸ Wright, V. (1989), pp.119-121.

³⁴⁹ Young, Stephen (1974), chapter 14.

³⁵⁰ Cronin, James E. (1991), p.228.

technical complexity, and the ability to assess the success or otherwise of implementation.³⁵¹

The post-war period began with a radical Labour government that might have effected significant structural changes to the relationship between government and private enterprise, aside from the widespread nationalisation programme. In fact this did not happen, and the attitude of the civil service was an important factor. In the key 1945-51 period, "Labour was reluctant to introduce major changes that would have swelled the bureaucracy."³⁵² It feared creating cumbersome administrative structures and accusations of 'bureaucratism'.

3.9.7 Reliance on industry

Despite the criticisms of the Fulton Report in 1968, which had looked at the structure, recruitment and management of the civil service,³⁵³ as well as other examinations of its operation, the generalist culture of the British civil service by and large remains.³⁵⁴ The wartime civil service relied heavily on secondments from industry and this model was kept by the Atlee government.³⁵⁵ The nature of the civil service meant that "the business world was really the only source of people with the appropriate knowledge and skills. For the most part senior civil servants were men with an arts background and with neither the talent nor the desire to control the economy."³⁵⁶ Price controls were conducted mainly by people drawn from industry, and very little other (worker or consumer) input.

This underpins a preference for co-operative forms of regulation. Grant notes how the post-war sponsorship of the chemical industry has been conducted by generalist civil servants reliant on information from the industry itself, as

³⁵¹ Pyper, Robert. (1995), chapter 5.

³⁵² Leruez, J. (1975), p.65.

³⁵³ Hennessy notes the narrowness of the Fulton Committee Report as one that did not deal with the basic ground rules of the civil service's operation. The narrowness of the Report would therefore mean it was unlikely to confront the basic culture of the service. See Hennessy, P. (1990), pp.190-195.

³⁵⁴ Peters, B. Guy (1995) pp.94-112

³⁵⁵ Leruez, J. (1975), p.64.

well as other outside organisations, for forming policy.³⁵⁷ Wright notes the lack of information gathering capacity at the outset of the VPRS in 1957, which contributed to the “virtual monopoly of information and data”³⁵⁸ held by the pharmaceutical industry.

Indeed the Ministry of Health at the time of the first VPRS has been characterised as politically weak, having scarcely recovered from bruising battles with the medical profession over the setting up of the NHS (see Chapter 2). This influenced their bargaining power when the voluntary system was initiated. The freedom of doctors to prescribe was also a directly related issue and had now been promised to the profession, limiting the sorts of price control mechanisms that might be implemented by the ministry.³⁵⁹

3.9.8 The state and government-industry relations

All these features of the British state are hypothesised here to affect government-industry relations in the PPRS, because they underpin the government’s perceived need and, critically, its *desire* to form policy within a co-operative framework. Grant refers to the ‘*exchange relationship*’ of government-industry relations through which government gains the information required to develop policy. It also relies on the *exchange process* for implementation.³⁶⁰ A policy community has at its centre this process of exchange between government and industry.³⁶¹

The laissez-faire origins of the British state underpin a more co-operative relationship between government and industry in general.³⁶² The aims of the government overlap, it is hypothesised here, with the aims of the industry creating an area of consensus that is a sufficient basis for bargaining over areas of controversy. This suggests that the industrial policy concerns of

³⁵⁶ Leruez, J. (1975), p.65.

³⁵⁷ Grant, W. (1990), p.152.

³⁵⁸ Wright M. (1991), p.513.

³⁵⁹ Hancher, Leigh (1989), pp.84-89.

³⁶⁰ Grant, Wyn (1993), pp.46-65.

³⁶¹ Macmillan, K. and Turner, I. (1987), p.121.

³⁶² Vogel, David (1986), chapter 6.

government facilitate bargaining and co-operation because large firms cannot easily be cajoled into investment and employment, and their private actions have public implications.³⁶³

The laissez-faire tradition of the British state does not mean that governments do not have industrial policy aims but it does shape the way in which they seek to achieve them, as it shapes the way in which government approaches industry in an area where its 'big state' welfare role brings the two into contact.

3.9.9 The co-operative regime

In the PPRS, as with other co-operative regimes, '*negotiated compliance*' is preferred to strict enforcement, and regulators wish to avoid taking legal proceedings to enforce regulation.³⁶⁴ Both sides see it as in their interests to engage in bargained agreement. They perceive 'gains from trade'. Government is able to limit the resources devoted to inspection and enforcement while business is relieved of the uncertainty about the arbitrary actions of public officials.³⁶⁵ Co-operation, as a regulatory good for each side, becomes a '*core value*' of the policy network – a feature of it that underpins and enables the various aims of each side to be achieved, or at least achievable.³⁶⁶

This assessment of the nature of the British state suggests that in the PPRS the government will limit its assessment of choices and analysis of policy options to maintain a low level of technical, administrative and legal resources and to maintain a co-operative relationship with industry through a voluntary regulatory framework.

The nature of the British state underpins a preference for a co-operative regulatory regime on the part of government, bolstered further by the

³⁶³ Hancher, Leigh and Moran, Michael (1989), p.275.

³⁶⁴ Peacock, A. (1984), p.115.

³⁶⁵ Peacock, A. (1984), p.94.

³⁶⁶ Wright, M. (1991), pp.510-11.

particular aims of industrial policy which lend themselves to a harmonious relationship between the two sides. This is hypothesised to be a central dynamic in defining the sorts of outcomes of regulatory bargaining that take place in the PPRS.

3.10 The role of Parliament

Assumption 4: Parliament has a peripheral role in this policy field and does not constitute a veto point or external influence on the policy community.

Hypothesis 4: Parliament will not be an influential actor in determining policy outcomes, which in turn will be reflected in the limited direct attention to it by both government and industry.

In the post-war period, industrial organisation, the state's de facto role in the economy, and the general decline in the power of the Commons have rendered the British Parliament a far more peripheral actor in the policy process than classical descriptions would suggest.³⁶⁷ In the relationship between legislature and executive, the UK is not a classically 'liberal' state. Beyond this generic feature of the UK system, the negotiation and administration of the PPRS is particularly confined to the executive and appears to be little influenced by parliamentary input, aiding and reinforcing the confined scope of the PPRS policy community.

3.10.1 Parliament and the policy process

The peripheral role of Parliament in much of the policy making process is a significant feature of policy making in the British polity. The UK has been characterised as a 'post-parliamentary' democracy'.³⁶⁸ The British Parliament's marginality is evident most in comparison to the American system, in which Congress has a central role.³⁶⁹ The 'iron triangle' was a close working relationship between lobby group, congressional committee and executive agency. This idea has obvious similarities to the later policy community approach to policy analysis, though within the context of an

³⁶⁷ Judge, David (1990), chapter 2.

³⁶⁸ Richardson, J.J. and Jordan, A.G. (1979).

³⁶⁹ Lijphart (1984), Chapters 5 and 6.

influential Congress.³⁷⁰ It built on Neustadt's 'bargaining' model of American politics.³⁷¹ Policy would be a compromise not only through the structure of the Congress, but because of the relationship between Congress and Administration.

The contrast here between the US and UK is noted by Lijphart who quotes Jean Blondel: while about "one-third of rule making may still be the prerogative of the U.S. Congress, ... not more than perhaps four or five per cent of the rule-making can be ascribed to the British Parliament."³⁷²

Executive dominance of the policy process is not unique to Britain. The US Congress stands as an idiosyncratically powerful legislative body among the parliaments of the major democracies. It has a genuinely legislative function, with representatives and senators able to introduce legislation in a way that is not possible in the Commons. The British Parliament is similar to the function of the French Assembly, Japanese Diet and Canadian Parliament. The German Bundestag stands somewhere between the US and UK models, with MPs having more freedom than their British counterparts and the timetable of the chamber being less dominated by the executive.³⁷³

The 'myth' of 'parliamentary' democracy in modern Britain is something that has developed over a long period of time. While the strengthening of the executive has been associated with the developing post-war economy, the loss of any significant legislative initiative by Parliament goes back to well before the Second World War.³⁷⁴ Scrutiny of the government is in addition dominated by highly disciplined political parties. The 'fusion of powers' between the legislative and executive branches, as emphasised by Bagehot in his 1867 analysis of the constitution,³⁷⁵ limits the effectiveness and influence of individual Members of Parliament and therefore the effectiveness

³⁷⁰ Marsh and Rhodes (1992) p.8.

³⁷¹ Neustadt (1960)

³⁷² Lijphart (1984) p.78.

³⁷³ Loewenberg, G. and Patterson, S. (1979); chapters VI and VII.

³⁷⁴ Middlemas (1979) p.307 ff.

³⁷⁵ Bagehot (1867)

of lobbying by industry (or any other group), while at the same time Parliament's real role in determining legislation is limited.

There is a further weakening of the legislature's place because of the balance of power between the political and permanent parts of the executive. Ministers may be accountable to Parliament for their actions but they are informed and advised by permanent civil servants who are likely to know far more about any policy area than the minister himself. Indeed the two factors are mutually supportive: "feeble ministers are an outcome of feeble parliaments."³⁷⁶

3.10.2 Policy subsystems

Nevertheless, the state is not monolithic. Richardson and Jordan characterise policy making in the UK as fragmented into policy subsystems that are largely closed to 'non-members': "a series of vertical compartments or segments, each segment inhabited by a different set of organised groups and generally impenetrable by 'unrecognised groups' or by the general public."³⁷⁷ This may itself imply a lack of legislative scrutiny, as vertical silos are executive ones. But as different policy areas may be structured differently, there is the possibility that Parliament has significant influence in some policy areas – such as those involving very large amounts of government spending or areas of particular concern to the public – and not in others.

3.10.3 Parliament and the PPRS

The PPRS arrangement especially sidelines Parliament and concentrates decision making among a few executive actors. It appears to be a policy community marked by a significant amount of 'black box' negotiations between a select few industry and executive actors. For the policy area under

³⁷⁶ Heclo, H. and Wildavsky, A. (1981), p.379.

³⁷⁷ Richardson, J.J. and Jordan, A.G. (1979), p.174.

study here, therefore, the legislature can, a priori, be said to have a peripheral role to play.

There had been some parliamentary attention to the PPRS but, as is described in Chapter 2, the operation and development of the scheme has remained only tentatively touched by Parliament since 1957. It has exercised some interest and influence in the past: the various committees that predated the VPRS – Cohen, Guillebaud and Hinchcliffe³⁷⁸ – and the scrutiny of the Public Accounts Committee have intervened in the process of policy making in this area with considerable effect. But on the PPRS itself, there had been little involvement. The relationship between industry and Parliament appears to have reflected this. The scheme was an arrangement between the ABPI and the DOH and industry's efforts were directed accordingly. Industry's relationship with government meant there had been little need to cultivate strong parliamentary contacts.

3.10.4 The 'Limited List' debacle

A major policy development in 1984-5 served to jolt this complacency. A 'Selected List' of medicines that could not be prescribed on the NHS was drawn up, known colloquially as the 'limited list'.³⁷⁹ The crisis precipitated a positive effort by industry to enhance its parliamentary contacts.

Parliament became vocally involved in the debate about the list, focused this time on the effects on patients, and the event became something of a turning point in industry's attitude to the role of Parliament. One industry commentator involved in public affairs through the 1980s and 1990s noted:

“When the Limited List was announced in the House by Norman Fowler in November '84, not one of us in the industry had retained parliamentary

³⁷⁸ The Standing Joint Committee on the Classification of Proprietary Medicines, the Cohen Committee, 1949; The Guillebaud Committee on NHS expenditure, 1953; The Hinchcliffe Committee on Effective Prescribing, 1957.

³⁷⁹ Schedule 10 of the GMS Regulations. See 2.4.2

advisers. The pharmaceutical industry didn't have a clue. After that we became far more active and did retain parliamentary advisers."³⁸⁰

3.10.5 Lobbying

It was not until 1993 that they really needed them, and this was again more for promoting discussion of the Selected List extension than for the PPRS. MPs signed a motion asking the government not to go ahead with the list extension.³⁸¹ Through the 1990s, industry did have useful parliamentary contacts on which to draw where necessary. They fall into different broad but not mutually exclusive camps: there are Parliamentarians with some medical interest in the industry such as members of the medical profession, especially in the Lords; there are those with an industrial interest, either from a constituency point of view where the industry is a major employer, or from a wider 'British economy' perspective; and there is an NHS-related constituency concern where patient interests are affected by policy on medicines.

The PPRS does not have implications for patient and medical interests directly and therefore it is the constituency commercial interests that are most linked to the scheme from MPs' perspective. The medical approach had proved the most effective in lobbying on the limited list in 1984-5, as there were direct implications for prescribing and the industry could also ensure that affected patients knew of the issues at stake, bringing pressure on MPs from their constituencies. The Health minister in charge of the Limited List admitted that the lobbying by industry (which failed to change the government's direction) had "certainly stirred up a lot of fears amongst Conservative backbenchers."³⁸²

A further aspect to industry lobbying is that where medical issues are concerned, the profession has a role to play. In 1984-5, the industry and the BMA (British Medical Association) stood on the same side of the argument,

³⁸⁰ Interview, industry executive 9.

³⁸¹ *Scrip* No 1805, 23 March 1993, p.3.

amplifying the constituency significance of the lobbying campaign. In 1984-5, this union of BMA and ABPI proved extremely effective, albeit eventually futile, as industry found itself sitting alongside an experienced player in the lobbying game. As the Minister of State noted:

“The BMA were particularly unscrupulous in their campaigning. They chose to present generic drugs as clinically inferior to the branded alternatives and orchestrated sustained campaigning to the effect that sick people would be deprived of the only efficacious treatments they could receive.”³⁸³

The hypothesis is that Parliament has not played a decisive role and continues to be on the sidelines of policy development in the PPRS, and that this is a significant factor in the nature and type of regulation in the PPRS. The three studies here will examine how influential Parliament has been in both agenda setting and in the process of policy formation, and how industry lobbying has affected the exercise of its role.

³⁸² Letter from Kenneth Clarke QC MP, Minister of Health during 1984-5; 23 May 2000.

³⁸³ Letter from Kenneth Clarke QC MP, Minister of Health during 1984-5; 23 May 2000.

3.11 Role of the Department of Health

Assumption 5: The siting of an industrial policy function within the Department of Health gives DOH authority and competence to act and highlights the government's industrial policy aims, enabling a co-operative regime.

Hypothesis 5: The dual role of the DOH will prove decisive in defining policy and maintaining the co-operative regime by counteracting the procurement focus of the Treasury.

A notable distinguishing feature of the British system of regulation is the particular institutional architecture that places a responsibility for the strength and success of the pharmaceutical industry with the Department of Health.

Group style theories of the policy process, such as policy community approaches, aim to show that government is not homogenous but rather a complex of interacting entities: "government leaders have competitive, not homogenous interests".³⁸⁴ The political process within government is of central importance to the outcomes of policy in this area, as any other. For example, the broader context of policy both within and outside the DOH (then DHSS) was the focus of much political and media debate at the time of the introduction of the 'Limited List' in 1985. As *The Guardian* noted at the time, "The real author of the DHSS's limited list proposal is neither Mr. Norman Fowler, the Secretary of State, nor his Health Minister, Mr. Kenneth Clarke. He is Mr. Peter Rees, Chief Secretary of the Treasury."³⁸⁵ Indeed the power of the Treasury in British government is a key factor in the nature of the British state, which is also assumed here to exercise an important influence on policy (see 3.5.5).

³⁸⁴ Allison, Graham and Zelikov, Philip (1971), p.146.

3.11.1 The power of the Treasury

The principle of 'Treasury control' has consistently stifled any proposed innovations in the administration of government. New institutions, such as the National Economic Development Council, charged in the 1960s with enhancing British economic growth through strategic support for industry, and the Department for Economic Affairs under Harold Wilson in the 1960s, failed to overcome the stranglehold that the Treasury had over economic policy.³⁸⁶ The Treasury, it has been suggested, limits the autonomy of any other departments to act.³⁸⁷

The Treasury's role remains to control expenditure and it expects departments to 'bid high' and ask for more money than they intend to get in budgetary negotiations.³⁸⁸ Given that the DOH consumes such a large share of public spending (23% in 2002),³⁸⁹ it is of central importance to the Treasury (and has historically been responsible for significant overspending³⁹⁰). The pharmaceutical budget represents around 12% of the NHS budget and therefore over 2½% of all public expenditure.

3.11.2 Departmental politics

Clearly, if the resources to 'sponsor' the pharmaceutical industry are to be agreed by the Treasury, the institutional arrangement of its sponsorship is a key factor. Conflating this role with that of procurement requires the DOH to take it into account in its discussion with Treasury officials. Without the resources to sponsor the industry through its procurement, the DOH would not be able to do so: "experienced officials know that expenditure is policy; policy is expenditure ... the machinery of British central government is deliberately designed to promote this mixture."³⁹¹ The sponsorship role of the

³⁸⁵ *The Guardian*, 14 December 1984

³⁸⁶ Cronin, James E. (1991), pp.11-17 & p.231; See also Brittan, Samuel (1964), pp.11-18.

³⁸⁷ Thain, C. and Wright, M. (1995), p.537.

³⁸⁸ Heclo, H. and Wildavsky, A. (1981), chapter 3.

³⁸⁹ HM Treasury (2003), p.8.

³⁹⁰ Beer, Samuel H. (1956), pp.29-32.

³⁹¹ Heclo, H. and Wildavsky, A. (1981), p.345.

DOH (i.e. responsibility for industrial policy aims) enables a closer regard to the industry's position to be taken into account through the PPRS and funded adequately in the spending round.

Through the government's industrial policy aims, the interests of the government are aligned with those of the industry. The government aims to achieve a competitive and globally successful British pharmaceutical industry.³⁹² But the government is also the primary customer. Significant interdepartmental friction could be expected to arise from this dual role, were its two aspects exercised by different departments.

Yet intra-government bargaining is significantly shaped by the breadth of competence of the DOH, which gives the Department of Trade and Industry (DTI) a more limited (and less formal) role in the 'sponsorship' of the industry. The DOH as a sponsoring department has formal responsibility for representing the industry's interests. This role, it is hypothesised here, decisively colours the Department's interaction with the Treasury when it comes to the overall pharmaceutical budget and regulatory regime.

As a core spending department, it is important in its discussion with the Treasury about its annual budget (the public spending round) that the Department of Health takes account of its sponsorship function. If the sponsorship function lay with the DTI, the DOH would represent only its spending concerns to the Treasury in the spending round and it would be up to the DTI – a non-spending department with limited influence in the Treasury – to argue for a sufficiently generous settlement for the DOH to enable the sponsorship function to be fulfilled. Even if the Treasury is seen as not entirely malign, the increased effort of a spending department to show industrial policy concerns will help persuade it of the case for spending more money.³⁹³

³⁹² Department of Health (1999a).

³⁹³ See: Deakin, Nicholas and Parry, Richard (2000), pp.79-98.

3.11.3 Dual sponsorship

As it is, both the DOH and the DTI face the Treasury as industry 'sponsors' (formal and informal), possibly skewing governmental actors towards supporting broader industry interests and away from a focus solely on procurement. Any change in the competence of the Department of Health would undermine the co-operative nature of the policy community because it would potentially shift decisively the government focus towards cost containment objectives and away from sponsorship objectives. Without the sponsorship role within the Medicines, Pharmacy and Industry Division (MPI),³⁹⁴ the Finance Division and its cost containment objectives would define the Department's approach to the industry. Pressure on costs may push departmental officials to seek pharmaceutical prices closer and closer to marginal costs, undermining the research base of the industry. On this basis, the pharmaceutical budget would likely be an early target within the DOH.

The bureaucratic organisation aligns and embeds pharmaceutical industry issues within a highly political area of policy. Macmillan and Turner note the sensitivity of health as a political issue, in the public domain: "Our interviews with government and industry representatives have led us to conclude that politicians will seek to avoid measures that can be portrayed as detrimental to the health service and patient care in particular." In relation to the introduction of the Selected List of 1985 they continue: "But here the target was much softer due to the pharmaceutical industry's image."³⁹⁵

3.11.4 Co-operative framework

Aside from the balance of power between departments and the greater ability of DOH and DTI together to represent the longer term interests of the industry, the sponsorship role creates a co-operative framework for the

³⁹⁴ For the 1993 and 1999 negotiations, the division was known as the International and Industry Division (IID).

³⁹⁵ Macmillan, K. and Turner, I. (1987), p.125.

formation of policy which would disappear. Wright sees this as a central point in the creation of the VPRS at its outset: "Crucial to the evolution of a community ...was the concentration of legal authority and policy jurisdiction (regulation *and* sponsorship) in one department."³⁹⁶

Although the PPRS itself does aim to support a successful industry, the change in the nature of the Department would make it more difficult to sustain at the point of each renegotiation of the scheme.

The hypothesis here is that the Department of Health's dual role is the key institutional device that enables government goals to be balanced and industry interests to be taken on board right at the centre of policy making. It gives the DOH broad competence to represent the industry and the interests of the DOH and to act on behalf of government as a whole: it is central to the balancing of sponsorship aims with the procurement concerns of the Treasury. This competence to act enables industry to put its faith in the DOH in the negotiating process and any shift of this function to the DTI would be resisted by industry.

³⁹⁶ Wright M. (1991), p.513.

Chapter 4

The negotiation of the 1999 PPRS

- 4.1 The political context
- 4.2 Government's aims for the negotiations
- 4.3 Industry's approach and aims
- 4.4 Principal changes in the 1999 scheme
- 4.5 Timetable of the negotiations
- 4.6 The process of the negotiations
- 4.7 The pharmaceuticals market
- 4.8 The global context
- 4.9 The co-operative state
- 4.10 The role of Parliament
- 4.11 Role of the Department of Health

The preparation by both the government and industry sides in 1999 was substantial, in contrast to all previous negotiations of the PPRS. Both sides had undertaken extensive research into the scheme, for months and even years prior to 1999, as a basis for developing quite specific, even quite radical, aims for the negotiations. They had done so in quite opposite directions. Industry sought to examine the basic validity of the scheme in changed circumstances; the Department of Health aimed to make enforcement of the scheme far more formal and robust and intended, in part, to pursue a statutory route.

Ironically, it appeared that the lack of substantial preparation in the past had persuaded each side that gains could be extracted from the other through meticulous preparation and boldness of presentation. Each side believed it had the advantage of surprise and consequently both were shocked. Battle commenced in the summer of 1998.

4.1 The political context

The 1993 PPRS, as with all previous schemes, became eligible for renegotiation after five years. It did not as a matter of course expire after five years. One party to the scheme had to state its preference for the negotiation of a new, replacement scheme. This is what happened in 1998, when the government indicated to industry that they wished to pursue a renegotiation.³⁹⁷

There had been a new Labour government elected in May 1997, bringing with it an overhaul of political faces for the first time in 18 years, in which the entire ministerial team in the Department changed simultaneously. An overhaul of political masters would not necessarily affect the PPRS, embedded as it was in the bureaucratic machinery of the DOH. Nevertheless, at first it seemed as though a break with the past might be sought by the new

team: “The new ministers found it deeply puzzling. They did not like the look of it at all and they thought it was a recipe for collusion,” noted a senior civil servant in the Department of Health.³⁹⁸

This negative view of the PPRS from the new ministers was, however, partly directed at the bureaucratic organisation of the various functions carried out by the DOH. The sponsorship and PPRS roles were at that time fused within the same Branch. This structure was changed promptly and a new Sponsorship Branch created. Changes to the PPRS itself would have to await the outcome of studies by the Department into alternative regulatory regimes, but there were nevertheless other factors that drew the government’s attention to the scheme and which suggested that a major change in its operation might be sought.

4.2 Government’s aims for the negotiations

4.2.1 Compliance

During 1998, there had been a persistent problem of compliance with the scheme. “There were some small companies that put two fingers up to us in 1998 in terms of ignoring price restraint,” said one senior civil servant.³⁹⁹ The cash value of their renegeing on their PPRS obligations was not significant but the press had got hold of the story: “They were not significant companies, they were very small companies, but there were a lot of them and it got quite a lot of publicity in the papers,” he added.

Through 1998, stories were widespread in the national press that drew attention to the flouting of the PPRS agreement. *The Guardian* noted the price rise by Alliance Pharmaceuticals of an important maternity drug to

³⁹⁷ Interview, DOH civil servant 10.

³⁹⁸ Interview, DOH civil servant 10.

³⁹⁹ Interview, DOH civil servant 5.

£1.40 from 18p a millilitre, in contravention of the PPRS.⁴⁰⁰ ICN Pharmaceuticals and Castlemead Healthcare had both made significant price increases without authorisation from the DOH.⁴⁰¹

In all three cases the products in question were recent acquisitions under license from large pharmaceutical companies including Novartis, Rhone-Poulenc Rorer and Roche. The granting of product licenses in this way appeared to be a means of getting around the PPRS and of avoiding the publicity that a large company would attract in contravening the scheme.⁴⁰² Furthermore, "... there was also one big company that didn't comply at all. Its lack of compliance meant that there were potential problems in terms of credibility."⁴⁰³ This circumventing of the PPRS did have real cost implications and it undermined the scheme from the perspective of other major companies that were playing by the agreed rules.

As well as the overt flouting of the scheme, there was also a backlog of case work in operating the PPRS, in part because companies had been lax in submitting their AFRs. Connected to overt non-compliance was an issue of cooperativeness and efficiency.

4.2.2 Transparency

Another important issue was the need for greater transparency. The lack of transparency in the scheme had been highlighted and criticised from several quarters.

- The Health Select Committee

In its report of 1994, the Health Select Committee had said that the scheme should be clearer and specified certain actions as part of this process,

⁴⁰⁰ *The Guardian*, 12 August 1998

⁴⁰¹ *The Guardian*, 13 August 1998

⁴⁰² *The Guardian*, 21 September 1998

⁴⁰³ Interview, DOH civil servant 5

including the presentation of Reports to Parliament. This Committee's report was a key cause of the DOH's position in the negotiations.⁴⁰⁴

- Reports to Parliament

The Reports to Parliament that eventually followed the request from the Select Committee showed that areas of the scheme were opaque to outside observers and they showed that the efficiency of the DOH was lacking in relation to the scheme, with case work on AFRs significantly behind schedule (see 5.3).⁴⁰⁵

- The Transparency Directive

The informality of the PPRS as a voluntary scheme might in itself be in contravention of the European Directive on the transparency of medicine prices of 1989. This 'Transparency Directive', as it had become known, required reform of the more obscure aspects of the PPRS.

The principal problem was the 'bands' of various allowances within which different companies would confidentially agree with government a particular place. It was not clear that the PPRS came up to the standards of the Directive, even though the government of the time had only accepted the Directive on the basis that the PPRS would not be affected.

Such 'behind the scenes' bargaining would have to be reformed in order to comply with European law. "Government had concluded that European transparency requirements made a range no longer viable," said an industry source.⁴⁰⁶ The only way of complying clearly with the Directive might be to put the scheme on some sort of a legal footing.⁴⁰⁷ The Directive had not been responded to immediately, but it was recognised that a legal challenge to the scheme may one day be brought. Indeed, Article 5 of the Directive (see box)

⁴⁰⁴ Interview, DOH civil servant 10

⁴⁰⁵ Department of Health (1996).

⁴⁰⁶ Interview, industry executive 13.

was orientated specifically to the PPRS. Although not mentioned by name, the PPRS was the only profit capping system of medicine cost control among EU countries. Section (c) in the Article was the one most obviously missing from the scheme.

Article 5 of the European Transparency Directive⁴⁰⁸

Where a Member State adopts a system of direct or indirect controls on the profitability of persons responsible for placing medicinal products on the market, the Member State concerned shall publish the following information in an appropriate publication and communicate it to the Commission:

- (a) the method or methods used in the Member State concerned to define profitability: return on sales and/or return on capital;
- (b) the range of target profit currently permitted to persons responsible for placing medicinal products on the market in the Member State concerned;
- (c) the criteria according to which target rates of profit are accorded to an individual responsible for placing medicinal products on the market, together with the criteria according to which they will be allowed to retain profits above their given targets in the Member State concerned;
- (d) the maximum percentage profit which any person responsible for placing medicinal products on the market is allowed to retain above his target in the Member State concerned.

This information shall be updated once a year or when significant changes are made. Where, in addition to operating a system of direct or indirect controls on profits, a Member State operates a system of controls on the prices of certain types of medicinal products which are excluded from the scope of the profit control scheme, Articles 2, 3 and 4 shall, where relevant, apply to such price controls. However, the said Articles shall not apply where the normal operation of a system of direct or indirect controls on profits results exceptionally in a price being fixed for an individual medicinal product.

4.2.3 Cost containment

The 1990s had seen a significant increase in the pharmaceutical bill to the NHS, and in the last year (1997-8) the total bill had risen by 9.7%.⁴⁰⁹ This

⁴⁰⁷ *Scrip* No 2372, 23 September 1998, p.2

represented a far steeper rise than health spending overall. The proportion of the health budget taken up by pharmaceuticals had risen from 8% to 14% between 1993 and 1997.⁴¹⁰ The pharmaceuticals bill to the NHS had been rising, on average, by 9% a year for the previous decade.⁴¹¹ This had not gone unnoticed within the Department of Health or by the new ministers now in charge of the NHS, which had been a key political issue at the 1997 General Election.

This constituted the third main aim of the government. The government intended to stem the rise in drug costs to the NHS: “We had, and we made it quite explicit to the industry, an aim of an expenditure saving,” said a senior DOH civil servant.⁴¹² Although the outcome of negotiations was an across-the-board price reduction of 4.5%, the government’s opening position was 6%, though this was one that they expected to be negotiated down. Immediately following the election, the new ministers had mooted a far bigger cut in the pharmaceuticals bill, which they saw as an easy target in the overall health budget. The figure they chose was completely arbitrary. “The aim in 1997 was to cut 10% from the drugs budget,” said a member of the pharmaceutical all-party parliamentary group (APPG).⁴¹³

4.2.4 Sponsorship / R&D

The government was also responsible for ‘sponsorship’ of the industry, to ensure its success in a global marketplace. To this end the government had a fourth purpose of the negotiations, driven from the top: “We aimed in particular to reward research and innovation. That was one of our principal objectives,” said a senior politician.⁴¹⁴

⁴⁰⁸ European Communities (1998). Directive relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems.

⁴⁰⁹ *Scrip* No 2413, 19 February 1999, p.3.

⁴¹⁰ Tucker A. and Taylor D. (2000), p.20.

⁴¹¹ *Accountancy Age*, 22 July 1999

⁴¹² Interview, DOH civil servant 5

⁴¹³ Interview, Parliamentarian 12.

⁴¹⁴ Interview, Government minister 7.

4.2.5 The aims of government: Summary

1. To secure more reliable compliance with the scheme (and better time keeping).
2. To achieve greater transparency in the decision rules of the scheme.
3. To achieve a significant price reduction.
4. To give greater support to R&D, innovation and competition.⁴¹⁵

While encouraging research and development would be supported through the details of the scheme, compliance and transparency impinged on its general character and the broader principles.

4.3 Industry's approach and aims

Industry embarked on a long process of preparation for the negotiations of 1998-9. The outcome of their efforts was a formal identification of their collective priorities for reform and a sufficient unity of purpose to enable them to undertake negotiations through a small group of delegates.⁴¹⁶ The industry was internally divided about the PPRS and other regulatory issues, along two fault lines. "There are deep divisions within the industry and this makes it difficult for the ABPI to speak for it as a whole. There are divisions along nationality and size lines and in particular, there is always tension between the British and American companies," said a member of the pharmaceutical APPG.⁴¹⁷

It was well known that a large American company in particular was very unhappy with the PPRS and was actively campaigning for greater deregulation of the pharmaceuticals market. A memo from a lobbying company representing several multinational pharmaceutical companies had suggested at the beginning of the negotiations that Merck Sharp and Dohme

⁴¹⁵ Department of health (1999), p.13

⁴¹⁶ *Scrip* No 2428, 14 April 1999, p.4.

⁴¹⁷ Interview, Parliamentarian 12.

was considering withdrawing from the PPRS.⁴¹⁸ It was from the American companies that pressure for a review of the market in the UK largely came. Industry's views of the UK market differed to a significant degree along this nationality faultline.⁴¹⁹ "The American owned and managed companies tend to object to the Scheme – even voluntary – whereas the British companies will happily go along with it and believed it provided them with a better basis for selling products at home in a reasonable market than any arrangement in other markets," a senior politician noted.⁴²⁰

4.3.1 The development of a negotiating structure

In order to reach a united position from which negotiations with the government could proceed, the ABPI had gone to great lengths to solicit industry opinion and to set up a structure that could see through the negotiations in a way that would be acceptable to its whole membership. It achieved this consensus by canvassing opinion and conducting votes among the membership on negotiating positions and on the amount of leeway to be allowed to the negotiators. This research included 'stakeholder' surveys of a broad range of opinion, including the medical profession and industry.

There were also sub-groups created to look at particular aspects of the scheme and report back. The membership meeting that followed this 28-month process gave the Negotiating Team of five people and the Advisory Committee of seven⁴²¹ a mandate to negotiate without referring back to the membership. This was done by drawing up a summary of desired outcomes and negotiating aims.⁴²² The outcome of intra-industry negotiations, and the basis of the mandate given to the teams to negotiate, was a 'scattergram', which defined their negotiating stance and strategy and the limits to their concessions.

⁴¹⁸ *The Guardian*, 21 September 1998; *Scrip* 2372, 23 September 1998 p.2

⁴¹⁹ Interviews, DOH civil servant 10; DTI civil servant 1; Parliamentarians 12 & 21; industry executive 9.

⁴²⁰ Interview, Government minister 7

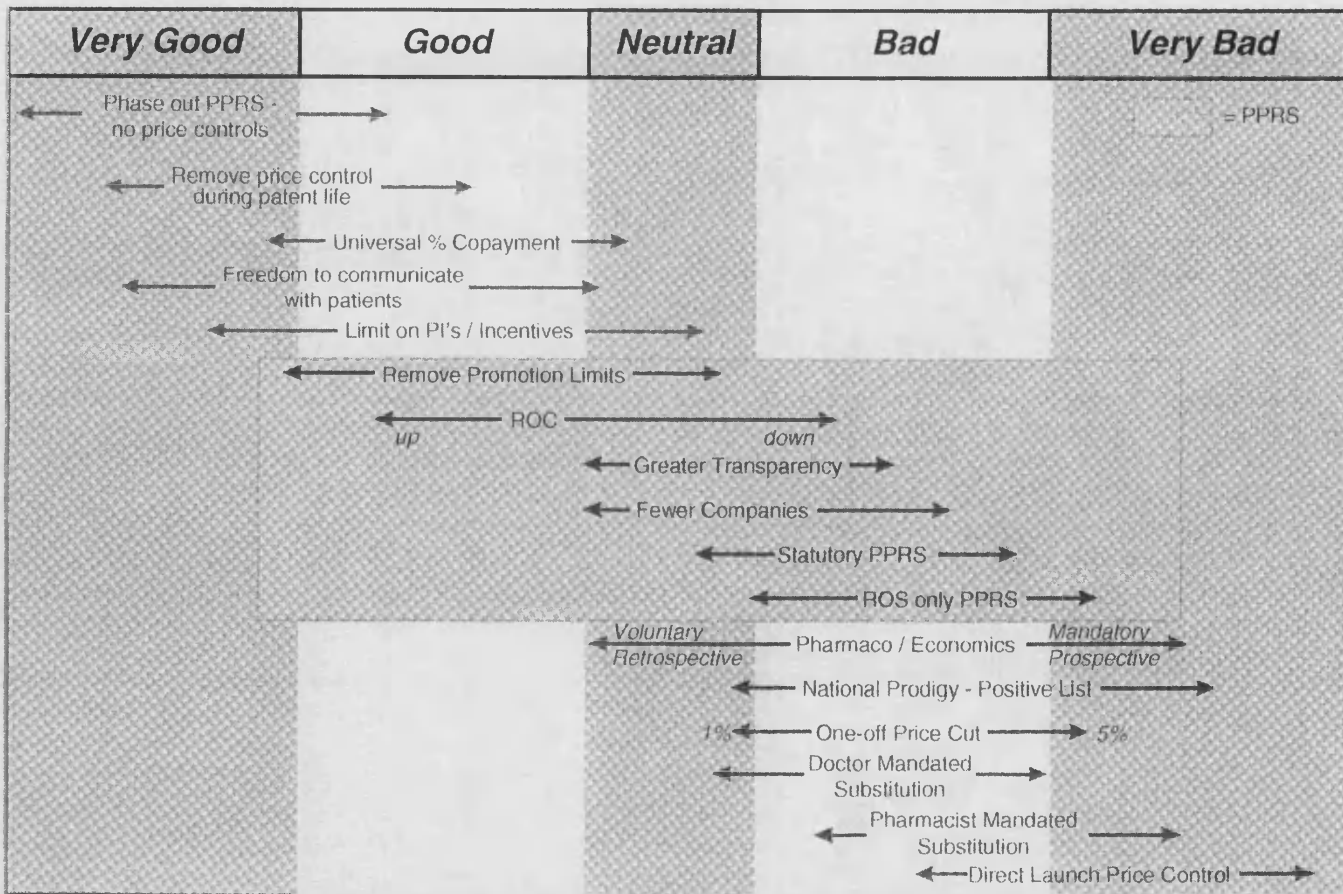
⁴²¹ 'Five plus two', consisting of five company representatives and two ABPI staff as a secretariat. There were therefore a total of 12 involved in either conducting or advising the negotiations.

⁴²² Management Forum (1999); Michael Bailey.

In the long-term they identified the areas they saw as crucial to their business and profitability as primarily research-based innovators of pharmaceutical products. In the short-term, this process enabled them to identify areas of immediate concern for the forthcoming PPRS negotiations. “By gridding it up like this, it helped pick out the features of the Scheme that were more or less attractive to us along the grid of ‘free market’, and it managed to give the industry a strategic framework within which to negotiate, because we could all agree we wanted to move in a particular direction. The goal was to hold them or shift them to the left.”⁴²³ (See Chart 4.1)

⁴²³ Interview, industry executive 9

UK DoH / ABPI Negotiation Menu



Source: ABPI negotiating team member⁴²⁴

⁴²⁴ Interview, industry executive 2

4.3.2 The identification of specific aims

The scattergram showed that an ultimate aim – or rather, an ideal – would be the phasing out of the PPRS in favour of a free market and other aspirations looked beyond the PPRS itself and would require its replacement rather than its reform. Another longer term aspiration was the removal of any price control during the patent term. The scattergram highlights, in the central box, the top aims for industry for the 1999 negotiations. After the relaxing of sales promotion restrictions, the next aim was an increase in the allowable rate of return on capital (ROC). Moreover, industry hoped to avoid the introduction of a statutory PPRS and an ROS-only (Return on Sales) PPRS. The so-called ‘export disincentive’ was also something industry wished to address. (This meant that companies could effectively be penalised for increasing exports if their UK market remained static, because the ROC mechanism would allocate fewer costs to UK production.)⁴²⁵

The removal of limits on promotional spending was also a key aim: “We wanted to loosen the restrictions on promotional expenditure and have more freedom to behave as ordinary commercial organisations.”⁴²⁶ The strength of industry feeling on this matter was expressed by another industry spokesperson:

“British government generally has a rather 19th century view of industry. They think that *making* things is brilliant because that’s what made Britain great; researching and discovering things is a bit iffy, because that’s done by people in white coats who didn’t read classics; actually *selling* things, in other words arranging for the patient and the taxpayer to get some benefit, is a disgraceful activity that ought to be stamped out. That’s the reason we have this very draconian control of sales promotion.”⁴²⁷

⁴²⁵ *Scrip* No 2385, 6 November 1998, p.4.

⁴²⁶ Interview, industry executive 9

⁴²⁷ Interview, industry executive 13

In addition, and aside from the PPRS itself, the industry had discussed the need to re-examine market conditions in the sector, which it believed had changed dramatically since the PPRS was first set up. The ABPI believed that essential factors affecting demand and competition had shifted in a way that meant a deregulatory path could be pursued and government policy aims still achieved. An additional aim was to get the government, whatever the new Scheme might be, to undertake a thorough examination of these factors and report formally on them, as a way of assessing the prospects for deregulation.

4.3.3. The aims of industry: Summary

1. To Remove promotional limits
2. To increase the ROC
3. To ameliorate the so-called 'export disincentive'
4. To prevent a statutory PPRS
5. To prevent an ROS only PPRS
6. To institute a 'competition review' of the pharmaceutical market

4.4 Principal changes in the 1999 scheme

Key areas of the scheme that were changed in 1999 were the Margin of Tolerance (MOT), which was widened significantly to 140% above and 50% below the ROC; a new lower promotional allowance for price rises of 3%; some additional R&D support mechanisms; the removal of 'grey areas' of the scheme for greater transparency; and the removal of an explicit reference to contribution to the 'economy' (see 2.3.7 for more details). See Table 4. for a summary of changes.

Table 4.1: Principal changes in the 1999 PPRS

Item	1993	1999
ROC range	ROC range of 17-21%.	Introduction of new lower rate of 17% for price increase applications. Fixed for normal business at 21%, replacing the range.
MOT / grey area	25% of target profit, either way; except in year of price increase	Widened significantly to 50% lower than the ROC limit and 140% above.
Promotional allowance	6% of sales plus £400K fixed amount per company, plus varying product servicing allowances of £100K, £50K, £40K and £30K per product.	Remained at 6% and a new lower rate of 3% was introduced for price increase applications.
R&D allowance	Negotiated with each company, according to average industry spend, company's UK investments, the company's global R&D spend as % sales.	20% rate for normal business and 17% for price increase applications; additional 0.25% of expenses per in-patent molecule could also be counted.
Price cut	2.5% over 3 years	4.5% across portfolio of the company, will ability to modulate prices.
Contribution to economy	Specific reference (para 4.6) as basis of negotiations on target ROR (Rate of Return); also one factor in agreement on promotional allowance.	<u>No explicit mention of this as a factor contributing to specific areas of the scheme.</u>
New products	Free pricing; profits can be kept to top limit of MOT	Free pricing; profits can be kept to top limit of MOT
General 'grey areas'	Several 'grey areas' for negotiations between company and DHSS, including over target ROR and promotional allowance.	The clear 'grey areas' were removed from the scheme.

There was also a commitment by the government to undertake a review of competition within the sector. The result was the *Pharmaceutical Industry Competitiveness Task Force* (PICTF). The task force examined the state of competition in the pharmaceutical marketplace and many of the contextual factors that impinge on pharmaceutical investment in the UK economy. This was as a response to industry's claims that the supply side of the market had become far more competitive over recent years, gradually making the need

for supply side regulation of any sort less necessary to contain costs.⁴²⁸ As one said: "There is a plethora of demand side controls which we think are very effective, and we clearly have a role in clarifying to government that all those demand side controls *are* effective and that they can therefore relax controls on the supply side."⁴²⁹

4.5 Timetable of the negotiations

Unlike in previous schemes, the negotiations themselves were the end point of a long process of research and discussion by each side to arrive at their respective negotiating positions. The timetable is detailed in Table 4.2.⁴³⁰

⁴²⁸ Department of Health and ABPI (2002).

⁴²⁹ Interview, industry executive 3

⁴³⁰ Management Forum (1999); *Scrip* No. 2455 16 July 1999; Interviews, industry executives 6, 11 & 13; DOH civil servants 5 & 10.

Table 4.2: Timetable for the negotiations of the 1999 scheme

1995/6	Government decision that there would be a renegotiation at the first possible opportunity in 1998.
February 1996	Industry task force formed, reporting to Vincent Lawton of MSD
Mar '96-Jan '97	Industry's 'external stakeholders' and 'industry attitudes' surveys conducted
Early 1997	mid-term review of 1993 scheme completed
April 1997	Industry's sub-groups formed
July 1997	Industry conducts CEO's meeting
Autumn 1997	DOH discounts therapeutic option and moves decisively towards favouring a renegotiation of the PPRS
July-Dec 1997	Industry's second 'industry attitudes' survey conducted
27 October 1997	Talks about talk between the two sides – to arrange timetable and locations
5 December 1997	Preliminary position agreed within industry
January 1998	Industry's second 'external stakeholders survey' conducted
May 1998	Industry conducts CEO's meeting
June 1998	<u>Formal negotiations commenced</u>
July 1998	Government presents its proposals to industry negotiating team ('Neg 9')
Aug-Dec 1998	Industry conducts internal meetings on government's proposals
September 1998	Press reports about the clauses in the Health Bill
October 1998	Current PPRS expires
January 1999	Health Bill published
February 1999	Industry conducts CEO's meeting
May 1999	Government presents revised proposals
June 1999	ABPI presents revised proposals; further CEO's meeting
July 1999	<u>Agreement reached and signed</u>
October 1999	New PPRS commences

4.6 The process of the negotiations

Both negotiating teams had clearly defined aims which they sought to deliver to their respective constituencies. Each party entered the negotiations with a

public position that was not acceptable to the other. The negotiations would determine to what extent each party would be able to use its bargaining resources to push the negotiations in its direction, and whether there would be a point where they would cease to believe that the PPRS could deliver their minimum regulatory needs.

4.6.1 Research and preparation

The politics of the 1999 PPRS therefore marked a significant watershed in the scheme's history. This was illustrated by the presentation to the ABPI of the government's opening position on the PPRS negotiations, in a paper named "Neg 9". One industry participant noted: "Their opening position was simply unacceptable. We thought Neg 9 was either a bargaining position or just naivety."⁴³¹

The early part of the negotiations were spent with each side coming to terms with the fact that the other had prepared as meticulously as they had. Industry spokespersons admitted that they were shocked by the government's preparedness for the negotiations and the amount of analysis they had done. They felt they had to gain back ground lost by this powerful opening gambit by the government side.

"In 1999 there was a quantum shift in our preparation – we did a very, very professional job. We spent a lot of money, a lot of time, we did it really well; we walked into the first meeting and we discovered to our horror that the Department had done exactly the same!"⁴³²

"They were surprised at how much preparation we had done. They came to the table with what they thought to be a well worked out position and we came with a position too, which was quite different from previously, where we hadn't come with a position. You could witness the tensions between the

⁴³¹ Interview, industry executive 6

⁴³² Interview, industry executive 13

companies on their side, as they were forced to accommodate themselves to what the government was proposing to do.”⁴³³

4.6.2 Negotiation through the press

By the autumn of 1998, it had been made clear in the press that the government was proposing the introduction of a *statutory* scheme that would be passed through Parliament in the form of several clauses attached to the 1999 Health Bill.⁴³⁴ The press mused over the possibility that the PPRS may be coming to an end, with perhaps the least radical option being to put the scheme on a statutory basis.⁴³⁵ Some press stories characterised the clauses in the Health Bill as a replacement of the PPRS, and they had clearly been briefed to that effect.⁴³⁶ *The Guardian* reported a likely “head-on collision” with multinational drug companies as it declared that the voluntary PPRS was to be “scrapped” in favour of a system of pegging prices through “legally binding contracts”.⁴³⁷

The government had responded decisively to moves by American companies – notably Merck, Sharp & Dohme – to withdraw from the PPRS. It had raised the spectre of a legally binding system of regulation, invoking its key resource as a lawmaker (with a ‘legal monopoly’), rather than only a customer. Equally, the revelation by companies that they might withdraw from the scheme was revealed through a leaked memo from the company’s political lobbyists, GPC Market Access.⁴³⁸ Industry reaction to the revelation of legislation was to publicise imminent danger to the economic well-being of the industry.⁴³⁹

⁴³³ Interview, DOH civil servant 10.

⁴³⁴ HMSO. Health Act 1999, paragraphs 33-38.

⁴³⁵ *The Financial Times*, 23 September 1998.

⁴³⁶ *The Times*, 21 September 1998; *The Guardian*, 21 September 1998.

⁴³⁷ *The Guardian*, 21 September 1998

⁴³⁸ *Scrip* No 2372, 23 September 1998, p.2.

⁴³⁹ *The Times*, 20 October 1998

4.6.3 Impact of other regulatory developments

In addition to the 1999 Health Bill, which contained clauses to enact a 'statutory scheme', industry was worried by 'noises' from ministers that they did not regard as favourable.⁴⁴⁰ Other measures made the policy landscape very complex: policy and economic analysts in the industry had to judge how a raft of separate measures might interplay. Several demand side measures, including cash limited budgets for doctors, had recently been introduced. It was difficult to understand how the PPRS as a supply side measure and these new demand side measures would impact on each other. The National Institute for Clinical Excellence (NICE), first announced as part of the White Paper on the NHS in November 1997, was also about to be inaugurated, though with little clarification on how it would affect pharmaceutical products.⁴⁴¹

One industry team member commented of NICE: "What is the point of negotiating freedom of pricing at launch, which is what we have under the PPRS, if in fact the government says you cannot launch your product, as it eventually did in the cases of Relenza and Propetia.⁴⁴² Your calculations on what this negotiation might mean for your industry or your company would be worthless."⁴⁴³

The declaration by government that there was going to be a statutory scheme was (given industry's negotiating priorities) a severe blow to the negotiations: "It made them much harder. We did not believe they were coming to negotiate in good faith."

⁴⁴⁰ Interview, industry executives 3 & 9

⁴⁴¹ *The Independent*, 2 July 1998

⁴⁴² Within a few months of the new PPRS agreement being signed, NICE recommended that Relenza not be prescribed on the NHS; Propetia was put on Schedule 10, which limits its usage within the NHS to specified cases.

⁴⁴³ Interview, industry executive 9

4.7 The pharmaceuticals market

Assumption 1: The market for pharmaceuticals in the UK underpins the PPRS by enabling sufficient rewards for both government and industry within the scheme, and enabling policy aims to be balanced.

Hypothesis 1: Actors on both sides will seek to maintain the current structure of the pharmaceuticals market, and hence the regulatory goods it yields, and will not pursue strategies that would undermine it.

In 1999, perceived changes in the market for pharmaceuticals underpinned the industry's insistence on a full examination of the market, which resulted in the PICTIF process. In addition, the negotiations yielded more familiar trade offs between the two sides in arriving at an agreement.

4.7.1 The price cut

There had been a tradition of an overall price cut in PPRS agreements and industry has been prepared to contemplate and agree to this as part of the overall deal in which its primary concerns are met.

In 1999, industry maintained this stance. One industry source described the focus of DOH's own agenda and industry's response to it as follows:

“The DOH had promised Treasury X-hundred million pounds savings from the drugs bill and they told us we had to give it to them. We said we would trade a price cut for other things: will give you X-hundred million off this year and let us negotiate what that X-hundred million is.”⁴⁴⁴

Industry sources agreed that the price cut was something they acquiesced in, in order to gain or maintain wider benefits:

“I think everybody feels that they got sufficient potential or actual benefit to compensate for the price they had to pay through the 4.5% overall price reduction.”⁴⁴⁵

“Nobody liked the 4.5% price decrease but we accepted it in order to give the government a good one-off hit, for which we got some good trade-offs in response.”⁴⁴⁶

“Without the free pricing element, you would have to ask the question whether the PPRS is a valid form of agreement for us.”⁴⁴⁷

It was, then, overall profits and, specifically, the distribution of funds across product ranges, as well as speed to market that most concerned industry.

How the price cut was distributed was also important to the ABPI – emphasising the value of the market as it was structured through the PPRS: they valued the higher prices available to them, through the free pricing mechanism, for their research-intensive products at the top end of the market. An industry source explained the approach they took to the negotiations: “If you want to save money, we will take it from the patent-expired end of our older, more established drugs.”⁴⁴⁸ The modulation attached to the overall price cut allowed companies to cut prices wherever they wished in order to achieve an aggregate percentage reduction across the whole of their portfolio. They therefore maintained some degree of control of their pricing strategies and the distribution of the required cuts.

4.7.2 Industry’s regulatory goods

Department of Health officials agreed that there were things more important to the industry than price, as one noted: “In the end they were prepared to

⁴⁴⁴ Interview, industry executive 9

⁴⁴⁵ Interview, industry executive 3

⁴⁴⁶ Interview, industry executive 11

⁴⁴⁷ Interview, industry executive 6

⁴⁴⁸ Interview, industry executive 9

take an extension of the price cut as part of the trade-off for not changing the rate of return on capital.”⁴⁴⁹ This was also the Treasury’s reading of the situation: “For the big companies, the UK market is relatively small but they have still seen it as quite important.”⁴⁵⁰

There was a broad consensus among industry team members and commentators that a quick launch is an attractive feature of the UK regime: “The UK market is one of the markets in the world where once you have your license you can launch with a decent price – freedom of pricing for your first entry to market with no other barriers to entry. That is very positive,” said one ABPI negotiator.⁴⁵¹ A senior civil servant in the DTI reflected the Department’s recognition of industry’s concerns: “For industry, it was mainly about getting things onto the market in the UK as quickly as they could.”⁴⁵²

Again, this feature of UK regulation is seen as positive in relation to other European markets: “After the United States, the UK has always traditionally been a country in which new medicines are launched early. One of the reasons for that is that you get immediate reimbursement.”⁴⁵³ He explained the importance of freedom of pricing to the industry:

“People in our industry do regard free pricing of New Chemical Entities as the jewel in the crown of the PPRS and it is true. If you’ve got a New Chemical Entity you can choose your own price. You can get your license on Monday and launch on Tuesday; you don’t have another hoop to jump through. The value of it is the fact that we can say, ‘we have got our license, we’re launching tomorrow, the price is £4.63’.”⁴⁵⁴

However, the industry side recognised the market-distorting effects of free pricing; they saw it as compensation for the lack of a freer market in which to sell their products:

⁴⁴⁹ Interview, DOH civil servant 10

⁴⁵⁰ Treasury civil servant 24

⁴⁵¹ Interview, industry executive 11

⁴⁵² Interview, DTI civil servant 1

⁴⁵³ Interview, industry executive 13

⁴⁵⁴ Interview, industry executive 13

“With freedom of pricing at launch, we launch drugs at a higher price than we would do if we were trying to launch them to be competitive with competing products on the market. You are not launching at a price to compete necessarily, because that's not how the PPRS is structured. You will never get a price rise in the future, so the price you set just erodes year on year.”⁴⁵⁵

The industry side recognised the value of this key part of the PPRS and can again be seen to have accepted quite a substantial price cut partly because of the value they placed on free pricing at launch.

4.7.3 The evolving market

On the more general level, there was a questioning unlike any before of the need and effectiveness of supply side regulation. While keen not to allow their advantages to be whittled away, and prepared to pay the price, literally, to keep them, the ABPI pushed hard and won an important concession from government: to undertake a thorough examination of the nature of competition in the sector.

The negotiation of the 1999 scheme therefore reveals that industry questioned the value of the sort of market structure the PPRS has shaped, but this was an outcome of conflict within the industry camp that the ABPI was obliged to reconcile and in the end all firms supported it collectively, contesting the basis and assumption of the PPRS of a lack of competition in the supply of medicines.

They sought recognition from the DOH of a growing competitiveness in the market and a growth in demand side controls. A quid pro quo reduction in supply side regulation was sought. “We believe that the market for pharmaceuticals – the supply of medicines to the NHS – will be an

⁴⁵⁵ Interview, industry executive 9

increasingly competitive area,” said one industry source.⁴⁵⁶ The 1999 scheme yielded for the industry an agreement to examine the state of the market and to institute a process of ‘progressive deregulation’ so far as a competitive market was shown to exist.

The context of this was a perceived shift in industry’s R&D focus to the US⁴⁵⁷ as well as growing demand side measures that made the consumption of medicines in the UK more sensitive to price. “If you introduce other demand side hurdles then you undermine the basis of the PPRS,” noted one industry negotiator.⁴⁵⁸

4.7.4 The government and cost control

Cost containment was a central part of the government’s agenda – one of its key regulatory goods and an enabler of the PPRS regime and the co-operative government-industry relationship in it. The negotiations were, after all, taking place because the Treasury had insisted on their doing so at the earliest possible opportunity and had insisted on cost savings as part of their outcome. Potential savings were identified by the Department. “We were aiming to knock £200 to £250 million of the bill for existing drugs, which we could then calculate for the years to come, and that’s what we did,” said a senior politician.⁴⁵⁹

Nevertheless, officials acknowledged the positive value of new medicines, in part as alternatives to more costly medical interventions: “I wouldn’t mind if the pharmaceuticals bill was 96% of NHS spending, providing it was making people well,” a senior politician noted.⁴⁶⁰ But the balance had to be achieved: “Our opening position and the subsequent positions were all ones that would try to recognise in the price the value of new, quality, innovative in-patent

⁴⁵⁶ Interview, industry executive 11

⁴⁵⁷ Indeed in the two years following the new PPRS, three European ‘giants’, Franco-German Aventis, Swiss Novartis and British GlaxoSmithKline, have moved their research headquarters to the US. See European Business Forum (2002).

⁴⁵⁸ Interview, industry executive 6

⁴⁵⁹ Government minister 7.

⁴⁶⁰ Government minister 7.

medicines, and pay for that by pushing down the price of the out-of-patent branded medicines towards the generic price.”⁴⁶¹

4.7.5 The government and industrial policy

As well as medical effectiveness, industrial policy aims were also salient and support for the science base was recognised explicitly. In this respect, the top-end of the market was the most critical: “If you’re trying to promote an industry with a long-term future then you need to help promote research and reward its outcome and that was what we were trying to do. It wasn’t a concession by us. We wanted it as well!”⁴⁶²

The success of the PPRS was demonstrable in the way that investment in R&D had been sustained in the UK: “We’re a small country, it’s a small market but we’ve sustained, pound for pound, a far bigger pharmaceutical industry than anybody else.”⁴⁶³ A senior civil servant in the DTI made the same point: “From our perspective, we wanted to make sure that when people are looking to make future investment in research centres and high added value activity, they choose the UK.”⁴⁶⁴

4.7.6 Conclusions

The industry’s collective view was that concessions within the PPRS – notably the substantial overall price cut – ought to be made. It was recognised that the government was determined to achieve a substantial expenditure saving over the short-term and that the integrity of the scheme would require it. Keeping spending under control proved to be an enabler of the system and therefore of its positive aspects for the industry side.

The DOH approached the negotiations forcefully but recognised the key regulatory goods that industry required to be kept on board (and unified

⁴⁶¹ Interview, DOH civil servant 10

⁴⁶² Government minister 7

⁴⁶³ Government minister 7

⁴⁶⁴ Interview, DTI civil servant 1

under the ABPI, given the unrest among some American companies). For the maintenance of the price restraint they accepted the competition review.

4.8 The global context

Assumption 2: The global organisation of industry lends it bargaining resources it would not otherwise have and makes government more alive to the need for an active industrial policy. ,

Hypothesis 2: Industry will seek to utilise its global structure as a bargaining resource to counteract the legal monopoly of government, which in turn will pay greater attention to their industrial policy aims.

The industry changed rapidly through the 1990s and senior politicians were concerned by its restructuring and its apparent shift towards the US and away from Europe. The sponsorship branch of the DOH regarded regulation in the UK as a potential material factor: “There are certain areas of policy the government is pursuing, or may not be pursuing, that affect the global competitiveness of the industry.”⁴⁶⁵

4.8.1 The political salience of the pharmaceutical industry

At the top of the political hierarchy (and regardless of the debate about the dual role of the Department of Health), senior politicians with across-the-board policy responsibility – not least the Treasury and the Prime Minister – have a broader perspective on the status of industry. A senior civil servant pointed out that as the negotiations began, the Prime Minister met with key business leaders to discuss some of these issues. “Sykes, McKillop and Leshly⁴⁶⁶ met with the Prime Minister over breakfast meetings to discuss the competitiveness of the UK economy and other issues such as science and research. They had a direct line of communication that was of a different

⁴⁶⁵ Interview, DOH civil servant 4

⁴⁶⁶ The then CEOs of the ‘global’ British companies Glaxo Wellcome, Astra Zeneca and SmithKline Beecham, respectively.

order to that of the other industry players.”⁴⁶⁷ While the PPRS negotiations were conducted by the Department of Health, the importance of the industry meant that they had a political context that went far further up the hierarchy, to the very top.

In fact the issues discussed at PM-CEO level were ones that did eventually find their way into the final PPRS agreement in the form of the Competition Review. Another DOH civil servant noted its significance, “The task force that has been set up with ministers from five departments and global CEOs is a unique body for an industry in this country.”⁴⁶⁸

In the end, the PPRS negotiations could not be separated from broader policy and confined to a procurement exercise for the NHS owing to the high-tech, high value nature of the industry and its global structure.

4.8.2 Global industry and bargaining resources

In April 1999 the ABPI held its annual dinner, to which it is customary to invite the Secretary of State for Health as a guest of honour. At the dinner, the ABPI President, Michael Bailey noted the position of the UK in the context of a globally organised industry: “He warned that pharmaceuticals was a global industry and the UK had to compete with other countries for investments in R&D and manufacturing, addressing his remarks at the other mid-dinner speaker, the Secretary of State for Health, Frank Dobson.”⁴⁶⁹ As well as a warning about the nature of the industry, this was a timely reminder, mid-way in the PPRS negotiations, that the industry is not obliged to invest as heavily as it does in the British economy. The structure of the industry was an important bargaining chip in negotiations with government. A senior DOH civil servant explained the extent of mobility in the British market in particular:

“Most of the major companies are global, or at least multinational. Some of them – Merck, to some extent GlaxoWellcome, to some extent SmithKline

⁴⁶⁷ Interview, DOH civil servant 10

⁴⁶⁸ Interview, DOH civil servant 4

Beecham, are global in the sense that they have a corporate headquarters somewhere, but they are not actually wedded to any country or any one operating regime and the chief executives of those companies, accountable to shareholders, have no particular affinity with any one country. The German companies, on the other hand, are multinational, but their German heartland is very important to them – their German base is a very high proportion of their sales and so on.”⁴⁷⁰

Industry sought to exploit the mobility of its investments during negotiations: “The danger of disinvestment was a fact that was constantly pointed out to the government side,” said one member of industry’s negotiating team.⁴⁷¹ This was dependent on a broad range of factors, including “reasonable pricing structures and also reasonable support for research and development and a reasonable academic environment.” Another member of the negotiating group also made the link between R&D investment and market conditions: “On balance the UK is still a reasonably good place to do research and development provided we’ve got a market for our products at the end of it.”⁴⁷²

The investment argument worked and government – at Secretary of State-level – overtly tried to bolster mechanisms that would encourage R&D investment: “The object was twofold. While we wanted a good bargain for the next five years for the NHS and the taxpayer, at the same time we aimed to encourage investment in research-led pharmaceuticals here,” said a senior politician in the DOH.⁴⁷³

4.8.3 Industrial policy and investment

Government largely accepted the investment argument during the negotiations. “Ministers wanted to work *with* the pharmaceutical industry because the government does value the investment in this country and it was

⁴⁶⁹ *Scrip* No 2429 16 April 1999 p.5

⁴⁷⁰ Interview, DOH civil servant 10

⁴⁷¹ Industry negotiator 13

⁴⁷² Industry negotiator 3

made quite clear that you couldn't have a voluntary reference pricing system; it would have meant legislation," said a senior DOH civil servant. This point also stresses the nature of the PPRS itself – as a voluntary scheme, industry has to agree to it, regardless of how correct or not government may have thought its economic arguments were. Industry could not be forced to sign.

The DTI also had a role in drawing attention to the connection between the activities of a globally mobile industry and the stringency of national regulation. "We wanted to make sure that when people are looking to make future investment in research centres or high added value activity that they choose the UK and we were concerned that the PPRS would impinge on those decisions because it did affect their operating environment, which is why we felt we had to take an interest in it."⁴⁷⁴

The PICTF study of competition that was set up as part of the PPRS eventually concluded that the global structure of the industry was a significant factor. "The conditions required for the industry to retain its competitive position are changing in the face of significant shifts in the global business environment. These shifts are driving pharmaceutical companies to take a much closer look at what each location offers in terms of ... attractiveness of local market conditions."⁴⁷⁵

4.8.4 Oversees policy and markets

Systems of regulation in other countries provided points of comparison for both government and industry during the negotiations.

People from both sides of the negotiations noted the importance of cross-referencing between countries in policy outcomes over the PPRS: "The danger was that the R&D investment would be sucked into the countries where the early launches are going to happen. You can't quantify this – you

⁴⁷³ Government minister 7.

⁴⁷⁴ Interview, DTI civil servant 14

⁴⁷⁵ Department of Health (2001), paragraph 2.2.

can't make an algebraic expression for it, but it was a possibility if we weren't careful," noted one industry negotiator.⁴⁷⁶ The value of the early launch was highlighted as an issue for the industry side, notwithstanding the possible effects of NICE judgements in particular cases. Indeed the arrival of NICE meant that freedom of pricing was all the more important in an atmosphere where industry felt its products may face a 'fourth hurdle' to the marketplace.

Some industry figures found it difficult to assess the effect of the PPRS in a global context with the shadow of NICE in the background, which was seen as highly significant for the interplay between the British market and overseas markets: "We made the point several times that if you're excluded from your home market, it has an impact on your global competitiveness. You can't export from a market that won't allow you to sell there itself because export prices are based on UK prices; overseas customers ask for evidence of acceptability in our home market and our home market is therefore a disproportionate percentage of value."⁴⁷⁷ 'Home market' here refers to the place of clinical trial and launch (not a company's origin) and therefore directly links pricing regulations with locations of R&D.

The importance of the place of first launch was emphasised by another industry figure: "Your trialists are your opinion leaders and are crucial to the reception of a product in other markets."⁴⁷⁸ These points give real backing to industry's arguments about disinvestment. If market conditions (not specifically value) are seen as adverse, one important reason for researching and trialing in the UK would be gone.

4.8.5 The Treasury's position

Even the Treasury had taken this argument on board in their internal discussions about how hard to push for savings in the PPRS, or for restructuring that would produce savings further down the line: "The UK

⁴⁷⁶ Industry negotiator 13

⁴⁷⁷ Industry negotiator 9

⁴⁷⁸ Industry negotiator 3

market is important to the industry for gaining regulatory approval. ... if they gain approval in the UK from the MCA and the drug is well established and gets a track record in the NHS then that is a significant benefit to them selling the drug in overseas markets.”⁴⁷⁹ All three government departments involved in the negotiations therefore recognised the broader international significance of the early launch that the PPRS provided.

However, Treasury officials further realised that recognising and maintaining this important aspect of the British system also enabled them to push for cost savings: “While I do not think the industry would be prepared to see their drugs as sort of loss leaders in the UK market, they do to some extent accept something of a trade-off between somewhat reduced margins in the UK against the potential for export sales.”⁴⁸⁰ An industry negotiator agreed with this point: “The big research-based drugs companies all said that because we’re innovation-based and the whole of our competitiveness is based on innovation, if you’ve got a tight drugs budget the best way to save money is through existing drugs.”⁴⁸¹

4.8.6 Overseas policy and regulation

Regulatory regimes can be directly compared by firms and industry. Where some aspects are better elsewhere, this can be used as a pointer by industry; where they are worse, they can serve as a warning. Most stark in this respect are statistical comparisons. The pharmaceutical industry in the UK may be regarded as having a high profitability but the 1990s were very profitable for the industry globally. The 21% ROR in the PPRS did not compare well with the industry’s main market: “The UK level is below the industry’s global average profitability. It used to be around the 21% mark but it isn’t now. The industry global average is now in the low 30s, maybe 33% so the UK is well below that, and, of course there’s no guarantee that you

⁴⁷⁹ Treasury civil servant 24

⁴⁸⁰ Treasury civil servant 24

⁴⁸¹ Industry negotiator 9

actually get that return, it's just an upper limit," said one industry negotiator.⁴⁸²

Nevertheless, one industry commentator noted that a significant driver in the industry's acceptance of the PPRS and its willingness to join government in a partnership was the prospect of practised alternatives; "The alternative doesn't bear scrutiny. That's direct price control and where it's been applied in the developed markets of Western Europe it has not been of value to the industry."⁴⁸³

It was not only on the government that companies were able to apply pressure: the ABPI also found itself under pressure from American companies that had become more dominant through the 1990s. In July 1999, *Scrip* magazine noted regarding the competition review that the American companies were less obliging than European ones in discussing regulation. "The DOH may have had to agree to this plan so that US-based companies, historically against such controls, would accept the PPRS terms."⁴⁸⁴ The 1999 negotiations show that the American companies were able to exert a pressure from within the ABPI that they had apparently not had back in 1993. "The proposers [of the competition review] were the major American companies," noted one industry team member.⁴⁸⁵ American companies bring with them assumptions about the operation of the market from their free market base. "There is a philosophical difference between the way in which American organisations view Europe, and Britain in Europe, and how the business of pharmaceuticals fits into health care provision."⁴⁸⁶

4.8.7 Corporate internationalism

Corporate internationalism both changes the attitudes and concerns of home-based companies and brings into play overseas companies with different

⁴⁸² Industry negotiator 9

⁴⁸³ Interview, industry executive 6

⁴⁸⁴ *Scrip* No 2457 23 July 1999 p.4-5

⁴⁸⁵ Interview, industry executive 6

⁴⁸⁶ Interview, industry executive 6

cultural approaches. They must also be accommodated in the structure and decision making process of the ABPI, in arriving at its negotiating stance. The global corporate structure of the industry does mean that the British trade association must take on board the perspectives of overseas companies.

A further way in which the global structure of industry impinges on the regulatory regime is through the internationalisation of the company's activities and the difficulty this creates for many of the complex calculations that need to be made in the PPRS. As the senior DOH civil servant in charge of the negotiations noted, "There's a difficulty of having a return-on-capital scheme in a global business. It's alright when the assets are all in this country, but when they are spread around the world it makes it more difficult and this is something that's happening through mergers. I don't think you could say that it's making PPRS inappropriate *now*, otherwise we wouldn't have renegotiated it but it is a question for the future."⁴⁸⁷

4.8.8 Conclusions

The global context was an important structural influence on the 1999 negotiations. Developments in the sector did give industry a strong bargaining position, especially at a very senior level where CEOs and top government officials and ministers – up to the PM – became involved in broad questions about the sector and the British economy. The competition review was an outcome of this emphasis on industrial policy aims.

Nevertheless, the Treasury and DOH did have a powerful procurement and regulatory agenda, in particular over the compliance issue. A balance of advantages was again achieved for the large firms, though dissent was palpable from some of the American firms and they exercised a novel and tangible influence over the proceedings.

This politicisation on a global scale and the added complications of regulating business that is spread across countries raised longer term questions for

government officials about the viability of the PPRS. Global corporate structure was thought likely to have an increasing impact on government-industry relations in the sector.

⁴⁸⁷ Interview, DOH civil servant 5

4.9 The co-operative state

Assumption 3: The 'liberal' nature of the British state means there is the desire by government for 'light-touch' and co-operative regulation using limited administrative, technical and legal resources.

Hypothesis 3: Policy proposals that require significant technical, administrative and legal resources on the part of government will not be pursued, in particular a legislative approach to regulation. They will seek maintenance of the co-operative regime.

The 1999 PPRS negotiations sat alongside an apparently clear attempt by the government to legislate over areas of the scheme. The government was seemingly willing to overturn the co-operative regime in favour of enforcement through the law.

4.9.1 Analysis of the government's options

The work of the Department of Health prior to the negotiations reveals that there was a dispassionate and broad ranging assessment of the status quo by the government. "The full monty was there, from a procurement function, through an RPI-X formula, to therapeutic substitution. What we did not consider was a completely free market," commented a senior civil servant in the Department of Health.⁴⁸⁸ Another senior civil servant in the DOH noted that the technical ability of government, within resource constraints, had improved considerably between the 1993 and 1999 schemes simply owing to the improvements in the technology available to it: "The use of information technology was not nearly as developed as it is today. Factors such as that have enabled us to do more this time than they did last time."⁴⁸⁹

⁴⁸⁸ Interview, DOH civil servant 10

Yet one by one the options for reform seemed to present obstacles, or to be inapplicable to the industry. RPI-X was considered to be unsuitable to the pharmaceutical industry. This relies on inflation prediction in order to set the 'X' figure, but the products of the industry are not uniform – research intensive new drugs cannot be valued in the same way as older drugs, whether brand name or their generic alternatives. The RPI-X formula was not thought to reflect the complex nature of value distributions throughout the sector's product range. "If you are regulating water, then water is water. Medicines are not one product and there are changes in population in terms of new products coming on stream and RPI-X cannot deal with new products," the civil servant added.⁴⁹⁰

Several months before the negotiations commenced, the government side had recognised these practical obstacles to radical reform. "We concluded relatively early on in the autumn of 1997 that the infrastructure really was not there for thinking about the therapeutic option.⁴⁹¹ We did not have the infrastructure for decision making or the infrastructure for delivery. We would have needed to transform completely the whole structure," said one senior DOH civil servant.⁴⁹²

With an eye on the need for immediate savings, the traditional route appeared to be the least cumbersome. It also reflected the Treasury's budgetary concerns: "We were a part of the process of examining alternatives to the PPRS and of developing the government's overall position," noted a Treasury official.⁴⁹³ The blanket price cut was recognised as a quick and effective mechanism to achieve this, as a senior DOH civil servant described: "It's very simple to say what the effect of a price cut will be

⁴⁸⁹ Interview, DOH civil servant 5

⁴⁹⁰ Interview, DOH civil servant 5

⁴⁹¹ 'Therapeutic Substitution' had been discussed for many years. It is a system where a pharmacist can substitute a generic for a brand name drug written on a prescription. The respondent here is referring to a more radical system where the appropriate drugs for all conditions are centrally defined by government and a positive list of prescribable drugs drawn up for every indication.

⁴⁹² Interview, DOH civil servant 10

⁴⁹³ Interview, Treasury civil servant 24

because you just pay 4½% less for your medicines than you otherwise would. It's easy to model that."⁴⁹⁴

4.9.2 Desire for a voluntary agreement

The government's cost containment aims can be achieved most simply in the PPRS through the across-the-board price cut. Part of this simplicity is related to its having been agreed voluntarily with industry, and this is a fact that formed the basis of many judgements about the PPRS and alternatives to it.

Of the various other options that had been looked at, the way in which they might affect the voluntary nature of the agreement proved central to the decision not to pursue them: "Reference pricing is something we would never have got a voluntary agreement on. Ministers wanted a voluntary agreement, they wanted to work *with* the industry. A reference price system would have meant legislation, and that is something you couldn't introduce very quickly."⁴⁹⁵ This potential option was therefore counted out despite a great deal of research having been undertaken.

So the desire for the continuation of a voluntary scheme was made clear from the top – the Secretary of State – even though it had initially been ministers in the new government that had been most suspicious about a 'cosy' government-industry relationship in this area.⁴⁹⁶ They were the ones that eventually insisted on a voluntary approach.

Voluntarism was also a key issue for the DTI. As would be expected, the Department was unequivocal about the need for a co-operative system. A senior DTI civil servant noted: "The most contentious business was whether the regime should be made statutory or not, and we knew the industry would not want that to happen. Our Secretary of State flagged that up at some

⁴⁹⁴ Interview, DOH civil servant 5

⁴⁹⁵ Interview, DOH civil servant 5

⁴⁹⁶ Interview, DOH civil servant 10

stage. He emphasised the importance of trying to get the negotiation done on a voluntary basis.”⁴⁹⁷

The PPRS negotiations reveal that both sides acknowledged the limit to the government’s appetite for replacing the voluntary PPRS with a different form of regulation, despite the clauses in the Health Bill that aimed to introduce a statutory scheme, which had been dubbed a ‘replacement’ by much of the press. The passage of the Bill was concurrent with the negotiations and the same people from both the DOH and the industry were involved in the two processes. Since the inspiration for both the broad examination of alternatives in the PPRS and the introduction of the clauses in the Health Bill were similar, the commitment to voluntarism had in practice still to satisfy the government’s need for assurances over compliance.

Industry eventually recognised that the government favoured a renewal of the voluntary agreement, once the uncertainty that arose in the autumn with the initial announcement of statutory provisions had subsided. “We worked on the basis that the officials did not want a statutory scheme. I think they were frightened of having to cope with a statutory scheme. The organisation it would take to operate would demand more than eleven chaps down at 79 Whitehall,” commented one member of the industry team.⁴⁹⁸

Nevertheless, there had undoubtedly, it was felt, been a shift in the government’s attitude. “Their approach was more compulsory and regulatory.”⁴⁹⁹ Industry’s perception that government wanted a voluntary agreement was thus tempered by this recognition that they were approaching the negotiations from a more determined perspective than in the past. The department intended to solve the immediate weaknesses of the scheme, and were prepared to contemplate otherwise undesirable changes if necessary. “I do not want to down-play the determination of government. It was very clear that government at all levels were utterly determined that if we were going to

⁴⁹⁷ Interview, DTI civil servant 1

⁴⁹⁸ Interview, industry executive 13

⁴⁹⁹ Interview, industry executive 6

have a new scheme it must be one that works and for which they can be accountable, and which can be transparent.”⁵⁰⁰ It seemed to some industry negotiators that the DOH might indeed sacrifice – albeit unwillingly – the voluntary form of the PPRS in order to secure the compliance and transparency that they sought. The aim for both parties was to avoid the position where such a choice had to be made, and the limitations on the government’s new determination to act proved decisive.

4.9.3 The limitations on government

There were two aspects to the desirability of a co-operative structure for the government. First, the administrative resources required to operate the non-voluntary alternatives would be far greater. Second, certain technical aspects were thought of as unnecessarily complicated, such as the therapeutic option.

A more vigorous regulatory regime was viewed as technically too difficult for the potential political benefits and a shift to a different type of system was counted out before the negotiations began. The government recognised that very minimal resources were required to operate the PPRS: “It is light-touch. There are only 15 people here dealing with it.”⁵⁰¹

Furthermore, despite the improvement in the Department’s technical ability, through the application of IT, this still presented a hurdle. “The base data were more readily available for nationalised industries, than for us operating a relatively loose regulatory regime, which is what the PPRS is.”⁵⁰² An alternative to the PPRS would likely mean having to gather this sort of data, and without the active co-operation of the companies involved.

Within the PPRS, the government does, in fact, have a very wide-ranging understanding of the pharmaceutical industry. One industry spokesperson

⁵⁰⁰ Interview, industry executive 13

⁵⁰¹ Interview, DOH civil servant 5

⁵⁰² Interview, DOH civil servant 5

noted, “Government had access to all the annual financial returns in a way that industry did not. They saw the figures before they negotiated.”⁵⁰³ This access to information is special, and unlike any other industry except the utilities. Nevertheless, government is reliant on industry co-operation through the PPRS in order to get it. “Industry is very willing to share the information that it has got about its own performance,” the industry team member added. The maintenance of this ‘willingness to share’ is something the DOH would wish to keep.

To some extent, ‘technical’ limitations on government consisted simply of a knowledge gap, which would have to be filled if a strict and inflexible regulatory system were to be implemented. Industry commentators also believed that government did not fully understand the impact of its various regulations on the industry, as they were then being introduced. This would seriously compromise their ability to design and operate a more complex regulatory system. The recent development of demand side measures were not analysed sufficiently according to one industry participant and this lack of technical assessment of various measures hindered their ability to regulate in a stricter way. The source commented: “They have not put the systems in place to measure the impact of things such as PACT or generic prescribing on medicines supply.”⁵⁰⁴ Better measurement of the impact of regulations would be essential to devising a more rigid statutory scheme because it would have to stand up to continuous legal scrutiny and it would be far more difficult to ‘tweak’ to take account of the interplay with other regulatory mechanisms, particularly on the demand side.

4.9.4 The potential for litigation

One significant feature of statutory regulation arises from the fact of non-cooperation itself, as an industry team member noted: “Legislation works both ways. It can be interpreted from both the industry’s side and the government’s side. Did they really want a situation where the pricing of

⁵⁰³ Interview, industry executive 3

⁵⁰⁴ Interview, industry executive 11

medicines to the NHS and the profitability of the industry – key elements for both of us – were constantly being put through the courts?”⁵⁰⁵

The prospect of regular litigation was a point that was almost universally referred to by participants and commentators on both sides. Litigation as a central feature of regulation was something that the DOH wanted to avoid. It was a point stressed far more than the direct resource implications of any alternative model of supply side regulation. “It would change the relationship, because we would be for ever in court, and they are a very litigious industry. Always suing. It [the PPRS] avoids the use of regulation, which is good in terms of the regulatory burden and involving us in conflict in the courts with the industry,”⁵⁰⁶ said one senior civil servant.

An industry member noted the same implications of a statutory scheme, and the likely origin of much of the potential litigation: “It would cost them a fortune; everything would take forever, and the ‘L’ word – endless litigation. You know what a litigious lot the Americans are. The first time anything hit the rocks, plane loads of corporate counsel would arrive at Heathrow, and the thing would become a nightmare.”⁵⁰⁷ The ‘legal monopoly’ of government can be seen to be seriously qualified in these concerns about litigation. While government can make law, industry can contest it and the government wished to avoid a regulatory regime that was constantly open to legal challenge.

This lack of technical and administrative capacity, lack of impact assessment and lack of willingness to pursue regulation through the courts are all indicative of the government’s own attitude to its limited regulatory role, at the ‘cultural’ as well as rational level. This was borne out by one senior DTI civil servant who volunteered: “I think really it is a general principle of not wanting to put in place extra burdens and detailed regulations to tie companies down

⁵⁰⁵ Interview, industry executive 11

⁵⁰⁶ Interview, DOH civil servant 5

⁵⁰⁷ Interview, industry executive 13

or up. It is more the general philosophy of not wanting to add to the burdens of business than anything specific about this particular industry.”⁵⁰⁸

4.9.5 Conclusions

The Department of Health did genuinely consider a broad range of options for the regulation of the industry, in light of the emerging criticisms of the PPRS – notably lack of transparency and lack of compliance. Some of these options were far more ‘interventionist’ than the PPRS and would have required both a legal framework and a significant increase in departmental resources in order to administer them. The options considered, including the therapeutic option and RPI-X, were thought either inapplicable or too complex.

These more interventionist options were rejected for several key reasons, including the unwillingness of the Department to devote resources to the regulatory framework that would not yield sufficient gains to warrant this extra effort. It was not thought that a legally binding system would deliver the broad range of policy objectives. In part the Department did not believe that it was easily able to administer alternatives, in part because the ‘base data’ necessary to implement a strict regulatory regime were not readily available. The ‘exchange relationship’ of the two parties in the PPRS policy community was thought to yield regulatory goods that could not be achieved easily by other means. The benefits of co-operation were accepted and the prospect of constant litigation was regarded with trepidation.

In addition there was a genuine recognition in the DOH (and a strong assertion in DTI) that industry had a ‘*right*’ to operate as freely as possible. There was no desire *in itself* to seek to control commercial activity more than necessary to achieve a fair deal in procurement. This was reinforced by the pragmatic recognition of industry’s *ability* to operate freely in a global context, and to invest elsewhere.

⁵⁰⁸ Interview, DOH civil servant 5

Having each used their ultimate bargaining resources – legislation and the threat of disinvestment – the core value of the government-industry relationship, co-operation, was re-emphasised.

4.10 The role of Parliament

Assumption 4: Parliament has a peripheral role in this policy field and does not constitute a veto point or external influence on the policy community.

Hypothesis 4: Parliament will not be an influential actor in determining policy outcomes, which in turn will be reflected in the limited direct attention to it by both government and industry.

The pharmaceutical industry's relationship with Parliament, and MPs in particular, has been a long-standing concern of the ABPI and this remained the case in 1999.⁵⁰⁹ One industry spokesperson commented that on balance, "the level of understanding of pharmaceutical issues in both Houses of Parliament is not as high as one might hope."⁵¹⁰ Industry lobbying is seen as centred on the executive branch: "The pharmaceutical industry are a big lobby machine and they lobby themselves but they also lobby through us," said one senior civil servant in the Department of Health.⁵¹¹ The industry association's own annual report notes "regular discussion at the most senior level."⁵¹² And of all the issues that might concern Parliament the PPRS is the most obscure and the least likely to generate direct constituency concerns, except for those MPs with industrial interests in their constituencies.

4.10.1 Legislation

The 1999 PPRS was distinct from its predecessors because at the time of its negotiation the passage of the Health Bill through Parliament meant that a statutory alternative to the voluntary scheme would now exist as an

⁵⁰⁹ ABPI Annual Reviews consistently showed Labour MPs in particular had unfavourable views of the industry. The view that industry was 'profit orientated' was shared by over 60% of all MPs, as reported in the 1995 ABPI Annual Review.

⁵¹⁰ Interview, industry executive 13

⁵¹¹ Interview, DOH civil servant 15

⁵¹² ABPI (1999a) p.9

enforcement mechanism. Because its detailing in the press suggested that the statutory scheme was a replacement of the PPRS, rather than as the 'back-up' scheme that the government later claimed, Parliament was thrust uncharacteristically centre stage in the politics of the PPRS.

The Health Bill, which began its passage through Parliament part way through the PPRS negotiations, meant that Parliament now had a central role but the clauses in the Bill were officially separate from the negotiations. The renegotiation of the voluntary scheme took place in the normal way, without any explicit role for Parliament.

4.10.2 Parliament and the negotiating agenda

The non-compliance with the 1993 scheme became a major issue because of the press attention. It had been raised in Parliament on several occasions. For example in the House of Lords, Baroness Lockwood had asked the government "What arrangements they will make to ensure compliance with the renegotiated Pharmaceutical Price Regulation Scheme."⁵¹³ The Parliamentary Under-Secretary of State in the Department of Health, Baroness Hayman acknowledged regret at the "increasing non-compliance by a limited number of companies with the current voluntary scheme."⁵¹⁴

Non-compliance had created a political impetus among both ministers and civil servants to seek changes in the new scheme to counter the possibility of it reoccurring. Specifically, the passing of manufacturing and marketing licenses by some large companies to small firms which then raised prices had gained significant attention and was brought up in Parliament.⁵¹⁵ The Secretary of State for Health, Frank Dobson, had replied on 25 November 1998 to a question about compliance: "In these circumstances the Government have concluded that to ensure full compliance with a new

⁵¹³ Hansard. House of Lords Debates, 26 November 1998

⁵¹⁴ Hansard. House of Lords Debates, 26 November 1998

⁵¹⁵ See, for example, *Commons Written Answers*, 26 October 1998; 25 November 1998

agreement it will be necessary to take reserve powers in the forthcoming NHS Bill.”⁵¹⁶

There was a degree of industry scepticism about the non-compliance issue. Some people believed the government had blown it out of proportion in order to precipitate a crisis. One industry figure described the ‘crisis’ thus: “One or two companies, which were not part of ABPI, had acquired products from ABPI companies that were very low price and they put the price up to a reasonable level.”⁵¹⁷ But many in industry believed that the substance of the crisis was not about cash but about perception – principally the way it had played out in Parliament. Industry sources noted the reaction of politicians to the parliamentary questioning: “Officials were embarrassed for their ministers by the lack of compliance and ministers similarly were embarrassed at Question Time and they would go back and kick the civil servants because they’d been made to feel embarrassed in the House.”⁵¹⁸ Parliament’s outspokenness previously on transparency suggested that any future examination of the scheme in committee would focus on deliberate non-compliance that was known in the public arena.

Alongside the Transparency Directive from Brussels, Parliament had been key to highlighting the issue of transparency, pointing to its opaque operation. The department had taken on board criticisms of the scheme by the Health Select Committee in 1993/4 (immediately following the previous scheme). The committee had also criticised the institutional structures within the Department of Health for dealing with pharmaceuticals and the industry, in particular the placing of the PPRS and sponsorship functions within the same branch. “They thought putting them in one person in one branch was far too close a relationship,” said a DOH civil servant.⁵¹⁹ This had inspired the splitting of the functions into two branches, which had now taken place.

⁵¹⁶ Hansard. Commons Written Answers, 25 November 1998

⁵¹⁷ Interview, industry executive 6

⁵¹⁸ Interview, industry executive 13

⁵¹⁹ Interview, DOH civil servant 4

Role of the Health Select Committee

The Health Select Committee is charged with scrutinising the work of government in the field of health by examining the “expenditure, administration and policy” of the Department of Health.⁵²⁰ It had produced a report in 1993-94 that focused on the NHS drug budget and which as part of this has analysed the working of the PPRS. While praising the scheme in many respects the report also criticised some aspects of it. The committee’s most strenuous criticism was over a lack of transparency in the scheme and its incomprehensibility to both public and Parliament:

“... evidence presented to us makes clear that there is a widespread desire for greater transparency in the scheme’s operation. We share that desire. The regulation of the price of medicines is a central part of the Department of Health’s management of the NHS’s £3.3 billion drugs budget, and yet it is not open to public scrutiny. This engenders an unhealthy climate of suspicion and misunderstanding amongst those who seek to understand the Scheme, and undermines the principle of public accountability ... We therefore recommend that the Department of Health introduce greater transparency into the Scheme: in particular, by means of publishing a report on the PPRS ... This report should be laid by the Secretary of State before Parliament.”⁵²¹

The result was a Report to Parliament in 1996, followed by a second in 1997 and a third in 1999. There have been reports in both 2000 and 2001, since the current scheme was signed. The 1999 report notes the lack of transparency in the PPRS prior to 1999.⁵²²

The work of the Committee and the Reports to Parliament were the background to the process of arriving at a departmental position for the 1998/9 negotiations. As a senior civil servant noted, “We faced a need to account to Parliament as a result of the Health Committee’s critique of the lack of transparency in the Scheme and we had to explain to Parliament that

⁵²⁰ See website: www.parliament.uk/commons/selcom/ctteesys.htm

⁵²¹ House of Commons Papers (1994), paragraphs 87-88.

⁵²² PPRS Report to Parliament 1999, paragraph 4.2

we were two years behind on the case work.”⁵²³ Important modifications to the scheme in 1999 were made as a result.

The Reports to Parliament

In order to make more clear how the scheme operated, the Department of Health prepared Reports to Parliament, beginning in 1996. These ranged over issues of technicality, operation, and compliance. On the latter, for example, the 1996 Report noted, “At 30 April 1996 action has not been completed on 19 AFRs from 1993 (of a total of 50 for that year); and of the 50 AFRs due for 1994 (the majority of which should have been received in the summer of 1995) 36 had been received and action completed on 11.”⁵²⁴

The reports highlighted (from the Department of Health itself) both the lack of efficiency of the PPRS Branch in completing its workload and of companies in submitting required data (their AFRs). Hence the reports answered, to some degree, Parliament’s call for greater transparency but in so doing they exposed some of the inefficiencies of the scheme, giving rise to further criticism. Making the operation of the scheme more efficient became a further aim of the government in the 1999 negotiations.

The transparency of the scheme was a subject that could be dealt with at renegotiation, and was taken on board by the officials at the Department. “We decided that the new PPRS, regardless of the figures, should be more transparent within the confines of respecting companies’ confidential data,” said a senior civil servant.⁵²⁵ Another senior civil servant noted the sense of urgency in organising the report. “Part of my instructions when I arrived were to get the Report to Parliament in place so that we could not be accused of running a gangster scheme that nobody could understand,” he said.⁵²⁶

⁵²³ Interview, DOH civil servant 10

⁵²⁴ Department of Health (1996), paragraph 3.2.4

⁵²⁵ Interview, DOH civil servant 5

⁵²⁶ Interview, DOH civil servant 10

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Non-compliance had been highlighted in Parliament and had become a minor political hot potato; lack of transparency had been a long standing parliamentary criticism of the scheme; and the efficiency of case work had become an issue after the Department's own Reports to Parliament had revealed just how behind with its work the Department had become, in part because companies were not taking their submission dates sufficiently seriously. These reports, in turn, were inspired by the select committee's criticism of the scheme.

4.10.3 Parliament and the negotiation process

In so far as the Health Bill was a mechanism of pressure for the DOH in the negotiations, Parliament's role was enhanced through the linking of the legislation to the negotiations (see Chapter 5). They were linked too because of what the government intended to achieve: one industry figure said that industry representatives in the negotiations suspected some sort of legislative approach from government as soon as they had seen the 'Neg 9' document. "What was in Neg 9 clearly could not be agreed voluntarily. We knew it would have to have a legal basis, so the clauses in the Health Bill didn't come as a complete shock to us."⁵²⁷

Parliamentarians, however, were not knowledgeable about the scheme and not easily able to make judgements about it. Industry's attempts to influence MPs and peers would generally require a great deal of information and explanation. "The PPRS is a pretty abstruse subject for most Parliamentarians. There are a lot of people who take a personal interest in health issues but the PPRS lies at the periphery of most people's radar screens as regards the health service and it is very technical and very complicated," said one Parliamentarian who was active in the passage of the Health Bill.⁵²⁸ Any debate about the PPRS – which would only come about as

⁵²⁷ Interview, industry executive 6

⁵²⁸ Interview, Parliamentarian 18

part of debates on the Health Bill, therefore seemed to suggest a role, and certainly an opportunity, for industry to lobby.

4.10.4 Parliament and industry lobbying

Industry did possess established parliamentary contacts where it could begin this process. Political advice and the parliamentary contacts that underpin it exist at three levels, in relation to industry organisation: through the trade association, the ABPI; through the broadly national 'groups' of companies, APG, BPG and the European group; and through individual companies. Advisers at all these levels worked to foster and utilise parliamentary contacts during the PPRS and the Health Bill debates.⁵²⁹ It is at the industry level – the ABPI – that the most important contacts for the PPRS exist and where most lobbying in 1999 took place. "Individual companies do employ lobbyists but the most important contact is through the ABPI. It's the Association that was important for the PPRS and the Bill," said a member of the Lords.⁵³⁰

The All-Party Parliamentary Group (APPG) provides an institutional link for the industry to MPs. "We have a constant dialogue with it," according to one industry source.⁵³¹ Interested MPs include those with constituency interests (the industry being an important high value employer) as well as other MPs and Lords whose interests are as part of the medical profession; and others who are interested from the perspective of particular patient groups. The APPG is an interest group and has no formal role in any legislation or regulation but members of the group had good communications with ministers, and communicated industry concerns to them. One member of the group said that he had regular meetings with the Secretary of State, and discussed the PPRS with him during 1999.⁵³² He noted how, prior to the start of the negotiations, the "Secretary of State wanted to meet industry figures,

⁵²⁹ Interview, Parliamentarian 12

⁵³⁰ Interview, Parliamentarian 20

⁵³¹ Interview, industry executive 11

⁵³² Interview, Parliamentarian 12

without civil servants present,” and a dinner meeting was duly arranged through the APPG contact.⁵³³

Parliamentary contacts were utilised more generally during the PPRS negotiations as an additional source of pressure on government, i.e. to direct pressure to the Department of Health regarding broader PPRS issues. “During the negotiations, individual companies certainly spoke to MPs about the PPRS,” an industry source commented.⁵³⁴

A senior politician also noted the use of parliamentary contacts: “The drugs industry wrote to quite a few people in the course of the negotiations in an effort to weaken our stance and strengthen their own hand.”⁵³⁵ Government also felt the need to explain to MPs their position: “We were able to say to the MPs, well these are the things we’re bearing in mind – we are trying to save money for the NHS but at the same time we’re trying to come up with a scheme which is more favourable to the research-based pharmaceutical industry and that’s what you want because you’ve got a great big laboratory in your area,” he added. Thus the economic clout of industry was a major factor in determining the activity of MPs owing to their constituency interests.

4.10.5 Conclusions

Parliament was certainly active during the negotiations, largely owing to the passage of the Health Bill. But it had also contributed significant input in the years leading up to the negotiations and played a major role in defining the government’s aims and direction in reform of the scheme. Transparency had become a central issue for the Department because of the Health Select Committee’s comments and the PPRS Reports to Parliament in 1996 and 1997. Compliance had become a political issue as well because of parliamentary questioning of ministers and the back-log of case work had

⁵³³ Interview, Parliamentarian 12

⁵³⁴ Interview, industry executive 3

⁵³⁵ Interview, Government minister 7

been highlighted by the Reports to Parliament. All of these issues formed primary parts of the Department's agenda for the 1999 PPRS negotiations.

The extent of involvement of Parliament in setting the agenda for reform is significant and its role here cannot be discounted or dismissed as 'peripheral'. However, the process of the negotiations in 1999 was not influenced directly from Parliament. Parliament, and in particular Parliamentarians, cannot be considered to have exercised a veto over proceedings in the PPRS. As in 1993 (see Chapter 6), Parliament was an arena through which the government and the industry communicated with each other during the process of the negotiations, and, while important, was a proxy for their relationship.

4.11 Role of the Department of Health

Assumption 5: The siting of an industrial policy function within the Department of Health gives DOH authority and competence to act and highlights the government's industrial policy aims, enabling a co-operative regime.

Hypothesis 5: The dual role of the DOH will prove decisive in defining policy and maintaining the co-operative regime by counteracting the procurement focus of the Treasury.

The 1999 PPRS negotiations were significant for the organisation of the executive because all three departments had made their role in the scheme a priority. The Treasury had initially insisted on a renegotiation; the Department of Health had undertaken an unprecedented examination of price regulation elsewhere and was seeking to create some sort of enforcement mechanism for the voluntary scheme; the DTI now had a specific responsibility for the Biotechnology industry, which was intimately connected commercially with the pharmaceutical sector, and in which Britain had become the leading European nation.

4.11.1 Objectives of the Department of Health

The sponsorship role was seen by officials in the DOH as an essential counterbalance to the attitudes of the broader department and health service: "Putting it rather crudely, there are quite a lot of people in the NHS who regard the industry in a very negative way – who see it almost as the enemy – and there are some elements of that within the Department."⁵³⁶ Because of the sponsorship function, the role of the head of division cannot be underestimated here. His task is to fuse the procurement and sponsorship

⁵³⁶ Interview, DOH civil servant 4

roles together in the PPRS. Indeed another senior civil servant put the effect on the DOH of the sponsorship role, executed through the Industry Division, in starker terms:

“There are 5½ thousand people working in the Department of Health. All of them bar one want to screw the pharmaceutical industry as hard as they possibly can. One person who’s got to be aware of something a bit wider than that is the Head of the Division that’s negotiating the PPRS.”⁵³⁷

Aside from influencing policy, sources in the Treasury saw the sponsorship function as bureaucratically more efficient: “If the DTI was to hold the sponsorship role for the industry you’d replicate that expertise. It’s a long standing policy that sponsorship rests with the Department that has got particular expertise.”⁵³⁸

A point made by both Treasury and the DOH was that the two aims of policy have to be reconciled at some point in the bureaucratic structure, it’s simply a case of choosing where that is. The overt conflict of interest had been addressed by the changes made within the Department of Health, ensuring the same individual was not responsible for PPRS and sponsorship as had previously been the case. A Treasury civil servant noted, “Government as a whole does have a set of objectives, in relation to different industries, that conflict. Putting the different objectives in different departments is not necessarily the easiest way to resolve them.”⁵³⁹ And a department of health civil servant concurred: “If the sponsorship role was put in DTI, we could imagine a fairly violent clash between the two interests. The close proximity makes for a more sensible and amicable resolution of any tensions that might exist between those two roles,” said a senior DOH civil servant.⁵⁴⁰

⁵³⁷ Interview, DOH civil servant 10

⁵³⁸ Interview, Treasury civil servant 25

⁵³⁹ Interview, Treasury civil servant 24

⁵⁴⁰ Interview, DOH civil servant 4

4.11.2 The approach to the negotiations

For the purpose of the 1999 negotiations, it was the task of new ministers to indicate the broad balance that was to be struck between the procurement and sponsorship roles of the DOH, and one senior civil servant was in no doubt that the emphasis was being shifted: “In the Health Department it was made pretty clear from the Summer of '97 onwards that what the Department was in business for [in the PPRS] was to get the best deal for the Health Service.”⁵⁴¹ Furthermore, “The requirement in the PPRS negotiations to have an eye to the balance between the NHS need for decent prices and the interests of the industry who need to be able to invest in R&D, is a central part of PPRS anyway,” said a DOH civil servant.⁵⁴² The pressure in the Department for a good deal for the NHS and the nature of the PPRS itself suggest that the overt sponsorship function may not have influenced the negotiations greatly.

This was not the view of the main actors. A senior politician noted that the sponsorship role did influence the approach to and outcome of the negotiations: “It made it easier to get a balance of advantage,” he said. “I think it would have weakened our position and therefore the government’s position if it [the DOH] weren’t the sponsoring department responsible for the industry.”⁵⁴³ In other words, the particular shape of bureaucratic organisation was a central factor in the ability of government to balance its conflicting policy aims. The PPRS, as a fusion of the health and industrial policy aims can still be shifted in its focus and the sponsorship role of the negotiating department was influential.

4.11.3 Industry’s view of the sponsorship role

Industry sources universally believed that the sponsorship role had been positive in 1999, again for the balance and breadth that it brought to the

⁵⁴¹ Interview, DOH civil servant 10

⁵⁴² Interview, DOH civil servant 4

⁵⁴³ Interview, Government minister 7

Department's approach to them. Some fear was expressed that the DOH should ever have a purely procurement perspective.

"At the moment it [the DOH] can balance the need to get a decent price on the products we have *today* with the need to make sure there's a stream of products coming forward for the *future*. Otherwise the Department of the Health would increasingly be forced towards the Treasury position, where it has no interest in our industry except buying the products we have *today* as cheaply as it can."⁵⁴⁴

"The fact that the sponsoring department has to bear the three parameters in mind – innovation, export, and costs – forces them into a more balanced view."⁵⁴⁵

"If the Department were simply the purchaser, it would probably take a very, very enlightened person within the Department to accept that there was the need for the R&D investment there is in our industry."⁵⁴⁶

The latter noted that the sponsorship role helps to emulate the relationships that occur in the private sector between many industries and their suppliers. "If you look outside our industry, all sorts of companies have genuine long-term relationships with their suppliers, and very often work with their suppliers to develop new ideas and new products. That doesn't normally happen with government but having the sponsorship role in the same place helps to overcome the absence of that aspect of a purely private sector relationship."⁵⁴⁷

4.11.4 The role of the DTI: Shuttle diplomacy

The DTI was also active prior to and during the PPRS negotiations. Like the Treasury, an important role played by the DTI was to influence the initial negotiating position of the DOH, to which its input was central. "Our

⁵⁴⁴ Interview, industry executive 13

⁵⁴⁵ Interview, industry executive 6

⁵⁴⁶ Interview, industry executive 3

Secretary of State wrote to their Secretary of State and raised a few general points of principle about what he hoped would be achieved in the negotiations, stressing things that were particularly important in terms of DTI policies on competitiveness and so on,” said a DTI civil servant.⁵⁴⁸ The DTI approach prior to the start of negotiations was in turn influenced by industry lobbying: “There was quite a lot of open sharing of information. The industry people talked to us and they told us which issues were most important to them and those were reflected in our Secretary of State’s letter.”

Once the negotiating process began, the DTI performed an important communications function. The negotiations began with deadlock at the publication of the DOH’s position paper, Neg 9, which was presented as ‘government-wide’. “We were told that the opening negotiating position was agreed across government before they started,” noted a senior industry negotiator, “so when we saw it, we went straight to the DTI to ask for clarity on what they’d sent us.”⁵⁴⁹

This ‘phoney war’ situation was repaired largely by DTI clarification. “DTI subsequently confirmed to us that they had seen the opening position, but they’d been assured that that was a fully negotiable opening position,” the industry figure added. Following DTI clarification of the DOH’s position, industry indicated its willingness to talk: “The top guys – Richard Sykes, Jan Leschly – passed the message that they were prepared to negotiate.”⁵⁵⁰ DTI could clarify the ‘position’ presented by DOH to whatever extent was necessary to get the negotiations moving. They therefore openly suggested that the position was indeed negotiable.

Some voices in the Department of Health suggested that DTI’s representation of industry’s complaints to the DOH was more political than real. A senior DOH politician noted: “We warned DTI that industry would start making representation to them and to the Prime Minister and said that both of

⁵⁴⁷ Interview, industry executive 3

⁵⁴⁸ Interview, DTI civil servant 1

⁵⁴⁹ Interview, industry executive 9

them should ignore them, and that broadly speaking is what they did. The DTI went through the motions of telling us what they were saying and we went through the motions of telling them, but they were doing exactly what we said we they would.”⁵⁵¹

Representatives from DTI perceived themselves as playing a more real role, as did industry figures and some officials from the DOH. A sort of ‘go-between’ role emerged as the DTI became ‘recruited’ by both sides to kick start the negotiations and put some perspective on each side’s opening position, for the benefit of the other:

“DTI said that the agreement they’d come to was that DOH was the lead negotiating body and that other Departments had agreed that it was right for them to come in hard – they fully expected us to come in hard. They [DTI] expected that there’d be a rapprochement between the two negotiating positions and that DTI was not going to intervene before we’d started negotiating seriously, but would remain available when we got down to the last one or two points, if we couldn’t close the gap.”⁵⁵²

4.11.5 Industry and the role of DTI

There was a general view among industry representatives that the DTI was genuinely helpful: “DTI’s backing was important. We kept in contact to make sure that when any discussions were taking place with Dobson or Hayman, DTI knew the implications and could say ‘stop’.”⁵⁵³

DTI officials represented their role as a go-between: “I think gradually during the process we were taken into the confidence of both sides about how far each would go. From time to time we would cajole one side or the other to be a bit more flexible on one point or another,” noted a senior DTI civil

⁵⁵⁰ Interview, industry executive 9

⁵⁵¹ Interview, Government minister 7

⁵⁵² Interview, industry executive 9

⁵⁵³ Interview, industry executive 6

servant.⁵⁵⁴ DTI officials were also clear that they had cards to play had negotiations not progressed well. “We would have been able to get our Secretary of State to write to Frank Dobson. Having that sort of external input can sometimes have added strength rather than the point coming up from within the same organisation,” said a DTI official.⁵⁵⁵

The role of the DTI in the negotiations – at least in terms of process – was significant. They constituted a vital link between the DOH and industry at a key time. There is no evidence to suggest that this role would have been any greater had DTI rather than the DOH been responsible for formal sponsorship; and yet any gap that they would have needed to bridge would doubtless have been wider.

4.11.6 The role of the Treasury

The negotiation of the PPRS in 1999 was heavily influenced by the Treasury from the beginning. The Treasury had been instrumental in initiating a new scheme: “The Treasury were not at all satisfied with the ‘93 settlement and were determined there would be a renegotiation at the first possible point,” said a senior DOH civil servant.⁵⁵⁶

All three departments were involved in arriving at the opening negotiating position of the government and the Treasury input was from a senior level. “There was formal discussion of what the negotiating position should be at ministerial level – the Chief Secretary for us – and there was also an exchange of letters.”⁵⁵⁷ Furthermore, the analysis of alternatives in which the Treasury was involved occupied a significant amount of the health team’s time over the previous year: “The PPRS was a big and fairly sustained piece of activity for us,” noted a Treasury official.⁵⁵⁸

⁵⁵⁴ Interview, DTI civil servant 1

⁵⁵⁵ Interview, DTI civil servant 1

⁵⁵⁶ Interview, DOH civil servant 10

⁵⁵⁷ Interview, Treasury civil servant 25

⁵⁵⁸ Interview, Treasury civil servant 24

The Treasury initiated the demand for a quantitative reduction in expenditure for the forthcoming financial year – the outcome of which was the 4.5% price cut, which had begun, at Treasury’s insistence, at 6%.⁵⁵⁹ “The Treasury had a particular interest [in the PPRS] at that time. We were looking for savings on the drugs bill as a result of the negotiations.”⁵⁶⁰

The government’s opening position in the negotiations (Neg 9) was attributed by industry to the Treasury’s influence and the presence of the Treasury was felt in their discussions of it with the Department of Health. “We didn’t think that Dobson was in a position to go back to the Treasury and negotiate an agreement with them, even if he thought our case was reasonable. We felt Treasury had told him what they wanted and it was his job to negotiate it.”⁵⁶¹

Moreover, a senior politician volunteered that the overall price cut was not an outcome of the negotiation. “We decided in advance what sort of reduction in overall cost to the NHS per year we were looking for,” he said.⁵⁶² And Treasury officials agreed that “the actual numbers were informed by the outcome of the comprehensive spending review of 1998.”⁵⁶³ As the DOH negotiates on behalf of the whole government, the Treasury had some initial input and final veto over any agreement.

Not all opinion saw the Treasury as solely focused on short-term cost calculations. Treasury officials themselves did claim a broad understanding of the industry and a concern for more than short-term cost savings: if the value of medicines could be illustrated in terms of the broader NHS budget then this would be taken into account.⁵⁶⁴ One Parliamentarian agreed: “Treasury sees the industry as an earner as well as an expense because of its contribution to the balance of payments,” he said.⁵⁶⁵

⁵⁵⁹ Source close to the Treasury

⁵⁶⁰ Interview, Treasury civil servant 25

⁵⁶¹ Interview, industry executive 6

⁵⁶² Interview, Government minister 7

⁵⁶³ Interview, Treasury civil servant 24

⁵⁶⁴ Interview, Treasury civil servant 24

⁵⁶⁵ Interview, Parliamentarian 12

Overall, the Treasury's influence can be seen as significant – initiating the renegotiation and defining the area of the overall cost savings in the short-term.

4.11.7 Conclusions

One feature of the 1999 negotiations is the active part played by the DTI. This substantial role was not precluded by its lack of a formal sponsorship function. Furthermore, the DOH's position was consistently informed by its obligation to consider the industry from a commercial perspective as well as a procurement one.

Meanwhile, the Treasury's influence was characteristically very significant and there is no indication that a DTI armed with a sponsorship function would have shifted the Treasury's position regarding the balance of health (procurement) and industrial policy. The head of the industry division in the DOH was critical to the achievement of a balance of policy (which is his function) and the reduction of the Treasury's initial objectives for expenditure savings. The role of the DOH in sponsorship was a central factor in the maintenance of the co-operative policy community, given its initial breakdown following publication of the government's Neg 9 document.

Chapter 5

The passage of the Health Bill 1999

- 5.1 Aims of the Health Bill
- 5.2 Passage of the Bill through Parliament
- 5.3 The pharmaceuticals market
- 5.4 The global context
- 5.5 The co-operative state
- 5.6 The role of Parliament
- 5.7 Role of the Department of Health

The passage of the Health Bill in 1999 appeared to mark a crisis in the relationship between government and industry. Attached to the Bill, which otherwise sought substantial reform of the NHS, were a few clauses relating to the purchase of medicines and the regulation of the pharmaceutical industry with regard to medicine prices and company profits: in short, clauses that referred explicitly to the PPRS and its operation.

This appeared to represent a 'doomsday scenario' for the PPRS policy community, in which the ultimate 'resource' of the government – its legal power – was pitted against the commercial power of industry. The government seemingly aimed to use its legal authority to undermine the very nature of the policy community and re-orientate the whole regulatory framework to a statutory one. The passage of the Bill would demonstrate how far the government was prepared to pursue this strategy and whether industry would seek to respond with its own considerable bargaining resources.

5.1 Aims of the Health Bill

The clauses in the Bill were intended as the government's means of enforcing the PPRS, in reaction to the recent non-compliance by some companies. The Bill, if passed into law, would set the PPRS within an enforceable statutory framework that would enable the Secretary of State to veto price increases with the force of law and impose the terms of the PPRS.⁵⁶⁶

The clauses sought to do two different things, both to serve this same purpose:

⁵⁶⁶ *Scrip* No 2391, 27 November 1998, p.5.

- First, they sought to introduce legislative provisions with regard to the PPRS – in the terms of the Bill, “Powers relating to voluntary schemes”.⁵⁶⁷ These would give powers to the Secretary of State to enforce the PPRS where it was not adhered to by a signatory. They appeared to represent the replacement of the PPRS as a genuinely voluntary arrangement with some sort of hybrid scheme – part voluntary and part statutory. These powers would also enable the direct imposition of price controls on products if the Secretary of State saw fit.
- Second, other clauses were aimed at making provision for the Secretary of State to introduce an entirely separate statutory price regulation scheme that could be imposed on pharmaceutical companies where the Secretary of State wished – titled “Statutory schemes” in the Bill.

The aim of both these groups of clauses was as an enforcement mechanism for the PPRS, which was now, simultaneously, being re-negotiated between the Department of Health and the ABPI.

The Health Bill therefore represented something quite special in the history of government-industry relations in the pharmaceutical sector. It undermined the key regulatory goods for industry, which were attributable to the co-operative regime between government and industry, and it raised questions about the role of the DOH as the sponsoring department. Fundamentally, it seemed as though the desire of successive governments to avoid statutory regulation did not hold for the newly elected Labour government and it appeared to accord Parliament an unprecedented role in the framing of pharmaceutical price regulation.

The Health Bill, in other words, had important implications for the assumptions about why the PPRS had survived for so long as a co-operative regime: the perceived unwillingness of government to administer detailed and legalistic regulations; the peripheral role of Parliament in the regulatory

⁵⁶⁷ House of Lords Bill number 15, 1998-9.

framework; the desire to maintain the structure of the British pharmaceuticals market and the regulatory goods that the PPRS underpinned within it; and the legitimacy – from different points of view – of the DOH's dual role.

The clauses in the Bill were initially press released, ahead of the Bill's publication, as a replacement of the voluntary scheme and contributed significantly to a deterioration in the relationship between government and industry towards the beginning of the PPRS negotiations.⁵⁶⁸

5.1.1 What the Bill sought to do: Summary

The detail of the Bill aimed to give the Secretary of State the power to:⁵⁶⁹

- Enforce the PPRS by giving legal force to some of the main principles of the scheme, including the prohibition on price rises that had been implemented without the consent of the Secretary of State.
- Control prices of medicines directly (alongside any PPRS), extending the Secretary of State's powers from price capping to price setting.
- Provide a regulatory framework for any company to whom the PPRS does not apply.
- Introduce a statutory scheme in place of the PPRS for any company, at his discretion.

5.1.2 The Heath Bill and the PPRS negotiations

The simultaneity of the Bill and the PPRS negotiations meant that the events in one arena shaped those in the other. They were also linked through personnel. A sub-group of negotiating members was assigned to work on amendments to the initial draft of the Bill.⁵⁷⁰ A group of three senior industry people studied the Bill in some detail and “suggested improvements to government” directly, the spirit of which were largely incorporated into the

⁵⁶⁸ For example, see *The Guardian*, 21 September 1998; *The Times*, 21 September 1998; *The Financial Times*, 23 September 1998.

⁵⁶⁹ House of Lords Bill number 15, 1998-9.

⁵⁷⁰ Interview, industry executive 13; Interview, DOH civil servant 5

final draft.⁵⁷¹ The people assigned to discuss the Bill were also involved directly in the PPRS negotiations. “What is formal and what is informal? Industry people were centrally involved in the amendment process and the link between the negotiations and the Bill was overt,” said one member of the Lords.⁵⁷² The Bill was changed in ways that were important for industry.

5.2 Passage of the Bill through Parliament

There were some key issues that dominated discussion of the Bill in the Lords and in Commons Committee. The issue raised most insistently concerned the apparent ability, according to the Bill, of the Secretary of State to impose a statutory scheme on the basis of completely subjective judgements. The Bill did not specify that there had to be a contravention of the PPRS for the statutory provisions to be imposed and this proved to be a principal sticking point. As a senior civil servant conceded, “There were several changes, including a clause that means that if a company has signed up to the voluntary scheme it cannot have a statutory price control measure or profit control measure imposed on it.”⁵⁷³ This change was amendment No.163, moved by Earl Howe, relating to Clauses 27 (control of prices) and 28 (statutory scheme). Earl Howe described these clauses, which stated that the Secretary of State can impose the statutory scheme, as “doing away with the voluntary nature of the PPRS by taking on powers to fix the prices of drugs as they choose.”⁵⁷⁴

Although Amendment 163 was withdrawn, there were concessions incorporated in the final draft of the Bill that ensured that discussion with the company concerned was required before any such decision could be taken.⁵⁷⁵ Furthermore, the company had a right to “make representations”

⁵⁷¹ Interview, industry executive 13

⁵⁷² Interview, Parliamentarian 20

⁵⁷³ Interview, DOH civil servant 5

⁵⁷⁴ *Hansard*, House of Lords, 1 March 1999. Earl Howe, Health Bill debate.

⁵⁷⁵ See The Health Act 1999, Sections 33 to 38.

about any points referred to by the Secretary of State.⁵⁷⁶ The Bill was altered to include provisions for discussion with the ABPI, including on the setting up of any statutory scheme.⁵⁷⁷

This issue of what the terms were to be under which the Secretary of State could impose the statutory scheme and of the required consultation formed a significant part of the debate in Standing Committee in the Commons. Opposition MPs drew attention to the scale of the powers being conferred on the Secretary of State to make arbitrary decisions regarding individual companies. Again, proposed amendments were withdrawn here on the basis that the minister would go away and consult with industry on the issues it raised. Such consultation was in any case taking place through the group of industry people assigned to look at the Bill.

The concurrence of the PPRS negotiations led to accusations of an ulterior purpose of the clauses in the Bill, namely to increase the government's bargaining power in the negotiations on the voluntary PPRS.⁵⁷⁸ Certainly, the interlinking of the two processes did have an effect on the negotiations and many involved in both those and in the passage of the Bill, from both government and industry, saw them as interrelated. The approach of the opposition therefore became not so much to promote the industry cause as to be extremely sceptical about the secondary powers being taken by government, and this was their focus in much of the debate.

5.2.1 Amendments to the Bill

Amendments, in both Lords and Commons, centred on several specific issues:

- The terms on which the Secretary of State could impose a statutory scheme on a company;

⁵⁷⁶ *Scrip* No 2453, 9 July 1999, p.3.

⁵⁷⁷ See *Scrip* No 2410, 24 February 1999, p.2.

⁵⁷⁸ The second motive was suggested by several interviewees.

- The notice that he ought to give when doing so;
- The right of appeal or representation by companies when this situation arose;
- The requirement to consult with industry in several areas where the Secretary of State was being given new powers, including secondary legislation;
- That there should be an overt limiting of the statutory scheme to companies who are not signatories to the PPRS;
- Limiting direct price setting powers to non-members of the PPRS;
- That the costs of R&D should be taken into account;
- That some definitions were very loose, including that of an “NHS medicine”; “fair and reasonable” and “reasonable in all the circumstances”, etc.
- The legal nature of powers to regulate bestowed on the Secretary of State and Henry VIII clauses.⁵⁷⁹

Many of these concerns did work their way into changes to the Bill and some amendments that industry considered essential to their broader relationship with government were made. The initial aims of the Bill largely worked their way through to the legislation, with the modifications noted above. There were six sections.⁵⁸⁰

1. Section 33, “Powers relating to voluntary schemes.” This allows the Secretary of State to judge that “acts or omissions” by a company mean the purposes of the PPRS are not being fulfilled, and a procedure to expel the company from the scheme can be undertaken. This section also gives one part of the PPRS a legal footing, namely the prohibition by the Secretary of State of price increases on health service medicines.
2. Section 34, “Power to control prices.” This section allows the setting of prices by the Secretary of State for products from companies that are not

⁵⁷⁹ Henry VIII clauses empower a Secretary of State to use secondary legislation to amend or repeal primary legislation.

⁵⁸⁰ The Health Act 1999, Sections 33 to 38.

part of the PPRS. (Statutory Instrument 2000/123 was introduced to enforce a 4.5% across-the-board price cut on NHS business for companies not part of the PPRS, principally under the auspices of the clauses in this section.)

3. Section 35, "Statutory schemes." This allows the Secretary of State to impose a statutory price regulation scheme on any company that is not signed up to (or who has been expelled from) the PPRS.
4. Section 36, "Statutory schemes: supplementary." Gives a broader range of possibilities to the content of any statutory scheme, allowing any actions that will achieve the purposes of such a scheme.
5. Section 37, "Enforcement." Outlines actions and penalties that may be implemented in order to enforce regulations and any statutory scheme.
6. Section 38, "Controls: supplementary." Specifies aspects of previous clauses; most importantly this section repeals parts of the 1977 National Health Service Act in relation to health service medicines.

5.3 The pharmaceuticals market

Assumption 1: The market for pharmaceuticals in the UK underpins the PPRS by enabling sufficient rewards for both government and industry within the scheme, and enabling policy aims to be balanced.

Hypothesis 1: Actors on both sides will seek to maintain the current structure of the pharmaceuticals market, and hence the regulatory goods it yields, and will not pursue strategies that would undermine it.

The Health Bill raised important questions regarding the market for pharmaceuticals. Most basic was that it seemed no longer to provide a positive structural context in which to conduct 'light-touch', voluntary regulation. It also appeared that the government may be prepared to create an ambiguous situation regarding the key regulatory goods of industry in the PPRS – free pricing and a quick launch.

5.3.1 Industry's regulatory goods

One of the benefits for industry within the PPRS was the relatively high initial price they could charge for new products (which would then be gradually eroded by inflation) and, crucially, the ability to get to market immediately following regulatory approval. The powers that the Bill aimed to introduce would allow the Secretary of State to set prices directly, seemingly making nonsense of the voluntary scheme by removing the assurance of this key aspect. However, a major benefit for government – and an enabler of the other features of the regime – was the overall containment of costs to the taxpayer and the Bill showed the government's determination to enforce this.

If the two sides benefited from different features of the structure of the market, then to threaten one of the key aspects that was seen by industry as

being to its advantage (and which underpinned its acceptance of other aspects that were not) could be expected to undermine the equilibrium of the government-industry relationship and the policy community. This part of the Bill would therefore be a test of the commitment of both sides to the nature of the market as it presently existed within the voluntary framework.

The price setting provisions in the Bill were curious. On the one hand, direct price setting was something that the PPRS specifically did not do; on the other, the clause in the Bill was a reformulation of an existing provision in the 1977 Health Act⁵⁸¹ (repealed by the 1999 Act) and not therefore entirely new. But the Bill aimed to introduce two types of price setting. As well as being able to set prices directly through clause 28(1)(a), the Bill would allow the Secretary of State to deny price rises for any NHS products, through clause 26(4)(a).⁵⁸² The first of these was the most worrying for industry but this was the provision that existed in the 1977 Act.

The innovation in this part of the Bill consisted of the other clause – to deny by law price rises of products from companies that are within the PPRS. While this was a pragmatic response to the compliance issue, it also marked a genuine watershed. One central aspect of the PPRS – the price cap – now had the force of law; and the scheme, through this provision, was now in part a statutory one. However, as this provision ‘shadowed’ the PPRS, its significance was in its form rather than its content.

More significant for judging the approach of industry representatives to the structure of the market was their reaction to the (unamended) clause 28(1)(a). When industry figures first saw the Bill, their reaction was severe. “It was outrageous,” commented one. “We went to the DTI and said to them that what we were being presented with was completely unacceptable. We are supposed to be entering a negotiation [on the PPRS] and we have been presented instead with this draft legislation.”⁵⁸³

⁵⁸¹ National Health Service Act 1977, Section 57.

⁵⁸² House of Lords Bill number 15, 1998-9

⁵⁸³ Interview, industry executive 9

5.3.2 Government's recognition of the industry's key 'regulatory goods'

The government did not persist with their clause 26(4)(a). They did recognise the gravity of this proposal and the way it would alter the nature of the market for industry. Their intention in the simultaneous PPRS negotiations was to *reinforce*, in the new scheme, the skewing of prices to ensure higher prices for new products, and this was explicit.⁵⁸⁴ As the government's aim in the PPRS negotiations was to ensure that the 'high-prices-for-new-products' principle remained, they would not undermine this in the legislation.

The clause was duly amended to state that this power would not be operable for the products of any company signed up to the PPRS. In this way the clause moved the overall regulatory framework in favour of the industry: it was a clarification of the existing 1977 legislation to specifically exclude PPRS signatories, which the 'emergency' powers previously did not do.⁵⁸⁵

Industry's approach became more congenial as the Bill was amended, but the amendment process showed that the government recognised the regulatory goods that the PPRS provided for industry – namely free pricing (and relatively higher prices) at launch, as well as the speed to market that this facilitated. Any regulatory process required to set prices would very likely undermine the speed to market while pricing decisions were made.

The amendment of the Bill dealt specifically with this issue and the final version added a clause that prevented the use of the direct price setting powers for any company that was a member of the PPRS. The provision for a future Secretary of State to limit any prices even for PPRS members was therefore removed and along with it the threat to this particular feature of the British market, the relatively high launch price and the quick launch. It also prevented a clause that may have become a basis for the slowing down of

⁵⁸⁴ Interview, Government minister 7

⁵⁸⁵ Interview, DOH civil servant, interviewee 5

the launch process while a pricing decision was made, depending on how its use developed in practice.

5.3.3 Conclusions

The process of the Bill's passage showed that the government did recognise and accept the centrality of industry's regulatory goods to the PPRS regime. The one part of the original Bill that might have threatened these was amended to ensure that this did not happen. The government's aims in the Bill were in any case limited and other areas of the Bill sought to reinforce, or alternatively did not affect, the central features of the functioning of the market through the PPRS.

The otherwise limited nature of the Bill's provisions is evidence of a conservative approach to policy by government in order to maintain the features of the scheme that both sides valued. Its chief purpose for the government was to make the PPRS work: at a very basic level, the Bill sought to reinforce and safeguard the structure of the market by preventing selective non-compliance by some companies, which could have undermined it, both politically and in its function.

5.4 The global context

Assumption 2: The global organisation of industry lends it bargaining resources it would not otherwise have and makes government more alive to the need for an active industrial policy.

Hypothesis 2: Industry will seek to utilise its global structure as a bargaining resource to counteract the legal monopoly of government, which in turn will pay greater attention to their industrial policy aims.

The Health Bill and amendments to it were argued for in Parliament by bringing many of the international features of the industry's structure and operation to bear. The Bill itself may have had serious implications for industry in taking one of the more liberal regimes in Europe into a legislative framework. Parliamentarians involved in the debate drew on many of the characteristics of the global industry to argue for restraint and this had an important impact on the resulting outcomes.

5.4.1 Global industry and bargaining resources

Just as the Health Bill was significant for the policy community here because it seemed to demonstrate the deployment of the government's legal authority, so the global structure of industry was the principal factor in industry's consideration of how much to employ its primary negotiating resource, the threat of disinvestment.

The focus of lobbying to Parliament and of discussions between government and industry was that if the atmosphere in the UK turned sour for the sector, investments would likely go elsewhere (in reality, the US). While the 'threat' of legislation had in this case become the reality of it, the industry 'threat' of disinvestment also had some force behind it. Over the previous decade the

centre of gravity of the research-based industry had shifted from Europe to the US, and on the assembly and manufacturing side, many UK operations had shifted to low-tax Ireland.⁵⁸⁶ The threat was therefore more real than it had been in previous times. “Government was quite worried about withdrawal of the industry. The industry, especially US firms, were getting a bit rattled by what was going on,” said one MP.⁵⁸⁷

Industry commentators suggested that disinvestment was brought up as an issue precisely in response to the decision to legislate, which industry had always tried vociferously to avoid: “The danger of disinvestment was a fact that was constantly pointed out to the government side. The UK represents only a few per cent of the large companies’ markets but the fact is that companies tend to do things in those countries that have good operating environments.”⁵⁸⁸ Another industry spokesperson agreed, and cited the fact of legislation as an important negative factor: “You are not going to attract investment or make the UK an environment where people will want to do business in this sector if you impose unnecessary legislation upon them.”⁵⁸⁹

5.4.2 R&D and the market

The extent to which the operating conditions in the UK market are connected to the investment decisions regarding R&D is ambiguous, as two Parliamentarians suggested:

“The big pull factors for the industry here are the strength of the UK science base and the English language. We have excellent scientists who are also far cheaper than anywhere else in Europe and certainly than in the US.”⁵⁹⁰

“The main thing that attracts them here is actually the quality of research labour in the UK because academic salaries are relatively low, especially compared with the US. There is a very competitive market for biological

⁵⁸⁶ See Chapter 1

⁵⁸⁷ Interview, Parliamentarian 16

⁵⁸⁸ Interview, industry executive 13

⁵⁸⁹ Interview, industry executive 11

scientists. Beyond that there is also a certain critical mass here in the sector now and there are benefits in that kind of agglomeration.”⁵⁹¹

The key issue regarding investment is extremely nuanced. The general atmosphere the UK as a place to do business is important and the regulation of the UK market in itself may not be functionally connected to R&D but it sets the scene and reflects the general attitude of government to industry. While the threat of legislation in the form of the Bill was something that focused industry minds, equally the threat of disinvestment was taken seriously by the government, and this is reflected in the amendments to the Bill, which reiterated the freedoms that the PPRS underpinned.

5.4.3 Oversees policy and regulation

The UK may have particular resonance when approaches to policy across Europe are compared because it is viewed in general as having achieved a successful balance between cost containment and industrial policy aims. During the passage of the Health Bill, the importance for industry of maintaining this, not for its own sake but as an example to other countries, was clear to Parliamentarians. One MP noted: “Their concern is not so much about the British market, and not being able to get a good enough return there, but the signals that sends to other regulatory schemes, as what the British do is often used as a guideline.”⁵⁹² An industry spokesperson concurred: “What sort of signals is that sending out? ... On the whole, in a European context, the UK has always been a reasonable place to be and this seemed to us to be a very retrograde step.”⁵⁹³

This cross fertilisation of policy has become more widespread as the pressures of health costs have deepened across European countries. Aspects of the PPRS have been overtly copied by, for example, France and Italy in modifying their otherwise very different approaches to regulation.

⁵⁹⁰ Interview, Parliamentarian 22

⁵⁹¹ Interview, Parliamentarian 21

⁵⁹² Interview, Parliamentarian 16

⁵⁹³ Interview, industry executive 11

Moreover, the US provided a point of comparison from the other direction: a more liberal operating environment. The influence of American executives was as an important pressure in all areas of policy, whether the Health Bill, the PPRS, or NICE. As one MP put it, "A lot of the people come from the US and say, 'well we can't advertise to consumers, we don't have freedom of pricing' and so on. There is a lot of pressure from these US executives."⁵⁹⁴

The Health Bill, coinciding as it did with the PPRS negotiations, meant that the CEOs, in their meetings with the PM and senior ministers, were able to impress upon government at the highest levels their concerns. The way the Health Bill was amended, with government backing, showed that the arguments were winning through. The ABPI also had to represent the views of American companies in its position, and they were instrumental in arriving at it.⁵⁹⁵

5.4.4 Conclusions

The general operating conditions for the industry in the UK was the focus of its lobbying. The message was simple: if conditions become sour, investment will suffer. Industry suggested legislation would mean disinvestment, although this argument was not taken seriously by many politicians active in the debates; the conditions for research were seen as far more important.

Nevertheless, the government did take notice of these arguments, which in any case were in part about quite nebulous notions of the operating environment. American firms were more sensitive to this change of atmosphere in the UK, which in part was a cultural attitude. In this sense the dynamic structure of the global industry was recognised as a determining factor in the structure of government-industry relations. Moreover, the effect of what was happening in the UK on other regulatory bodies was a primary

⁵⁹⁴ Interview, Parliamentarian 16

⁵⁹⁵ Interview, industry executive 6

concern of industry, and recognised as so by some of the MPs involved in the Bill.

5.5 The co-operative state

Assumption 3: The 'liberal' nature of the British state means there is the desire by government for 'light-touch' and co-operative regulation using limited administrative, technical and legal resources.

Hypothesis 3: Policy proposals that require significant technical, administrative and legal resources on the part of government will not be pursued, in particular a legislative approach to regulation. They will seek maintenance of the co-operative regime.

Scrip magazine commented of the 1999 agreement, "The new PPRS is in effect no longer a voluntary scheme."⁵⁹⁶ The 1999 Health Bill appeared to counter quickly and decisively the assumption underlying the hypothesis that government will not pursue a legislative approach to regulation.

5.5.1 The co-operative system and the purpose of the Bill

The Bill appeared to be a major shift in the government's own assessment of its regulatory role and a significant broadening in its array of options for reform of the PPRS. It was also, by definition, a change in its position regarding co-operation and a voluntary form of regulation. The questions the Health Bill raised were whether these apparent shifts in position were genuine and substantial; and whether the previous limits to the government's action could now be considered not to apply.

The statutory scheme, if ever used, would represent a significant increase in administrative resources. Other aspects of the Bill also gave to government the kind of legal backing that would undermine the informal and co-operative relationship between government and industry. This begs the question of

⁵⁹⁶ *Scrip* No 2457, 23 July 1999 p.4

whether the Health Bill indicated that the government was willing to deploy the resources to define, introduce, implement and police statutory regulation of medicine purchases.

The non-compliance from some companies suggested that the co-operative relationship had already been undermined by their actions. The Bill was aimed at overcoming what the Secretary of State had described as the “shortcomings in the PPRS”.⁵⁹⁷ The Bill must be seen in the context of the government’s determination in the PPRS negotiations to tighten up parts of the scheme. The clauses in the Health Bill served as a reminder to the industry that they were serious about this task. The Bill provided a good bargaining chip in the formally separate negotiations over the new scheme.

Furthermore, there were statutory provisions already in existence for the direct imposition of prices on medicines, present in the 1977 Health Service Act. These in turn were the descendants of wartime special powers (see 5.5.5). The Act provided an opportunity to update these and make them relevant, rather than to introduce new powers. It enabled these powers to be specifically directed at companies to whom the PPRS did not apply.⁵⁹⁸

These four points suggest that the Bill cannot easily be presented as evidence of the government’s willingness to undertake comprehensive statutory regulation of the industry. In summary, the four points are:

1. Specific purpose related to existing regime, i.e. compliance
2. Limited use of the law
3. A bargaining chip in the PPRS negotiations
4. Clarification of existing law

5.5.2 Compliance

The years leading up to the PPRS negotiations and the Health Bill were marked by a period of non-compliance with the PPRS by several

⁵⁹⁷ *Scrip* No 2432, 28 April 1999, p.4.

⁵⁹⁸ See *Scrip* No 2455, 16 July 1999, p.2.

companies.⁵⁹⁹ Most of the companies concerned were small but one was a large multinational; and while the sums involved were not great, they were nevertheless significant for the drugs budget and could potentially become larger still. The Bill was presented in these terms to the industry. A senior politician explained the government's position:

“We thought that the statutory back-up to the scheme was necessary because there was an increasing number of mavericks who were not willing to comply. There were two aspects to that. One was that it was costing money – £30 to £40 million a year; and secondly, if major companies were allowed to get away with it then the more reputable ones would start questioning their agreement to the voluntary arrangement in the face of non-compliance by their major competitors.”⁶⁰⁰

Hence the law was being used because the co-operative relationship was seen to be failing. If the scheme was not fulfilling its purposes for the DOH, questions were bound to be raised about what the government and tax payer were getting out of it. Second, because there was in fact still a co-operative relationship between government and most of the industry, there were large parts of the industry that were themselves alarmed at the non-compliance by, in particular, the large multinational firm. This meant that the government's finding of a solution to the problem was something the majority of firms were happy, in principle, to support. As one put it, “There were certainly parts of industry that were aggrieved that other parts of industry had been profiting from not playing the game and therefore would join the government in finding a way to solve the problem.”⁶⁰¹ It was understood that the non-compliance by industry was the root cause of the need to legislate: “We only have ourselves to blame as an industry for that because we could not discipline our members to come into line,” noted another industry commentator.⁶⁰²

⁵⁹⁹ See also Chapters 2 & 4

⁶⁰⁰ Interview, Government minister 7; Figures also quoted by Baroness Hayman, Health Bill Debate. *Hansard*, House of Lords, 1 March 1999

⁶⁰¹ Interview, industry executive 13

⁶⁰² Interview, industry executive 3

The reasons for the DOH's recourse to legislation, while not welcomed by industry, were understood by the majority of firms and its purpose, if not its form, was welcomed to a degree. Rather than evidence that government felt capable of initiating a new legalistic framework, the use of legal instruments can be seen as a successful outcome of the relationship that existed between the two sides and as an accepted means of preventing it from deteriorating inexorably.

5.5.3 Limited use of the law

There are two separate aspects to the legislation that was proposed in the Health Bill. One aimed to come into operation only when the voluntary arrangement had failed or been reneged upon; the other was to confer powers that would be directly related to the PPRS and which would derive their content from it and enforce certain aspects of it, such as the price capping mechanism (present in all schemes since 1957). The Bill also enabled the Secretary of State to strike a company from the PPRS (in the Act, with stated reasons and a right of appeal) and for prices to be imposed directly (at first, even on companies that had signed up to the PPRS but in the Act, only on those not part of it).

The limited scope of the law served to emphasise rather than contradict the point that government would not wish to design and implement legislation that would achieve their complex aims on its own, and, crucially, within a context of adversity and ill-will between government and industry. The Bill proposed quite loose legislation that could not work except alongside the PPRS. There was no pressure to legislate with detailed perfection because of the existence of the "voluntary scheme" to which much of the Bill referred directly on many occasions. Indeed, the whole framing of the Bill relied on the presence of a voluntary PPRS, and the clauses would have been vacuous in its absence.

Said one MP, "With a statutory scheme alone, there would be a huge amount of work and they would have to get it right. Government would certainly worry

about that.”⁶⁰³ The present government has, he added, been very keen not use the law to regulate complex industries: “if you look at the genetic and insurance industries they [the present government] are very keen on voluntary agreements. They’re not very keen on statutory moratoriums on the use of genetic testing, for example.” The implication is that over the course of the post-war period in which the VPRS/PPRS has existed, the present government were rather less keen on statutory regulation than many of its predecessors and unlikely to opt for a legal framework. Another Parliamentarian (Lords opposition) agreed, “The government do not want to have to face the prospect of a statutory scheme if they can possibly avoid it.”⁶⁰⁴

The broad principles in the Bill are more important than the detail because the law would not apply to companies in the PPRS, and the content of the law when enacted would be defined by the detail of the PPRS. Those parts of the industry that were compliant with the PPRS would not need to worry about the legislation and the government did not have to focus on the minutiae of the law because they did not intend, ordinarily, to use it.

Indeed in the end the Bill itself had the character of an agreement between government and industry. Ironically, to a degree it was itself an additional aspect of their informal relationship. One member of the Lords commented, “What one would have to recognise is that government wouldn’t be too keen on putting something forward that they thought there was widespread opposition to. They wouldn’t bring it forward until they had basically got the industry broadly in agreement with what they wanted to do.”⁶⁰⁵ Another concurred that in the end, “the effect of the Act is not to end the voluntary nature of the PPRS.”⁶⁰⁶ The Act became one feature of the landscape of their co-operative relationship – a legal dimension to an otherwise voluntary arrangement.

⁶⁰³ Interview, Parliamentarian 16

⁶⁰⁴ Interview, Parliamentarian 18

⁶⁰⁵ Interview, Parliamentarian 21

5.5.4 Bargaining chip

As the process of debating and amending the Health Bill coincided with the PPRS negotiations, the Bill became a de facto issue in the progress of those negotiations. Although officially a quite separate process, the politicians debating the Health Bill were aware of the concurrent negotiations and there was a widespread feeling among them that the DOH were using the Bill in its original form to show that it 'meant business' and would be prepared to go down the statutory route if necessary, if it did not achieve its aims in the negotiations. "It brought this through at this time because of the PPRS negotiations that were taking place. The government wanted the statutory scheme there purely to increase its bargaining power in the negotiations," said one MP active in proposing amendments in Committee.⁶⁰⁷

In his view, the government's foray into the statutory field was not one they wanted to go very far. Rather, a principal purpose of it was to assist in the negotiations over the new scheme. "There's always an element of bluff. If they could get what they wanted anyway without a statutory approach then they wouldn't go down that road," he said.⁶⁰⁸

All Parliamentarians interviewed expressed the same view about the concurrence of the Bill and the negotiations:

"The government were quite clearly using the Bill as part of their broader negotiations with industry."⁶⁰⁹

"It was really all part of a negotiating ploy on the part of government because they wanted to have some kind of stick to hit the industry with. They undoubtedly were negotiating on both fronts simultaneously and success on one front would be reflected in the attitudes on the other."⁶¹⁰

⁶⁰⁶ Interview, Parliamentarian 18

⁶⁰⁷ Interview, Parliamentarian 16

⁶⁰⁸ Interview, Parliamentarian 16

⁶⁰⁹ Interview, Parliamentarian 20

⁶¹⁰ Interview, Parliamentarian 21

“It was perfectly clear that while these issues were being debated under the Health Bill, the negotiations were also going on. We certainly got the impression that the government felt the Bill was helpful to them in relation to the negotiations, although they didn’t say so explicitly.”⁶¹¹

Although a specific link was not made, the government did allude to the political purpose of the Bill, according to one member of the Lords: “Although there was no direct mention of trade-offs between what was done on the Bill and what happened in the negotiations, the minister did refer to the PPRS constantly.”⁶¹² The ‘proof’ of its specific purpose during 1999 was, for one Parliamentarian, that “we have not heard a squeak about any sort of statutory power since the PPRS was signed. It was a useful sword to hang over their head.”⁶¹³

Furthermore, while many within the industry may have appreciated the purpose of the government’s aims and the background to them, legislation was by no means seen in a positive light in itself, and very definitely seen as a means of forcing issues in the negotiations. One industry spokesperson called it “blackmail; we were being asked to negotiate the new PPRS with our hands tied behind our backs.”⁶¹⁴ Another said that the Bill was used by the government quite openly in the PPRS negotiations: “They had the big stick – the threat of the Health Bill – and the civil servants kept mentioning the stick throughout the negotiations.”⁶¹⁵

If the first rendering of the Bill was indeed, as many people suggested, a weapon in the PPRS negotiations, then again it cannot be seen as a serious attempt by the government to change the status quo and build a new type of regulatory regime in which a more legalistic and formalised (not to say adversarial) relationship between government and industry would operate. Rather it can be seen in part as a timely bluff. The government fashioned a

⁶¹¹ Interview, Parliamentarian 22

⁶¹² Interview, Parliamentarian 21

⁶¹³ Interview, Parliamentarian 18

⁶¹⁴ Interview, industry executive 9

⁶¹⁵ Interview, industry executive 13

Bill that was far more stringent than they intended the final Act to be and amendments would be (informally) conditional on progress in the PPRS negotiations. A senior DOH civil servant confirmed the effectiveness of the Bill in focusing industry minds in the negotiations: “The industry were trying not to listen to us and it was only when the Health Bill was published in October that they realised we were serious. Then they went berserk and they went AWOL.”⁶¹⁶

5.5.5 Clarification of existing law

Equally significant for an analysis of the purpose of the Bill was its clarification of existing law. The provisions to control prices directly were an update of clauses from the 1977 Health Act.⁶¹⁷ This Act had incorporated some provisions more or less directly from the Defence of the Realm Act (‘DORA’)⁶¹⁸ of 1914, which had allowed sweeping price setting powers for Secretaries of State, and they were considered too crude to be of any use (see 2.3.1). The relationship between the PPRS (i.e. companies that agreed to it) and these laws was not explicit. So the 1999 Act clarified that relationship and made the 1977 laws applicable and useable. “There was a lot of tidying up done in the 1999 Act; the powers in it were not all new,” said a DOH civil servant.⁶¹⁹

The 1977 schedules, which enabled the Secretary of State to control the prices of any medicinal product directly by order, were repealed as part of the 1999 Act. In this sense, the 1999 Act in fact *limited* the basis of statutory price control powers to specific circumstances, defined in the context of the PPRS. The government considered the 1977 powers “too crude” to be of any use. Industry now had these powers defined clearly in a way that took into account both its and government’s rights and obligations. Industry accepted this particular function of the Bill, as those previous powers had always hung

⁶¹⁶ Interview, DOH civil servant 10.

⁶¹⁷ National Health Service Act 1977, Section 57.

⁶¹⁸ The Act of 1914 gave the war time government wide ranging powers over, among other things, the media, the legal system and the economy. Many aspects of the Act survived in various forms until long after the second world war.

ambiguously in the background. One commented about it: “The Act sets into law the concept of a voluntary agreement. Other powers in the Act are in fact reformulations of existing powers.”⁶²⁰

5.5.6 Conclusions

The clauses of the Health Bill had a specific purpose directly related to the existing regime – it aimed to solve a particular problem of compliance – i.e. a *failure* in the co-operative regime that was acknowledged industry representatives. Hence, the legal provisions it did propose were delimited by the PPRS or directly modelled on it: it only proposed a new legal framework where the voluntary one had broken down. It was used, too, as a bargaining resource for the government in the PPRS negotiations. Furthermore, there were aspects of the Bill that in fact already existed in legislative form, but in an inappropriate way.

The clauses of the Health Act did not create statutory provisions that would be the norm but rather an enforcement mechanism. It would serve to ensure that companies negotiated the scheme in good faith and kept their side of an otherwise legally unenforceable agreement. It was, therefore, linked into the existing regime – the PPRS – and sought to provide a framework for it. The Act, with its important amendments, did not undermine the essentially co-operative relationship, although it can be characterised as ‘negotiated compliance’ given the mixture of statutory and voluntary means that were employed to achieve an agreement on the PPRS.

The ABPI expressed its contentment with the final clauses and emphasised that the final Act reinforced the voluntary nature of the PPRS.⁶²¹ The passage of the Bill tested the extent to which both sides valued the co-operative form of regulation and proved that this was valued highly by both sides.

⁶¹⁹ Interview, DOH civil servant 5

⁶²⁰ Interview, industry executive 6

⁶²¹ *Scrip* No 2453, 9 July 1999, p.3.

5.6 The role of Parliament

Assumption 4: Parliament has a peripheral role in this policy field and does not constitute a veto point or external influence on the policy community.

Hypothesis 4: Parliament will not be an influential actor in determining policy outcomes, which in turn will be reflected in the limited direct attention to it by both government and industry.

The basic nature of the British Parliament and of the relationship between the legislative and executive branches is important in the debate about its role in regulating the industry. As one MP made clear, objective debate about individual points can be secondary to the normal dynamics of the British Parliament. Even where points are strongly and convincingly argued, the government majority can usually be relied upon. “Basically, the government hate conceding to opposition members and this is the only reason that our major points failed to be taken on board. We had him [John Denham, the Minister of State] on the back foot but the government can never accept it’s wrong or accept our views,” he said.⁶²² Another Parliamentarian noted the general lack of legislative accountability in the British system:

“In this country the power of the executive has increased and ought to be diminished. We need to see Parliament being much more effective in holding the executive to account, which requires moving in the direction of the separation of powers. The problem is, we effectively have a presidential system combined with a government with a large majority in the Commons, and this means an elective dictatorship.”⁶²³

⁶²² Interview, Parliamentarian 16

⁶²³ Interview, Parliamentarian 21

5.6.1 Parliament and the PPRS

These are general points about the limitation of Parliament's role in the legislative process. The PPRS is peculiarly embedded in the executive and Parliament would appear to have even less of a role than in many other policy areas. But the Health Bill appeared to challenge that marginalisation. First, it gave an overt role to Parliament in regulating the industry; and second, amendments to the Bill would appear to suggest that there were good contacts between industry and Parliamentarians that could ensure its voice was heard. Industry seemed to regard it as an important 'veto point'.

5.6.2 Parliament and the legislative agenda

Parliament had been an important player in determining the agenda for the Health Bill. The relevant clauses of the Bill had been influenced by the scrutiny that Parliament had undertaken of the PPRS over preceding years. The highlighting of the compliance issue; the work of the Select Committee and its emphasis on transparency; and the subsequent Reports to Parliament that showed the inefficiency of the PPRS Branch's work. All of these factors were central to defining the '1999 agenda', which underpinned both the PPRS negotiations and the contents of the Health Bill (see 4.10.2).

5.6.3 Parliament and the process of negotiations

The discontent shown by many Parliamentarians with their limited role in general was illustrated by the passage of the Health Bill in so far as there were a large number of amendments tabled, which were largely well argued by their proposers and supporters, but which failed to be accepted into the final form of the Bill. But as well as the large number of failed amendments, those that did succeed represented radical changes in the Bill: its final form was vastly different from its initial rendering, in ways that were important for the industry.

The key changes were the specification that a company signed up to the PPRS could not have a statutory scheme imposed on it; and that where a company was removed from the PPRS, there would be some right of appeal. These were government amendments. They were introduced through the Lords by Baroness Hayman and they were the result of discussion between the Department of Health and representatives of industry (see Chapter 4).

But the limited role of Parliament in the amendment process can be qualified: because other amendments were made, introduced by the opposition, that were not without significance. Earl Howe, an opposition member of the Lords, initially introduced the amendment that exempted PPRS signatories from price setting powers, although it was taken up by the government (and became clause 34(2) in the Act); and amendments were made in the Commons that required the Secretary of State to give notice and reasons for removing a company from the PPRS, and requirements for consultation where information is sought from companies.

The changes made to the Bill were in part the result of industry lobbying of Parliament, as well as 'behind the scenes' discussion between industry and the Department. Furthermore, so far as the Bill was a bargaining chip for the DOH in the PPRS negotiations, amendments have to be seen in the context of the government's true intentions and the possibility that amendments to

the Bill were intended once they had achieved agreement on the new scheme.

Table 5.1: Amendments carried, Health Act 1999

Nature of amendment	Location in Act	Introduced in
The Secretary of State must give written notice to a manufacturer that the PPRS no longer applies.	33(4)	Lords
Secretary of state must give reasons for removing a company from the PPRS.	33(5)	Commons
A company must be given the opportunity to make representations when it is removed from the PPRS (a right of appeal).	33(5)	Lords
There must be consultation with the industry body before the Secretary of State can require the submission of information from companies.	33(7)	Commons
The price limiting regulation cannot apply to a company signed up to the PPRS.	34(2)	Lords
A statutory scheme may not apply to any manufacturer to whom a voluntary scheme applies.	35(7)	Lords
Companies will have a right of appeal against enforcement decisions.	37(5)	Lords
Any regulations made under this section must be consulted on with the industry body.	37(9)	Lords
In exercising the various powers contained in the Bill, the Secretary of State must bear in mind the importance of the need for medical products to be available for the NHS and the costs of R&D.	38(4)	Lords

5.6.4 Parliament and industry lobbying

Several industry representatives noted the importance of their parliamentary contacts in getting significant amendments incorporated into the Health Bill. They were in no doubt that their parliamentary contacts played an important role in their success in getting discussion of the Bill and changes made to it.

“We did have a lot of support over the changes we felt we had to sponsor in the Health Bill. We got a lot of co-operation from various figures in both Houses.”⁶²⁴

“Parliament was absolutely crucial. There was no question that industry lobbying of Parliament was a significant factor in enabling us to achieve some considerable successes in getting changes in the Health Bill. If you compare the original Bill with that which was eventually passed into law, there were very significant differences. Making sure that key, relevant MPs were on-side was a very important part of the strategy.”⁶²⁵

A traditional perception on the part of industry that its support was mainly on the Conservative benches⁶²⁶ could be qualified to some degree by support for the value of the industry voiced from all parties during the second reading in the Commons.⁶²⁷ Indeed, this was an opportunity to influence the now important Labour benches and the perception of the industry is less defined by party divisions than in the past.⁶²⁸

Limited industry influence

However, the extent to which MPs and Lords felt they were influenced – or in contact with – the industry gives a more varied picture. Indeed a few Parliamentarians with health portfolios and significant parts to play in discussion on the Bill noted an absence of industry lobbying. One MP active on the health policy field commented, “I didn’t get lots of people coming to see me. I would have had no qualms about being lobbied much more.”⁶²⁹ He added that the content of the amendments he proposed were not the result of any liaison with or even information from industry: “I drafted the clauses of my amendments myself, with no help from industry.” An active participant in

⁶²⁴ Interview, industry executive 13

⁶²⁵ Interview, industry executive 03

⁶²⁶ See for example the ABPI (1995)

⁶²⁷ *Scrip* No 2432, 28 April 1999, p.4.

⁶²⁸ Interview, industry executive 6

⁶²⁹ Interview, Parliamentarian 16

the debate in the Lords concurred: “I received very few representations from industry through the whole passage of the Bill.”⁶³⁰ Becoming somewhat of a running theme, another MP and former health minister commented: “Industry made no representation to me on any of these issues. When issues of prescribing were being legislated on, with great implications for the pharmaceutical industry, I received no representations either.”⁶³¹

Records for both Houses show that very few MPs and Peers participated in the debates. In the Commons Standing Committee, government MPs served only a ‘vote fodder’ role, without a single contribution from anyone other than the minister. They voted down well-argued amendments that the Minister of State had had difficulty arguing against and seemingly without understanding the implications of what they were voting on. In an area as technical and complex as the PPRS, it would appear that many did not have a sufficient grip of the issues at stake. One MP and member of the standing committee referred to this specifically: “Because this hasn’t really come before Parliament in any detailed way before, there were very few MPs who knew what the PPRS actually was. I had to have it explained to me and I never really got into the detail. I would have liked to have seen a working example.” The missed opportunities for industry lobbying were, it seems, extensive. “The pharmaceutical industry do not lobby as hard as they could – they have a bit of a ‘chip on their shoulder’ type attitude about it, I think.”⁶³²

Information

However, not all agreed that industry had not briefed Parliamentarians sufficiently: “There was certainly a great deal of information sent by industry to MPs and Peers during the debates on the Bill,” noted one peer. Furthermore, the views of some that industry was not as active as it might have been may be explained by the focus of their lobbying: “The main links industry had were with the Conservatives. They were being briefed directly

⁶³⁰ Interview, Parliamentarian 20

⁶³¹ Interview, Parliamentarian 12

⁶³² Interview, Parliamentarian 16

by the ABPI. They were feeding directly into the Conservative position,” noted one Parliamentarian.⁶³³

The Conservative opposition explained that they had had industry backing in arriving at their position: “The amendments that I tabled in the Bill were drafted by the ABPI and I was also sent supporting notes for each amendment. I remained in close touch with the ABPI throughout the passage of the Bill.”⁶³⁴

The direct contact between industry and the executive meant that there was a two pronged approach by industry to its lobbying. The process of examining the Bill by industry representatives and feeding back their concerns to government was the route of much of the reviewing process from the original draft to the final form of the Bill. “There would have been enormous input from industry at the time of the Green and White consultation papers. They would have made it clear to government what they didn’t like.” This was borne out by a leading participant:

“I raised the detailed concerns that they [the ABPI] had in committee. To my surprise Baroness Hayman capitulated and it made me think there’d been an awful lot of work going on behind the scenes between the industry and the Department. ... I didn’t know when I got to my feet that I was pushing against an open door but that became very clear to me afterwards.”⁶³⁵

Nevertheless, the parliamentary angle was still important: “Although it was in direct contact with government, industry knew that it would be more effective there if it got amendments down in Parliament for the government to respond to and that’s what they did, working through the Conservative benches. Most of their input at that stage was through getting amendments laid.”⁶³⁶

⁶³³ Interview, Parliamentarian 21

⁶³⁴ Interview, Parliamentarian 18

⁶³⁵ Interview, Parliamentarian 18

⁶³⁶ Interview, Parliamentarian 21

Importantly, the industry could claim to have limited the applicability of the scheme – one of the central amendments – through its contacts with Parliamentarians, as some of the important amendments taken up by the government were laid by opposition members that they had lobbied, including the limitation of price limiting regulation to companies not part of the PPRS.

5.6.5 Conclusions

The passage of the Health Bill demonstrates an ambiguous role for Parliament over the PPRS. As legislation, it inevitably included Parliament in the PPRS policy community in a way that it had not been before. But the legislation did not give Parliament any 'governance' role in the PPRS. Rather, it set out further powers for the Secretary of State, even entrenching further the role of the executive in this area.

The process of the Bill's passage did not show an entirely successful relationship between industry and Parliament. It cannot be said that industry directed no attention to Parliamentarians or that it did not have some productive contacts. The non-government amendments could not have happened if there had not been such contacts. The principal mover of amendments said so explicitly. But it remains that the most important amendments were concessions from government, agreed between them and industry outside of the parliamentary arena. It would appear that there was some potential gain to be had from further communications with and lobbying of Parliamentarians, not least on the government side, which industry failed to act on.

Industry valued greatly the amendments to the Bill but their lobbying of Parliament can be seen as *supplementary* to their lobbying of government. The intention of the government to make concessions on the Bill in so far as they were using it as a bargaining chip in the PPRS negotiations also qualified the extent to which Parliament *could* play any meaningful role.

The extent of any 'success' of the lobbying of Parliament must be measured against the extent of the government's flexibility over the Bill, which has been shown to have been ample. The link between the Bill and the PPRS negotiations remained an important one. The evidence is that both routes were used.

5.7 Role of the Department of Health

Assumption 5: The siting of an industrial policy function within the Department of Health gives DOH authority and competence to act and highlights the government's industrial policy aims, enabling a co-operative regime.

Hypothesis 5: The dual role of the DOH will prove decisive in defining policy and maintaining the co-operative regime by counteracting the procurement focus of the Treasury.

The Health Bill was a blow to the policy community and no more so than because the proposals to legislate and create provisions for a statutory regulation scheme were designed by the Department that possessed the formal sponsorship responsibility for the industry. The clauses suggested to the industry that the sponsorship function was not a guarantee of a balanced PPRS. The Bill also gave an opportunity for a wider group of people to analyse and discuss the compatibility of the two roles of purchaser and sponsor residing in the same department.

5.7.1 The parliamentary process

Although the sponsorship role was not central to the discussion of the Health Bill in Parliament, opposition MPs did discuss it in the Commons Committee stage. While the general principle that the purchasing department should not be the sponsoring department was discussed, particular emphasis was given to the anomaly of a customer having formal regulatory powers. "It is deeply unsatisfactory for the Department of Health, as a customer, to enter into contractual relations with a supplier, which it seeks to underpin with statutory arrangements."⁶³⁷

⁶³⁷ House of Commons Standing Committee A (pt 9) 18 May 1999, Mr Hammond.

The Liberal Democrats had been central to introducing the idea of shifting the sponsorship function on the basis of a fundamental conflict of interest (i.e. regardless of the particulars of the Health Bill), and potentially against the interests of the tax payer, as well possibly of industry. Amendments were tabled to this effect, with the Liberal Democrats proposing in both the Lords and in Committee in the Commons that the DOH sponsorship function be moved to Trade and Industry, in the event of a statutory scheme being applied.⁶³⁸ Conservative Party representatives such as Philip Hammond seemed to see this role, in light of the Bill, as one that may be against the interests of industry. The pharmaceutical industry, he noted, shared with the defence industries the “dubious privilege of falling under a sponsoring Department that is also its biggest customer.”⁶³⁹

But politicians were equivocal in their views about the role of the DOH. One commented that “there are civil servants in the Department of Health who think the pharmaceutical industry are just robber barons out to fleece the NHS.” Nevertheless, he continued, “I think there is a basic virtue in separating the purchaser from the regulator in this context.”⁶⁴⁰ Some Parliamentarians therefore continued to judge the role in terms of a conflict of interest rather than a need to fuse divergent policy aims.

The passage of the Bill and the way in which amendments were adopted or pre-empted by the government suggests that the sponsorship role was a factor in the DOH’s toning down of its original proposals, once progress was being achieved in the PPRS negotiations. As the department responsible for the Bill, the DOH’s role counted in favour of industry. Its concern to reach a ‘balanced’ PPRS settlement meant that it was open to major changes of emphasis and of provisions in the Bill in order to maintain the co-operative policy community necessary for that purpose.

⁶³⁸ House of Commons Standing Committee A (pt 9) 18 May 1999, Government Amendment 216.

⁶³⁹ House of Commons Standing Committee A (pt 9) 18 May 1999, Mr Hammond.

⁶⁴⁰ Interview, Parliamentarian 18

5.7.2 The view of industry

From the perspective of the industry, the Bill, published at the time of the beginning of the PPRS negotiations, came as a shock to executives and made them question the position the Department had taken. Regarding the PPRS negotiations in light of the Health Bill, one commented:

“When we heard about the legislation, we didn’t know what they were going to do and this obviously makes you question the role of the Department as one that’s meant also to have the industry’s interests in mind.”⁶⁴¹

Any questions over the DOH’s sponsorship role from industry’s point of view were settled by the amendments which required that the new statutory powers could only be used in relation to a non-signatory to the PPRS. The longer-term support for the DOH as sponsoring department was re-established (see Chapter 4). The amendment to change the role fell. Some of those speaking in favour of the amendment felt it was one that would help industry, though possibly in the absence of detailed knowledge of how the function works in relation to all the industry’s concerns and the role the DTI remains able to play. One MP commented: “There would be conflict between two cabinet ministers, whereas at the moment the DTI doesn’t have a role. It would in my view be helpful to industry but industry say they don’t want it.”⁶⁴²

Indeed there was no specific pressure from industry to move the sponsorship function. There was a proposal to shift sponsorship to the DTI where any statutory scheme was instituted by the Secretary of State (which became irrelevant when this competence was limited by amendment) but these proposals did not originate from Parliamentarians who had been lobbied on the issue by industry.

The Bill had been an important event for industry spokespersons. Traditionally industry had supported the function remaining within the DOH

⁶⁴¹ Interview, industry executive 9

⁶⁴² Interview, Parliamentarian 16

because they viewed it as improving the breadth of understanding of the industry within the very Department that made the important procurement decisions. The introduction of the Bill led some to query that role because it gave rise to the question of how the sponsoring department could devise draft legislation that the industry saw as counter to its long-term interests – by creating legal provisions that would be at the disposal of all future Secretaries of State for Health, when the pressures of budgets and so forth could not be known. But even the DTI itself saw any protestations from industry about the function remaining in the DOH as tactical rather than strategic: the transfer of the function to the DTI is something that “chief executives raise from time to time, when there’s something they’re very hot under the collar about,” said a DTI official.⁶⁴³

5.7.3 Conclusions

Although the industry were confounded by the Department’s initial legislative proposals, they took them in large part to be a bargaining chip in the PPRS negotiations and once amendments were made in the Bill to take account of their concerns, they no longer saw the Department as overtly hostile. The re-establishment of the co-operative relationship and the positive aspects (for industry) of the PPRS were evidence enough of a department that took its sponsorship role seriously.

Parliamentarians had mixed views of the role but this was not a direct issue in the Bill and discussion of it was confined to one Liberal Democrat amendment that was not carried.

The dual role of the Department was a central feature of the direct linkage between amendments to the Bill and the progress of the PPRS negotiations and so although the initial Bill gave rise to questions over its exercise of this role, its successful amendment to re-establish the largely amicable

⁶⁴³ Interview, DTI civil servant 1

relationship between government and industry in a co-operative policy community was also a result of its broad competence over all areas of policy.

Chapter 6

The negotiation of the 1993 PPRS

6.1 Political background to the negotiations

6.2 Changes in the scheme in 1993

6.3 Negotiating aims

6.4 The pharmaceuticals market

6.5 The global context

6.6 The co-operative state

6.7 The role of Parliament

6.8 Role of the Department of Health

The historic balance of aims in pharmaceutical price regulation was set out clearly by the Secretary of State for Health, Virginia Bottomley, in an article in *The Times* more than a year ahead of the expected date of a new PPRS agreement, in January 1992. She extolled the success of the industry and the need to support it while noting that government must consider the market from the point of view of the taxpayer. The means of achieving this balance was also made clear: “We want to move forward in partnership with industry,” she said.⁶⁴⁴

6.1 Political background to the negotiations

Despite the Secretary of State’s conciliatory declaration, the government seemingly press-released an intention to reduce the spend on the pharmaceutical budget early in 1993⁶⁴⁵ – something that would be achieved through both the new PPRS and the extension of the Selected List of medicines on Schedule 10, prohibited from NHS prescription.

A debate about the merits of the industry, the PPRS and the positions that ought to be taken in the negotiations was carried out through the press. The government was encouraged to drive a ‘hard bargain’ following significant price increases in the drugs budget in recent years.⁶⁴⁶ On the government side, there were leaks to the press about the operation of the scheme, which was said by a former department of health official to enable company lawyers and accountants to “run rings” round his team of officials.⁶⁴⁷

The long duration of the 1986 scheme is explained in part by the timing of the general election. Ordinarily the scheme would have been negotiated in 1991, after five years, but the election was looming. Following the general election

⁶⁴⁴ *The Times* 27 January 1992

⁶⁴⁵ *The Guardian* 27 January 1993

⁶⁴⁶ *The Financial Times* 23 December 1992

⁶⁴⁷ *The Guardian* 13 April 1993

of 1992, the scheme quickly appeared on the Department's agenda. "My understanding was that a renegotiation had already been agreed. I inherited a situation with an expectation of an imminent renegotiation," a senior DOH politician commented.⁶⁴⁸ Neither side forced a renegotiation overtly. From the government's perspective, a senior civil servant commented, "There was no overwhelming drive from the government side for renegotiating the scheme."⁶⁴⁹ The negotiations were expected by both sides and agreed mutually.

Despite the public airing of positions, the negotiations took place in a reasonably amicable atmosphere. One pharmaceutical executive said at the time, "There is quite a lot of goodwill. We hope to conclude the negotiations over the next few weeks, although there is still quite a gap between what we want and the Department's proposals."⁶⁵⁰ Industry had made clear that it was not opposing the PPRS and was happy to renegotiate the scheme, which could achieve positive things for both sides.⁶⁵¹ However, the negotiations ran in parallel with other significant issues for the industry and there were specific areas of concern for the negotiating parties. There were concerns about both procurement and industrial policy aims for the government and about proliferating regulation from industry.

The issue of the Selected (or 'Limited') List focused attention on issues of drug costs; concurrently, the Medicines Information Bill was introduced into Parliament as a Private Members Bill, sponsored by Giles Radice MP, a Labour (opposition) backbencher. There was an intertwining of these various discussions with the PPRS in government, industry and Parliament.

⁶⁴⁸ Interview, Government minister 17

⁶⁴⁹ Interview, DOH civil servant 27.

⁶⁵⁰ *The Financial Times*, 10 May 1993

⁶⁵¹ *Scrip* No 1778, 11 December 1992, p.4.

6.2 Changes in the scheme in 1993

The major clause of the 1993 scheme – a success for government and an unwelcome reality for industry – was a 2.5% price cut, across-the-board, on NHS sales. There was a tightening of some aspects of the scheme that industry also disliked. Other areas were altered in line with industry wishes, as well as the Department's own analysis of the scheme, which showed areas of anomaly and perverse incentives. The principal features of the new scheme were:⁶⁵²

- A price cut of 2.5% for three years across all products sold by a company to the NHS.
- The 'grey area' in the ROC allowance was replaced by a 'Margin of Tolerance' (MOT) of 25% in either direction. This meant that a company could not apply for a price increase until its profits on NHS business fell to 25% under their permitted ROC, or that no refund was available to the Department until a company's profits rose to 25% above its ROC.
- The threshold for companies to submit full AFRs was raised from £4 million to £20 million, meaning less paper work for many more smaller companies. They would now only have to submit audited accounts, stating turnover and the proportion of NHS to non-NHS business.
- Recognition of some fixed costs of UK manufacture. The purpose of this was to increase the amount of costs allocated to UK production to alleviate the 'export disincentive' (this refers to the disincentive to companies to increase exports as the apparent input costs of domestic sales will decrease and profits from NHS sales be reduced – see 2.3.7).
- A new provision for taking some drugs out of the PPRS where genuine price competition can be demonstrated.
- The ROC was held at the range 17-21%.
- No change was made in the promotional allowance.

⁶⁵² *Drug and Therapeutics Bulletin* (December 1993), pp.103-4; *Scrip* No 1847, 17 August 1993, pp.2-3; Department of Health (1993).

The agreement was endorsed by both parties on 26 August 1993 and the scheme came into effect on 1 October 1993, to run for five years.⁶⁵³

Table 6.1: Principal changes in the 1993 PPRS

Item	1986	1993
ROC range	Negotiation within a "published range"	17-21%
MOT / grey area	50% of target profit, either way; except in year of price increase	25% of target profit, either way; except in year of price increase
Promotional allowance	To be set as a % total industry sales to NHS then divided among companies in agreement with ABPI. In addition, £500K p.a. per NCE, for 2 years after introduction.	6% of sales plus £400K fixed amount per company, plus varying product servicing allowances of £100K, £50K, £40K and £30K per product.
R&D allowance	Negotiated with each company, according to average industry spend, company's UK investments, the company's global R&D spend as % sales.	Negotiated with each company, according to average industry spend, company's UK investments, the company's global R&D spend as % sales.
AFR submission thresholds	<£500K sales to NHS, no financial info required \$500K-£4m audited accounts but no AFR required >£4m full AFR required	<£1m sales to NHS, no financial info required \$1m-£20m audited accounts but no AFR required >£20m full AFR required
Apportionment of capital costs	Recognition by DHSS of imperfection of dividing capital employed between home and export sales; agreement to discuss with industry.	Provision for additional info to be provided by companies with AFR to consider modifications to division of capital employed.
Contribution to economy	Specific reference (para 4.6) as basis of negotiations on target ROR; also one factor in agreement on promotional allowance.	Specific reference (para 4.6) as basis of negotiations on target ROR; also one factor in agreement on promotional allowance.
New products	Free pricing; profits can be kept to top limit of grey area	Free pricing; profits can be kept to top limit of MOT
General 'grey areas'	Several 'grey areas' for negotiations between company and DHSS, including over target ROR and promotional allowance.	Several 'grey areas' for negotiations between company and DHSS, including over target ROR and promotional allowance.

⁶⁵³ House of Commons, Written Answers, 27 Oct 1993, Columns 694-5; Mr. Sackville.

6.3 Negotiating aims

The principal aim of the government, overwhelming any more strategic aims, was to reduce the growth in the pharmaceuticals bill: “For us, the issues centred very much on the growth in the drugs bill,” commented a senior DOH civil servant.⁶⁵⁴ This aim was driven by the growth in the drugs bill that had taken place over the preceding few years. Now that inflation was low, this appeared out of place and drew the attention of the Treasury (see 4.4.3).

While the government intended that the 1993 scheme should succeed in reducing the growth in the overall pharmaceuticals bill to the NHS, what they required most of the PPRS agreement was a short-term cost saving. Any other changes to the way the NHS purchased pharmaceuticals, which may be needed to make large long-term savings, would require the overhaul of the regulatory system. What the PPRS could achieve for government was a cost saving in a politically relevant time frame – i.e. the coming two or three years.

Criticism had been levelled at the PPRS in the context of new demand side measures of cost containment, on the basis that the PPRS was a way in which savings on the demand side could be lost on the supply side, in so far as demand side measures affected the profits of the industry, rather than volumes.⁶⁵⁵

For industry's part, one aim of the negotiations in general terms was to persuade the government that the growth in the overall drugs bill was a positive development, signalling the growth of primary care in preference to the far more expensive hospital treatment that some newer drugs (such as anti-ulcer treatments) were now supplanting. Limiting the cost to the taxpayer could be achieved by other mechanisms, such as greater patient co-payment for drugs. This had been suggested by ABPI Director, Dr. John Griffin.⁶⁵⁶

⁶⁵⁴ Interview, DOH civil servant 27.

⁶⁵⁵ *Drug and Therapeutics Bulletin* (May 1993), pp.41-44.

⁶⁵⁶ *The Lancet* (1 May 1993), pp.1156-57.

They pointed out in advance of the negotiations not only the low rise in prices in the sector but also that return on capital of 17-21% was below that for the top 100 UK companies on average.⁶⁵⁷ Industry's primary aim was to prevent any significant cut in overall prices and to defend the allowable rate of return on capital but they, like government, did not seek any overhaul of the PPRS.

Industry also had concerns about the introduction of other measures, both on the demand side and the extension of the Selected List of medicines (Schedule 10). How these would impact on them as individual companies was unclear. For some companies this was a minor issue, but for others, including some small companies who relied heavily on a few affected drugs, it was potentially very significant indeed. Without a clear idea of how the Selected List might be extended, for those few firms it was difficult to assess the effects of any changes in the PPRS. Companies were unsure how the new scheme would affect them until they knew the effect of any extension to the Selected List. The experience of the original list in 1985 suggested that some companies might be affected quite severely and others barely at all.

Nevertheless, industry representatives felt that they had to recognise the political realities of the time: cost containment was a major political issue across Europe. Regulation in other markets was not favourable to them. Most important was the situation in the US, where the new Clinton administration was seeking to limit medicine prices because of rapidly rising public health care costs. The US was (and remains) by far the most important market for the industry, responsible for the lion's share of its profits. There were also developments in Europe that were somewhat alarming for the industry. Germany (one of the two largest markets, along with France, yet unlike France a less regulated market by European standards) was also planning more stringent purchasing rules.⁶⁵⁸ This boosted the position of the British government and provided a check on the position of industry.

⁶⁵⁷ *Scip* No 1776, 4 December 1992, p.3.

⁶⁵⁸ *Scip* No 1849, 24 August 1993, p.3.

6.4 The pharmaceuticals market

Assumption 1: The market for pharmaceuticals in the UK underpins the PPRS by enabling sufficient rewards for both government and industry within the scheme, and enabling policy aims to be balanced.

Hypothesis 1: Actors on both sides will seek to maintain the current structure of the pharmaceuticals market, and hence the regulatory goods it yields, and will not pursue strategies that would undermine it.

There had been developments in the shape of the market during the eight years since the 1986 scheme was agreed, and these had implications for the position and aims of the two sides in the 1993 negotiations.

6.4.1 Developments in the marketplace

The period of the 1986 scheme had seen growing inflation and a deep recession but by 1993 the economy was on an upward trend and inflation firmly down from levels seen at the turn of the decade. The annual inflation rate was 4%.⁶⁵⁹ However, the growth in the pharmaceuticals bill was far higher. It had been growing far faster than both inflation and NHS spending, pushing the pharmaceuticals portion of total NHS funding higher year on year. The medicines bill was not cash limited and had been growing, according to the Department of Health, by between 12% and 14% a year for the previous few years, and in the longer run by about 8% per year.⁶⁶⁰ This marked an acceleration in what was already a fast-growing cost to the NHS, and one no longer driven by high inflation. Over the whole decade 1982-1991, the drugs bill rose by 39% in real terms.⁶⁶¹ Some reports even

⁶⁵⁹ *Scrip* No 1769, 10 November 1992, p.3.

⁶⁶⁰ Interview, DOH civil servant 27.

⁶⁶¹ *Scrip* No 1809, 6 April 1993, p.4.

suggested that the speed of growth was accelerating beyond 14% during 1992⁶⁶² and the rising drugs bill therefore stood out as exceptionally high.

There had already been some political focus on the rising pharmaceuticals bill, and attempts were under way to find some means of limiting it. As the negotiations approached, the NHS advisory committee on drugs was sitting to decide how the Selected List of medicines excluded from NHS reimbursement (Schedule 10) might be extended. Government's emphasis in the early 80s had been to cut the drugs bill by as much as possible, in a more general atmosphere of cuts and uncertainty in public services. The controversial Selected List had been introduced on this basis.

The large rise in the drugs budget – in both cash terms and as a proportion of the overall NHS budget – was, however, believed by the Department to be attributable to factors not directly affected by the PPRS. The rises were caused by two forces at work in the market: volume and 'product mix'. The Head of the Industry Division of the DOH, Melvyn Jeremiah, set out the results of the Department's research into the causes of the rising drugs bill, concluding that these were the two chief factors, with product mix the main driver of growth over a sustained number of years (see Table 4.2).

Table 6.2: Causes of medicine cost increases 1982-1992

	% average growth year-on-year	
	1982-92	1991-92
Pure demography	0.3	0.3
Scripts per capita (volume)	2.7	4.3
Quantity per script	1.1	2.8
Paasche (price of basket of drugs)	1.4	0.0
Product mix	5.5	5.5

Source: *Scrip*⁶⁶³

⁶⁶² *Scrip* No 1764, 23 October 1992, p.2; *Scrip* No 1823, 25 May 1993, p.2.

⁶⁶³ *Scrip* No 1858, 24 September 1993, p.5.

6.4.2 Implications for the PPRS

There was evidence that price increases played almost no part in the rise in the overall bill,⁶⁶⁴ and that 'trading up' to better products was a key factor.⁶⁶⁵ This was effectively accepted by the Parliamentary Under-Secretary of State for Health, Tom Sackville, in Parliament, who stated that the cost of existing medicines had risen by only 1% in each of the past five years.⁶⁶⁶ The ABPI later revealed prices in 1992 to have risen by just 2.5%, compared with a manufacturing industry average of 3.8% and a consumer goods average of 3.7%. The average annual rise for pharmaceuticals over the past five years had been just 2.6%.⁶⁶⁷

This analysis of prices and costs raised questions about the suitability of the PPRS to contain the drugs bill because one of its principle mechanisms of market manipulation is to encourage drugs companies to release new and better products onto the market so that they can recover their full profits allowance, with the prices of all existing products generally being static in nominal terms, and therefore decreasing in real terms.

Changes appeared to be emerging in features of the marketplace that had in the past enabled the government to achieve its dual aims and for a co-operative relationship between government and industry to persist: volumes were increasing rapidly and doctors were prescribing higher value (i.e. newer) drugs. The statistics showed that the influence of therapeutic conservatism on the value of the market was possibly diminishing, and this had historically imposed some control on the potential impact of new drugs released on the basis of free pricing.

⁶⁶⁴ *Scrip* No 1841, 27 July 1993, p.7.

⁶⁶⁵ *Scrip* No 1805, 23 March 1993, p.2.

⁶⁶⁶ *Hansard*, House of Commons, 24 March 1993, Col. 1213ff.; *Scrip* No 1809, 6 April 1993, p.4.

⁶⁶⁷ *Scrip* No 1882, 17 December 1993, p.5.

6.4.3 Government and the market

The inflation of the preceding decade was a major factor in the motives of the government for the negotiations. However, the senior civil servant responsible for them noted that there had not been a great deal of urgency about conducting the negotiations or expectations of radical reform. The new PPRS was a matter of normal business, with eight years having passed since the last scheme was drawn up.⁶⁶⁸

Government aimed to bring down the growth in the overall drugs bill through a one-off, across-the-board price cut. Cash savings could then be made instantly and calculated precisely, answering the government's immediate political concern of a saving in the short-term.⁶⁶⁹ The Treasury in particular perceived a need for some significant cost containment in the negotiations,⁶⁷⁰ even if the relationship between the PPRS (as a cause) and rising pharmaceutical costs as analysed was a tentative one. Furthermore, the analysis showed that the PPRS would be a blunt instrument with which to achieve savings, as the scheme has no direct controls over volumes and encourages a shift 'upwards' in product usage from the supply side.

From the government's perspective volumes were not as big an issue as product mix. Statistics in 1993 showed that the number of prescription items per person fell from four to three per year over the preceding decade for those of working age, although for the over 65s they increased from 13 to 19 per year. Overall, the rise represented demographic trends to some degree.⁶⁷¹

6.4.4 The position of industry

Industry could be seen as having gained from the growth in the market in preceding years. This served to weaken its negotiating position because it

⁶⁶⁸ Interview, DOH civil servant 27.

⁶⁶⁹ Interview, DOH civil servant 27.

⁶⁷⁰ Interview, Government minister 17.

could not claim that unexpected damage was being caused by the PPRS in practice. In addition, its bargaining power was qualified by the situation elsewhere and especially the proposals for cost containment in the US – the location of first resort for any investments that may be shifted from the UK. Showing a direct link between market conditions and incentives for R&D investment had been dealt a serious blow by these developments in America.

6.4.5 Imperatives for consensus

Despite its weaker position, the industry was not pushed into structural changes in the PPRS that would fundamentally have affected its regulatory goods because the DOH's agenda was broader and it recognised that the PPRS delivered the industry benefits without which it could not be expected to maintain the co-operative framework. Hence, there were some things that were not up for negotiation: freedom of pricing was regarded as a commercial necessity and as some compensation for the other restrictions.⁶⁷²

An important motive in not advancing proposals for structural reform that may have facilitated better cost containment initiatives was the government's industrial policy concerns. Despite the inflation in the sector and the measures being taken elsewhere, in the US and Germany, one industry negotiator noted that politicians were questioning their approach to the sector:

“In the mid-80s the industry fell below average industrial profitability in the UK and there was evidence that we had been quite seriously damaged by the preceding three years, following the introduction of the Selected List and this gave both government and the industry pause for thought: were we really a fat cat sector making huge profits? By the time of the 1993 PPRS negotiations, there was the first real attempt to ask the question of what damage a push for really cheap drugs for the NHS might have on the

⁶⁷¹ *Scrip* No 1882, 17 December 1993, p.5.

⁶⁷² Interview, industry executive 9

industry; and there was the first attempt to try to benchmark it to other industries with high R&D investment.”⁶⁷³

The government was concerned at what looked like a potential drift of the industry away from the UK.

“What the *companies* valued was freedom of pricing over new products and we needed to make sure we had a system that would make the pharmaceutical industry continue to feel that Britain was the place to be, as opposed to Germany, Holland, France, or anywhere else, many of whom were hotly contending our position [as the leading EU country for pharmaceutical R&D].”⁶⁷⁴

To this extent the 1993 PPRS marked some sort of watershed in government’s recognition of the economic value of the industry, which had in fact *formally* been a part of the scheme since the 70s.

6.4.6 Conclusions

The rise in drug costs was the most important contextual factor of the 1993 negotiations and the one that formed the basis of the government’s aims for the negotiations. Moreover, a key feature of the market – the therapeutic conservatism of GPs – had seemingly waned in the years preceding 1993, as the ‘product mix’ had driven inflation in the drugs budget. Yet the 1993 agreement did not threaten to undermine any of the key regulatory goods from industry’s point of view, although it did limit their freedom of manoeuvre through the reduction in the ‘MOT’. Profits would now be curtailed far earlier than previously once they rose above the target rate of return.

The agreement that was reached further emphasised the tendencies of the scheme. Downward pressure on existing drug prices but freedom of pricing for new products and it was welcomed by industry for increasing their

⁶⁷³ Interview, industry executive 9

⁶⁷⁴ Interview, Government minister 17.

manoeuvrability in their pricing strategies.⁶⁷⁵ The negotiations showed clearly that the benefits and costs of the scheme provided a balance that the ABPI accepted.

These changes in the scheme were not a direct attack on the causes of the rise in the medicines budget. “The critical question [for total drug costs] is consumption of pharmaceuticals in expenditure per head and the PPRS exerts no volume control whatsoever. The fact that the UK has quite low volumes has nothing to do with the PPRS; it’s due to medical culture and the structure of the NHS.”⁶⁷⁶ Indeed, the upshifting to more expensive products had suggested that one feature of the market that enables the PPRS – the conservatism of GP prescribing – might have been undermined to some degree and was a motivating factor behind the government’s desire for savings.

The PPRS did not deal with the underlying causes of costs but then it was attempting to achieve other aims as well, and in terms of costs the government’s horizon was a political and therefore short one. “I think there was recognition that the PPRS was not an appropriate tool to achieve a reduction in growth, more an opportunity to achieve a one-off reduction, to re-set the base line so that growth then resumed from a lower point,” noted a senior DOH civil servant.⁶⁷⁷ The DOH recognised that this was the only means of achieving savings while leaving key features of the market in place, and it had not contemplated any structural overhaul of the regulatory regime.

The PPRS can be seen as a significant tightening of some parts of the scheme and it included a price cut that was large in cash terms. But there were no changes in its broad structure nor, in particular, any threat of such changes. In this respect it remained similar to previous schemes. Neither the overall price cut nor the change in the MOT dealt directly with the causes of

⁶⁷⁵ *Scrip* No 1866, 22 October 1993, p.5.

⁶⁷⁶ Interview, DOH civil servant 27.

⁶⁷⁷ Interview, DOH civil servant 27.

growth in the drugs bill, but they sought to use the PPRS to redress these changes in the shape and cost of the medicines bill.

6.5 The global context

Assumption 2: The global organisation of industry lends it bargaining resources it would not otherwise have and makes government more alive to the need for an active industrial policy.

Hypothesis 2: Industry will seek to utilise its global structure as a bargaining resource to counteract the legal monopoly of government, which in turn will pay greater attention to their industrial policy aims.

In 1993 there were specific international dimensions to the context of the PPRS negotiations. Progress in the European single market had produced plans for the integration of medicines licensing within the EU, and member states were competing to host the new institution, which might have positive implications for the 'critical mass' of pharmaceutical interests in that country and was of great significance to the major companies.

At the same time, the issue of cost containment in health care had risen up the political agenda in the early 1990s across western countries, where demographic trends compounded by technological advance were pushing up costs quickly.⁶⁷⁸ There was widespread concern to check the rise in health care costs in all major markets. The shape of the industry was beginning to change as well, with a process of consolidation that looked set to reduce the number of large British firms.

6.5.1 Global industry and markets

The regulatory framework for medicine purchases is one of the factors determining where a pharmaceutical company locates its facilities (along with corporate, research, manufacturing and sales issues) and the warning from

industry that a hostile political environment would impact on pharmaceutical investment was taken seriously by the DOH: "The threat that worried me was if the climate in the UK became too hostile, or perceived as too hostile, then the industry would go offshore, primarily to the United States, but also elsewhere in Europe," noted a senior DOH politician of the PPRS negotiations.⁶⁷⁹

This attitude reflects the view of industry that there had been some re-thinking in government about the value of reigning in the drugs budget too much, at the risk of damaging the research-based industry. Nevertheless, the balance of advantage in 1993 lay with the government. The threat of relocation was necessarily based on comparative analysis of other markets and regulatory regimes and because the major markets of the US (see 6.5.2) and Germany were pursuing vigorous cost containment regimes, the potency of this key bargaining resource was diminished to a significant degree. This encouraged ministers to largely dismiss the credibility of the threat of disinvestment.⁶⁸⁰

The UK market was also growing, so could not be characterised by industry as suffering from undue cost containment pressure. Within Europe, the German and Italian markets actually fell in value during the first quarter of 1993, while growth in the UK market was relatively robust. The industry still employed this argument to some degree but recognised its limitations in the circumstances of 1993: the UK looked remarkably buoyant at a time when the situation in Germany, both the actual market and proposed legislation, was deteriorating (see Table 6.3).

⁶⁷⁸ Abel-Smith B. (1984); Mossialos E, Ranos C, Abel-Smith B (eds). (1994); Le Grand J, Mossialos E (eds). (1999).

⁶⁷⁹ Interview, Government minister 17.

⁶⁸⁰ *Scrip* No 1849, 24 August 1993, p.3.

Table 6.3: Growth in major European pharmaceuticals markets, 1993

	<u>Total purchases \$m</u>	<u>Growth % Jan-May 1993</u>
France	5,181	6.5
Germany	5,180	-11.1
Italy	3,704	-1.8
UK	2,045	11.6
Spain	1,996	13.6
Netherlands	666	13.4
Belgium	650	5.8

Source: *Scrip*⁶⁸¹

6.5.2 The global corporate structure

The 1993 PPRS negotiations appeared to mark a split between ABPI member firms along nationality lines, exacerbated by global corporate restructuring. Much had changed since 1986. The six large British firms had now become four through mergers and acquisitions. American companies were regarded as being less content with regulation and more vociferously in favour of commercial freedom than their European counterparts, which had grown up alongside public health care systems.⁶⁸²

To begin with, reaching a starting point for negotiations in 1993 was hindered by this factor: "The industry had problems having a consistent position. There was always a tension between the American companies and the European companies. Merck was at one extreme of the American companies, arguing that regulation was not just unnecessary but immoral!"⁶⁸³

The various groups of companies met to form their own policy position prior to organising their collective position under the ABPI. Government officials also met with them separately and knew something of what divided them within the ABPI. "We met the Americans as a group twice a year," noted a senior civil servant. They also visited headquarters of US companies in

⁶⁸¹ *Scrip* No 1844, 6 August 1993, p.6

⁶⁸² Interview, industry executive 3

America and met with the trade associations of Germany and Switzerland.⁶⁸⁴ Clearly, British officials felt that a new scheme could not be designed and agreed to without input from overseas head offices and associations, quite aside from the British divisions of American-based global companies.

It was clear to officials from these broad ranging discussions that sticking points in the negotiations would likely come from particular groups among industry's ranks: "We were conscious that there were things we had to do to meet the objectives of some of their constituent elements."⁶⁸⁵ And the ABPI itself had to balance the various parts of its membership. "They would have found it very difficult not to have a representative from an American company, and in fact they had two."⁶⁸⁶ As indirect pressure was applied by government through comments to the press before the negotiations began, a divided industry responded with a suggestion that the American multinationals may desert the PPRS, forcing a system of direct price controls.⁶⁸⁷

The role of foreign-based multinationals meant that the government felt the need to speak directly to senior executives abroad. DOH officials visited the US to explain their proposals for the PPRS and address any concerns.⁶⁸⁸ This shows the degree of understanding of the global nature of the industry on the part of officials, and although the American industry association, the PMA (now called PhARMA), criticised the PPRS as a whole and suggested it was counterproductive, there was, in the end, agreement on it.⁶⁸⁹

Despite the weaker position of industry, in part because of regulatory developments elsewhere, the scale of the industry and its international character did shape the government's strategy: the DOH was very keen to keep American CEOs on board.

⁶⁸³ Interview, DOH civil servant 27

⁶⁸⁴ Interview, DOH civil servant 27

⁶⁸⁵ Interview, DOH civil servant 27

⁶⁸⁶ Interview, DOH civil servant 27

⁶⁸⁷ *Scrip* No 1768, 6 November 1992, p.2.

⁶⁸⁸ *Scrip* No 1847, 17 August 1993, p.3.

⁶⁸⁹ *Scrip* No 1852/53, 3/7 September 1993, p.2.

6.5.3 Oversees policy

In 1993, there were particular events in some major markets that set an important context for the PPRS negotiations and the respective bargaining power of the two sides.

The interlinking of the British and other markets was specifically recognised by the Secretary of State. The use of Britain as a springboard for exports by the international industry was impressed upon the Department by the industry: "Certainly if a product was used within the NHS, that was an excellent basis on which they could advance their exports," noted a senior DOH politician. Implicitly recognised in this is the importance of getting to market quickly, a key aspect of the PPRS. Ironically, the negative developments in other countries was likely to make the large firms (at CEO level at least) more keen to get a favourable hearing in the UK.

In 1993 there was an additional dimension to the interplay of regimes. Aside from the direct effect of one system on another, multinational companies could see their position in one country as a way of offsetting a deteriorating position elsewhere. In 1993, the major market for all multinational companies, the United States, representing around 30% of the global market, was in the process of significant reform.

The Clinton administration in the US was seeking ways to limit medicine prices, as the publicly funded Medicaid (for the poor) and Medicare (for the elderly) health regimes faced the same sort of cost pressures as the universal European systems.⁶⁹⁰ The situation there was clearly important for all the major companies. Multinationals were keen to maintain their pricing freedom of new products in light of US downward pressure: the UK would become a more important example to other markets if lower prices were forced in the US.⁶⁹¹

⁶⁹⁰ For a critique of the Clinton health care plans see: Danzon, Patricia M. (1994).

⁶⁹¹ See *Scrip* No 1809, 6 April 1993, p.4.

Nevertheless, the international context gave government a stronger hand. Cost problems seemed universal and there had been recent downward pressure by public authorities in Europe, notably Germany (one of the less heavily regulated and higher-prices European markets), as well as the US.⁶⁹² This enabled the government to present the need for cost savings as a universal one while also enabling it to present the free-pricing-at-launch aspect of the PPRS as a significant 'cherry' in a seemingly hostile environment for the global industry.⁶⁹³

6.5.4 Conclusions

The global dimension of the industry had important contextual implications for the 1993 negotiations, primarily owing to its global corporate structure but also the way this interplayed with regulatory reforms in its many separate markets.

There were changes taking place in the corporate dynamics of the industry towards ever larger firms and a consequent shift in the corporate centre of gravity towards the US. The influence and attitude of American companies were noted by Department of Health officials, at a time when they were beginning to become more dominant than their European counterparts. There was a recognised need to take account of the international dimension of internal ABPI politics by the Department of Health and a recognition that reaching agreement with the big British companies did not necessarily mean reaching an agreement to which the ABPI could sign up. The structure of the industry clearly underpinned the government's industrial policy to an important degree.

Nevertheless, the international firms also recognised their weaker position because of events in their other major markets, especially the US where proposed cost reduction measures were being mooted. They did not have

⁶⁹² *Scrip* No 1841, 27 July 1993, p.4.

⁶⁹³ *Scrip* No 1849, 24 August 1993, p.2.

the bargaining power – in particular the solidity of reasoning – to back up the disinvestment argument. There was therefore an international policy dimension that worked in the government's favour.

Both these factors showed that even in 1993 (before the consolidations of the mid to late 1990s), global corporate factors changed the nature of bargaining between government and industry in an apparently insulated policy making arena such as the PPRS. Their negotiations were also affected by the international policy landscape to which industry participants were subject in their different markets. These did not directly affect the UK-based individuals involved in the negotiations but they did mean that if they were to call upon senior executives with a broader regional or global view, the situation in other countries would be an important point of argument not open to them this time round.

6.6 The co-operative state

Assumption 3: The 'liberal' nature of the British state means there is the desire by government for 'light-touch' and co-operative regulation using limited administrative, technical and legal resources.

Hypothesis 3: Policy proposals that require significant technical, administrative and legal resources on the part of government will not be pursued, in particular a legislative approach to regulation. They will seek maintenance of the co-operative regime.

The 1993 PPRS represents a reaffirmation of the PPRS system of regulation. The operating dynamics of the scheme remained the same: a scheme, or its replacement, that did require of the government increased technical, administrative or legal resources was not signed. Despite some significant changes on particular points, the 1993 scheme reads with very few distinctions from its predecessor.

The two parties in the negotiations set out to achieve their respective objectives, and greater regulation was certainly not something the industry aimed for. The government, on the other hand, had examined alternative options for regulating prices. It had done so in the light of its aim for the new PPRS to reduce the growth of the drugs bill.

6.6.1 Analysis of the problem

The government's examination of the market and regulation sought to analyse what was driving the growth in the bill. "We concluded from that that demography was a factor and drug prices were a factor but neither was a major factor. The main driver of the bill was the switch from older to newer

drugs.⁶⁹⁴ This was also something other countries, such as Sweden, had concluded from their own research.”⁶⁹⁵ The industry for its part drew attention to data which suggested that actual prices had been rising by less than inflation, at 1.9%.⁶⁹⁶

Evidence therefore suggested that tighter regulation, or differently focused regulation, was the only way to solve the problem and strike at the growth in the medicines bill at its cause. Any bearing down on the growth of the drugs bill would be difficult, and at least indirect, through the limit on companies' ROC. New drugs are capital intensive and this would likely be reflected in the overall drugs bill.

6.6.2 Assessment of the government's options

Those in government responsible for the negotiations agreed with this analysis. “At that time we were looking at other mechanisms of controlling the drugs bill such as GP fundholding and other demand side measures; the PPRS is largely irrelevant to the growth in the drugs bill and this was not our aim in renegotiating it.”⁶⁹⁷ The traditional one-off price reduction would reduce the bill over the short-term, and re-set the trajectory of growth, but would not contain its growth. However, stricter supply side regulation was not considered in any detail. The government had no intention of going down the continental route of directly regulating prices but rather of containing costs by emulating a normal market through limits on demand.

The growth in the overall bill, according to the ABPI, was due to the success of the Department's policy of encouraging primary care solutions (GPs) in place of secondary care (hospitals),⁶⁹⁸ and this, again, was identified by Tom

⁶⁹⁴ This switch to more expensive products is often referred to as the effect of 'product mix' on overall costs.

⁶⁹⁵ Interview, DOH civil servant 27

⁶⁹⁶ *Scrip* No 1776, 4 December 1992, p.3.

⁶⁹⁷ Interview, DOH civil servant 27

⁶⁹⁸ *Scrip* No 1776, 4 December 1992, p.3.

Sackville, Parliamentary Under-Secretary of State for Health, as a major contributory factor to increased drugs costs.⁶⁹⁹

Other options were looked at in the run-up to the negotiations that might perhaps have controlled prices in a more structured and longer term way. "We did consider 'radical options', including statutory price controls, but all these were dismissed quite early on. They were never really given serious, detailed consideration."⁷⁰⁰ This suggests that greater regulation was not considered realistic by the civil servants who prepared the ground for the negotiations. "While deregulation was not an option, we were in the Thatcher/Major era where regulation was not fashionable, so the idea of more explicit regulation wasn't attractive at all."⁷⁰¹ The status quo therefore stood out as the option that would not require deeper regulation but would keep some basic mechanism of control in the government's hands and achieve a saving in the short-term. This arbitrariness was appreciated at the highest level. "Any price mechanism was only a proxy. It had to be invented because there was insufficient price pressure in the system. In this case, the PPRS just appeared to be the least worst option."⁷⁰²

So government saw the PPRS as a means of saving money and bringing some pressure into a market where normal price pressures are absent. It did not see it as a scientifically proven approach to regulation but as a pragmatic response to its circumstances.

6.6.3 The bargaining process

The negotiating 'resources' of each side, which have reinforced the nature of the policy community through the PPRS, were employed to some degree. Industry had suggested, both directly and through the press, that investment would suffer if profits were squeezed.⁷⁰³ It repeated this claim after the

⁶⁹⁹ *Hansard*, House of Commons, 24 March 1993, Col. 1212-3; *Scrip* No 1823, 25 May 1993, p.2.

⁷⁰⁰ Interview, DOH civil servant 27

⁷⁰¹ Interview, industry executive 9

⁷⁰² Interview, Government minister 17

⁷⁰³ *Scrip* No 1773, 24 November 1992, p.2.

agreement was signed, protesting at the 2.5% price cut to which it had in any case acquiesced.⁷⁰⁴ The industry had highlighted its economic contribution and figures showed that the trade surplus for the industry was up by 15% in 1992, further above inflation than the rise in the NHS's pharmaceutical bill.⁷⁰⁵ Nevertheless this argument was muted by cost containment measures being pursued in precisely the country normally referred to as more favourable to the industry, the US, as well as another less regulated EU market, Germany. The department had openly dismissed this argument as "empty threats", reflecting their confidence in the relative benefits of the UK system as a whole.⁷⁰⁶

For its part, the government had in fact hinted at the idea of further regulation. During the negotiations, at a conference held by the Adam Smith Institute in May,⁷⁰⁷ the Head of the DOH's Industry Division, Melvyn Jeremiah had alluded to the idea of some economic evaluation of medicines prior to the Department's agreement that they would be available on the NHS. This followed similar moves in Australia and was a timely suggestion given that negotiations were underway on the PPRS. He suggested, however, that this sort of framework would not be possible alongside the PPRS, reinforcing the value of the scheme for industry. He valued the voluntary nature of the PPRS but added that if it did not exist some other control – likely European style direct price control – would be necessary to keep the drugs bill in check. The timing and occasion was a clear attempt to push industry to agree a new scheme at a time when negotiations were dragging.⁷⁰⁸ Such a process of assessment for medicines would undermine a central benefit (perhaps *the* key benefit) of the PPRS for industry, namely speed to market following authorisation from the MCA or EMEA. Requiring an economic assessment would mean a further hurdle would have to be passed before medicines could be marketed to the NHS.

⁷⁰⁴ *Scrip* No 1851, 31 August 1993, p.2.

⁷⁰⁵ *Scrip* No 1777, 8 December 1992, p.10.

⁷⁰⁶ Interview, DOH civil servant 27

⁷⁰⁷ Adam Smith Institute (May 1993).

⁷⁰⁸ *Scrip* No 1823, 25 May 1993, pp.2-3.

Nevertheless, neither side pushed these arguments to a point of overt confrontation – they had more the character of shots across the bows of the other party.

The government had already introduced demand side measures which would not only target more precisely overall costs but which emulated a more 'normal' market. The PPRS was understood to affect the nature of the market in a positive way but also to have quite a limited effect on overall costs. In the end, the government declined to pursue radical options more because it did not feel the need than because it was restricted in doing so. It dismissed tighter control early on and actively sought to continue the co-operative framework of regulation.

6.6.4 Desire for co-operation

The limitations of the PPRS were recognised. One industry negotiator noted: "What government wanted was some certainty about the drugs bill – they wanted their hand on the tiller. But the UK is a capitalist country and the Conservative government had a free market philosophy. They wanted maximum freedom for industry." The PPRS was seen as a bespoke system suited to the British bureaucracy, government and industry: "The profit ceiling is this light touch on the tiller. It doesn't really matter if you lose some on the swings and gain some on the roundabout. It's a very pragmatic, flexible and commercial approach – a very British way of doing things."⁷⁰⁹

Equally, what the government sought to avoid, the industry source believed, was excessive bureaucracy, and they were quite open with industry about that: "Successive civil servants from the industry division have said to me that they run the PPRS with a handful of people and if you look at the bureaucracy that's required in other countries you've got vast hordes of people administering the regulation."⁷¹⁰

⁷⁰⁹ Interview, industry executive 9

⁷¹⁰ Interview, industry executive 9

And the voluntarism of the PPRS created conditions within which the two sides could co-operate on areas other than purely supply side controls. ABPI-DOH working groups were set up during the negotiations of the PPRS to look at the drugs bill as a whole and the use of medicines in health care.⁷¹¹ With an adversarial, statutory regulatory regime, such broader co-operation would be much more difficult, if not impossible. Both government and industry conducted the negotiations on the basis that the voluntary framework was the best one for both sides.⁷¹²

6.6.5 Conclusions

Analysing the complexity of price controls in the sector, given the quite fundamental nature of growth in the drugs bill (demography and technology), government realised it would have to overhaul the PPRS to have any significant effect through its supply side controls, which it was not prepared to do. It recognised that the PPRS was a 'proxy' for intervening into a flawed market. The lead negotiator suggested that the purpose of the PPRS was in fact extremely limited: "Essentially it's a comfort blanket for the government. It provides a framework which allows them some possibility of preventing serious abuse by companies of what is actually quite a powerful position."⁷¹³

The 1993 PPRS did not aim for or deliver any radical change in the PPRS. Other aspects of pharmaceutical regulation were being pursued with more vigour, and were expected to yield some savings in pharmaceutical expenditure.

Radical reform was dismissed early on in favour of voluntarism and co-operation. From start to finish the government had stated its support for continuing voluntary arrangements in the PPRS. Even prior to the negotiations, the Secretary of State had expressed support for the current

⁷¹¹ *Scrip* No 1796, 19 February 1993, p.5.

⁷¹² *Scrip* No 1778, 11 December 1993, p.4; *Scrip* No 1805, 23 March 1993, p.2.

⁷¹³ Interview, DOH civil servant 27

arrangement and had extolled the virtues of the industry.⁷¹⁴ She aimed to maintain the pragmatic and commercially focused structure of the PPRS.

The government did aim to cut the drugs bill and re-base it but did not intend to introduce any changes that would restructure the scheme. During the negotiations, the ultimate bargaining resources of each side – disinvestments and legislation – were hinted at and drawn attention to but not seriously pursued by the negotiating parties. The maintenance of the co-operative relationship proved to be a primary *regulatory good* and a *core value* of the relationship between government and industry.

⁷¹⁴ *Scrip* No 1774, 27 November 1992, p.2; *Scrip* No 1778, 11 December 1993, p.4.

6.7 The role of Parliament

Assumption 4: Parliament has a peripheral role in this policy field and does not constitute a veto point or external influence on the policy community.

Hypothesis 4: Parliament will not be an influential actor in determining policy outcomes, which in turn will be reflected in the limited direct attention to it by both government and industry.

In the first half of 1993, Parliament seemed to have been given an uncommonly prominent role in the pharmaceutical sector. A Private Members Bill on consumer information about medicines had gained government backing and was doing rather well;⁷¹⁵ the Selected List extension was being discussed through an Early Day Motion; and there was a debate on NHS medicine costs, through the Adjournment Debate procedure. The PPRS was also being renegotiated and there was the possibility that the interest of MPs in NHS medicines might spill over from one of the other areas and precipitate a discussion of the scheme.

6.7.1 Parliament and the negotiating agenda

During the latter part of the operation of the 1986 scheme, the PPRS was the subject of several questions in the Commons. Most of these requested specific financial information about the scheme, including the value of sales required by a company for it to become liable to submit a full AFR⁷¹⁶ (a key issue as this was changed markedly in the 1993 scheme), money repaid to the Department under the scheme,⁷¹⁷ and the level of price increases on

⁷¹⁵ Private Members Bills are notoriously unsuccessful. They rarely succeed without gaining the support of the government and, with it, a greater allocation of parliamentary time.

⁷¹⁶ House of Commons, Written Answers, 5 February 1992, Column 208; Mr. Sims to Secretary of State for Health.

⁷¹⁷ House of Commons, Written Answers, 19 December 1991, Column 225; Mr. Speed to Secretary of State for Health.

pharmaceutical products over recent years.⁷¹⁸ This revealed annual increases of 1.9% and 2.5% respectively for the years 1989 and 1990, highlighting the difference between price increases and the growth of the overall pharmaceutical bill of 12-14% a year.

Another question about the scheme, in July 1991, sought to decipher its effects on the total drugs bill. The question and reply illustrate both the complexity of the scheme regarding its ability to achieve its goals (or, rather, to assess what these are), and the concerns of many MPs about its lack of transparency.⁷¹⁹

Mr. Michael Morris [MP]: To ask the Secretary of State for Health what is the impact on (a) profitability of pharmaceutical companies supplying medicines to the national health service and (b) the national health service drugs bill of the pharmaceutical price regulation scheme.

Mrs. Virginia Bottomley [Minister of State]: The pharmaceutical price regulation scheme seeks to strike a balance between securing the supply of drugs to the national health service at an acceptable cost to the taxpayer and offering pharmaceutical companies a reasonable level of profitability on their NHS sales.

It is not possible to estimate the impact of the PPRS on companies' profitability or the NHS drugs bill since that would depend on what the level of drug prices might be or what other expenditure controls might exist in the absence of the agreement.

Many such questions could be seen as 'setting the scene' for the later negotiations, from one point of view or another, but none can be regarded as having 'set the agenda' for the government's negotiating position. Requests for some details, where MPs would likely have known the commercial confidentiality of such information under the scheme, were seemingly aimed

⁷¹⁸ House of Commons, Written Answers, 25 July 1991, Column 905; Mr. Michael Morris to Secretary of State for Health.

⁷¹⁹ House of Commons, Written Answers, 15 July 1991, Column 63.

at drawing attention to its lack of transparency. No major debate on the scheme took place in its own right in the time preceding the negotiations.

There was one source of parliamentary pressure on the negotiations – the planned Health Select Committee enquiry into the drugs budget. This was intended to look at the efficiency and effect of measures designed to control the drugs bill.⁷²⁰ It would examine the causes of the rise in the drugs bill and the continued upward pressure on it, comparing it to other countries. It would also look at the role of government in controlling drug costs.⁷²¹

It would not begin sitting until after the new PPRS was signed but it represented a clear role for Parliament in judging measures across-the-board, including the PPRS, and would entail a thorough examination of the scheme, primarily from the taxpayer's perspective. This forthcoming enquiry therefore represented a background factor in the agreement on the new scheme, especially for industry, which might be worried by the approach to be taken by the committee.

6.7.2 Parliament and the negotiation process

The concurrent pharmaceutical discussions meant that Parliamentarians and industry representatives were already in contact during the PPRS negotiations. In particular, there was continued discussion of the Selected List, which led to a "barrage of parliamentary questions" directed at both the DOH and the DTI in this regard.⁷²² There was also a debate specifically on overall NHS drugs costs, again inspired from the backbenches.

These three legislative events created opportunities to question the government, in addition to departmental questions, about the PPRS, on which there was no specific debate:

⁷²⁰ *Scrip* No 1841, 27 July 1993, p.6.

⁷²¹ *Scrip* No 1847, 17 August 1993, p.4.

⁷²² *Scrip* No 1776, 4 December 1992, pp.3-4.

- The Selected List extension: Early Day Motion, James Couchman MP; 26 July
- NHS drugs costs: Adjournment Debate, Andrew Hunter MP; 24 March
- The Medicines Information Bill: Private Members Bill, Giles Radice MP; debated 15 January and 30 April

The Selected List Early Day Motion

The Selected List early day motion provided the most extensive period of debate on pricing and cost issues, lasting about 90 minutes. Questions were tabled about the details of the government's position in the negotiations. The confidential nature of the negotiations meant that these were not answered fully in ministerial replies.⁷²³

The accountability and transparency of the scheme were criticised in the Commons. "There is more openness in debates on defence contracts than on (pharmaceutical) price regulation," noted one opposition MP in the summer of 1993.⁷²⁴ Specific elements of the scheme were criticised during the period of the negotiations, such as the promotional allowance and clinical surveillance, which was characterised as promotion in disguise:

"The industry has been able to extend the parameters of its research and development bill by considering what it provides in post-marketing surveillance. The Government have allowed the industry to develop this area to the point where it is no more than promotion masquerading as research. We must consider the limits on advertising and promotion to see how effective they are and whether this method of securing the support of GPs is the best for the health service and patients."⁷²⁵

⁷²³ House of Commons, Written Answers. See 11 January 1993, Column 611-12; 27 October 1993, Column 694-5. Mr. Blunkett; reply from Minister of State, Mr. Mawhinney.

⁷²⁴ *Hansard*, House of Commons, 26 July 1993, Column 958; Mr. Ian McCartney.

⁷²⁵ *Hansard*, House of Commons, 26 July 1993, Column 959. Mr. Ian McCartney.

NHS Drugs Costs Adjournment Debate

The most significant role for Parliament was through the adjournment debate on the NHS drugs bill, as this was introduced to enable a few MPs to present the case in favour of a rising drugs bill – in large part in response to the Selected List proposal but also in the context of the PPRS negotiation. However, the form of this debate meant that it was extremely restricted.

Aside from MPs pointing out how the PPRS gave the industry ‘too good a deal’ from the NHS, many MPs sought to explain rising costs in broader medical and health care terms, and avert a harsh PPRS settlement. This had been the purpose of Andrew Hunter’s debate and he proposed that the basic reason for the rise on the overall drugs bill was the shift from secondary (hospital) to primary care.⁷²⁶ This point was also emphasised during the Selected List debate on 26 July, by Roger Gale MP.⁷²⁷ It was an important point for the government, as their aim of transferring demand from secondary to primary care was a key part of their strategy for the NHS in order to contain overall health costs.

An incompatibility of the Selected List with the PPRS was raised here. The more significant debates on the Selected List provided an opportunity for MPs to express opinions about the relationship between the industry and the NHS, and the concurrence of the PPRS negotiations meant that there was some interlinking of the two in this arena, albeit having little effect on their separation in discussions between industry and the Department.⁷²⁸

Medicines Information Bill

The Medicines Information Bill, a Private Members Bill sponsored by Labour MP Giles Radice,⁷²⁹ was a more curious vehicle for PPRS issues. There was

⁷²⁶ *Hansard*, House of Commons, 24 March 1993, Column 1212.

⁷²⁷ For example, Mr. Roger Gale, *Hansard*, House of Commons, 26 July 1993, Column 956

⁷²⁸ *Hansard*, House of Commons Debates. See 15 January 1993 Col. 1218-1231; 24 March 1993 Col. 1211-1217; 26th July 1993 Col. 948-968.

⁷²⁹ *The Lancet* (8 May 1993), p.1219.

little direct overlap between pricing and cost issues and the proposals in the Bill about information on clinical trials. Yet the timing made it an important test for the relationship between government and industry. Having been thought likely to make the statute book by securing government backing, the Bill eventually failed through lack of time. It was suggested at the time by Labour MP Ian McCartney that this was part of a direct trade-off with industry on the PPRS negotiations.⁷³⁰

6.7.3 Parliament and industry lobbying

During the run up to the negotiations, lobbying by industry was directed to the executive. But attention was drawn to the strength of industry's lobbying of Parliament by the sudden exit of the Medicines Information Bill, during the PPRS negotiations. Although opposition MPs accused the government and the industry of having colluded, the 'filibuster' in Parliament required the tabling of 70 amendments by a large number of Conservative MPs – evidence of a significant lobbying ability on the part of industry, if the Labour accusations were true.⁷³¹

In the debate secured by Mr James Couchman MP on the 26 July (ostensibly on the proposal to extend the Selected List), he sought to argue against the significant extension of the Selected List, representing industry's views as a declared adviser to Pfizer. He suggested that the PPRS and the Selected List were incompatible as cost containment measures (it had been argued by industry that companies could return to their profit ceilings in the months following a Selected List extension by releasing new drugs. The cost containment was therefore only short-term). He also argued that medicines expenditure represented a cost saving to the NHS through reduced hospital expenditure, in cases such as stroke prevention and diabetes treatment.⁷³²

⁷³⁰ *Hansard*, House of Commons Debates, 30 April 2003 Col. 1322. Mr. Ian McCartney

⁷³¹ *Scrip* No 1818/19, 7/11 May 1993, p.2.

⁷³² *Hansard*, House of Commons, 26 July 1993, Columns 952-3.

The continued pressure in Parliament was a reflection of what was happening behind the scenes between the industry and the government, and served as an additional pressure point to influence the government's position. In this sense, the disquiet over the Selected List meant that the government had to be less severe with the concurrent PPRS than it might otherwise have been. And it was in the debates over the Selected List that Parliament gained a significant role: this was a serious issue for their constituents who received prescriptions of drugs that were about to be delisted from NHS funding. Indeed, it came "a close second to the issue of sub-post offices in the postbags of hon. Members" in the Commons.⁷³³

The PPRS had no direct constituency angle other than the overtly industrial one and without the broad base of appeal it was not an issue on which Labour MPs were likely to persist in exerting pressure. On the other hand, opposition MPs could more or less side with the industry view on the Selected List because it was seen to directly affect their constituents in a way that the PPRS did not. Questions were tabled enquiring about representations made by industry to the government about the PPRS,⁷³⁴ and in this sense lobbying itself became a minor issue of discussion. But while there was a clear base for co-operation between MPs and the industry on the Selected List, the PPRS has implications for pricing and investment and support was bound to be narrower. Indeed, it was MPs with investments in their constituencies that were most active on these sorts of questions.

6.7.4 Conclusions

Parliament played a role in the 1993 PPRS negotiations but it was certainly peripheral. Questions were raised about the PPRS, in part to draw attention to its lack of transparency (something the committee would later criticise) and accountability, though none of the questioning can be said to have set the agenda for the negotiations. Industry was able to highlight its concerns

⁷³³ Mr. Ian McCartney MP. *Hansard*, House of Commons, 26 July 1993, Columns 959.

⁷³⁴ House of Commons, Written Answers. See 11 January 1993, Column 611-2; 27 October 1993, Column 694-5

through its supporters in Parliament, who were sufficient to secure a debate on issues important to industry but the PPRS was the least important of all the issues that presented themselves to industry during 1993 and the one where there was least direct constituency interest to command MPs' attention and MPs did not demonstrate a sound knowledge of the scheme.

All of these debates drew attention to the PPRS and some explicitly questioned its effectiveness and its compatibility with other areas of regulation. However, there is little evidence from the debates surrounding the Selected List extension, the Medicines Information Bill and the various questions relating to the PPRS that ministers were particularly put on the spot by parliamentary questioning and there is little evidence of points being raised in the industry's favour regarding the PPRS by MPs lobbied by their representatives. The confidentiality of the scheme and the primacy of the role of the executive left little scope for effective parliamentary intervention, in either direction.

Indeed, the DOH said so explicitly: "I received very little pressure from Parliament for the scheme to be reformed. There was *some* pressure about openness of information and a few other matters but I cannot say this was a huge issue on my agenda."⁷³⁵

Government-industry relations appear to have enabled Parliament to be bypassed and a deal possibly done over the PPRS and unconnected legislation in Parliament. Support for the private members bill may have been withdrawn following direct industry-government contacts over the PPRS.

Ironically, given that it would be at least five years before the next PPRS negotiations, Parliament was about to acquire an explicit and central role in assessing the value of the PPRS through the Health Select Committee report.

⁷³⁵ Interview, Government minister 17

Given the limitations on Parliament's role, the effectiveness of industry's lobbying of Parliament is not easy to judge, precisely because of the close relationship between industry and the executive. But 1993 can be seen as having set up a model for industry lobbying, around two principles: linkage and supplementary pressure. By chance, the PPRS was linked in with an issue that was extremely important for the public and therefore MPs, and industry found itself on the same side as the Labour opposition on the Selected List issue. It also showed that industry believed exerting additional pressure to that which was being placed directly on the government was of some use, and the discussion in Parliament of the PPRS showed that this obscure subject could be brought before MPs through their contacts in Parliament, even if they cannot be said to have constituted a veto point in the reformulation of the scheme.

6.8 Role of the Department of Health

Assumption 5: The siting of an industrial policy function within the Department of Health gives DOH authority and competence to act and highlights the government's industrial policy aims, enabling a co-operative regime.

Hypothesis 5: The dual role of the DOH will prove decisive in defining policy and maintaining the co-operative regime by counteracting the procurement focus of the Treasury.

The negotiation of a new scheme in 1993 had important implications for the role of the Secretary of State for Health. It was a time of increased cost pressures on European health systems generally, yet there was also recognition of the need to address the concerns industry had about its regulatory environment. The context of the time therefore seemed to suggest that the dual role of the Department of Health for procurement and sponsorship was particularly apposite.

During the 1993 negotiations the Secretary of State stressed, both privately and publicly, the need to value the pharmaceutical industry for its scientific and commercial success, not least its success as an export earner for UK plc.: "I took seriously the view that the pharmaceutical industry is one of the most creative success stories for the UK."⁷³⁶

That the balance to be struck was recognised at the top of the Department was not in doubt: "I wanted to get, as it were, our pound of flesh for the government but I was always worried that we would go just a step too far and result in a situation where Britain stopped being the place that

⁷³⁶ Interview, Government minister 17

pharmaceutical companies wanted to be.”⁷³⁷ What is not immediately clear is whether a Secretary of State would continue to have that balance of approach without it being his or her overt responsibility to do so.

6.8.1 The EMEA campaign

The broad role played by the Secretary of State was demonstrated during 1993 by the campaign to win the EU’s new joint licensing body, the European Medicines Evaluation Agency (EMEA). The government campaigned vigorously for the new agency to be sited in London, which it eventually was. The new EU-wide authorisation procedure that would be administered by the EMEA would streamline the licensing of new products and was directly applicable to all EU member state’s markets. In terms of industrial ‘critical mass’, the siting of the EMEA in the UK would undoubtedly strengthen the position of the industry here.

The Secretary of State for Health was responsible for promoting Britain’s case and through this she gained knowledge of the international dimensions of the global pharmaceutical industry. The campaign was one which “occupied a lot of my time and to which I devoted a lot of energy”, according to a senior DOH politician.

The EMEA campaign broadened the understanding of the Secretary of State for Health of the industry and its operations beyond its relationship with the NHS. A great deal of communication with industry on the EMEA issue resulted in her gaining a broad perspective on its global organisation and where the UK stood in it. “Winning the EMEA for London was a great opportunity. The large pharmaceutical companies have a base in the States, a base in Japan and somewhere in Europe; EMEA went a long way to making sure that Britain would be the somewhere in Europe.”⁷³⁸

⁷³⁷ Interview, Government minister 17

⁷³⁸ Interview, Government minister 17

Given that the PPRS negotiations were almost simultaneous, the EMEA campaign served as a timely instruction in the international nature of the industry and its complex regulatory interests ahead of her involvement in this area of purely domestic policy. Furthermore, as sponsor, the Secretary of State was directly involved in export promotion for the industry and travelled extensively for this purpose.

6.8.2 The sponsorship role

In addition to the EMEA campaign, the global nature of the industry and its location strategies would be impressed on politicians by the close involvement in their affairs through the sponsorship function. Aside from the discussions surrounding the EMEA, the Secretary of State was involved, as sponsor, in commercial promotion abroad. "I made a number of export visits overseas, to Russia, Hungary, Thailand, Malaysia, Australia, Hong Kong, the United States – and I thought that was an appropriate role."⁷³⁹ The commercial promotion served to reinforce in the minds of responsible ministers and the Secretary of State the broader context of the industry and its interests beyond its relationship with the NHS. As industry sponsor, the Secretary of State made herself available to discuss the bigger contextual issues with senior executives throughout the period of the negotiations, gaining an appreciation of their views.⁷⁴⁰

Had the sponsorship function been the responsibility of the Secretary of State for Trade and Industry, the focus of the top of the DOH would not have been subjected to some of these other issues and dimensions of pharmaceutical policy, quite aside from the particular aims of the PPRS.

6.8.3 Departmental interests

Sure that the PPRS as a framework sufficiently defended and promoted the interests of industry, the principal aims of the government in the 1993

⁷³⁹ Interview, Government minister 17

⁷⁴⁰ *Scrip* No 1803, 16 March 1993, p.4.

negotiations were explained thus by the senior negotiator, head of the PPRS Branch:

“There were three objectives: one was the bureaucratic objective, to streamline the scheme and to clarify some of the definitions and make it work better; the second objective was the Treasury objective – to find some savings; and the third was the DTI objective, which was to maintain good relations with the pharmaceutical industry – and that was a Department of Health objective as well. The first of these – the bureaucratic objective – was the main aim of the Department of Health for its own sake; the second objective is obviously something imposed on us from the Treasury and the third objective was a direct concern of both ours and DTI’s.”⁷⁴¹

The various objectives are identified here as belonging to each of the three departments with an interest in the outcome of the negotiations – illustrating the effect of the dual role on the DOH as one which gives it an overview of all of the government’s aims. There is an implication here as well that the sponsorship role’s residing in the DOH does not mean the DTI disappears from the picture – it still has an objective and an interest in the PPRS. Furthermore, the “DTI objective” is explicitly referred to by the senior civil servant as an objective of the DOH, while the “Treasury objective” is not.

6.8.4 The nature of the DOH

Another important aspect of the sponsorship debate is to what extent it changes the nature of the Department of Health itself, quite aside from the strength or weakness of the DTI and its likely ability to influence DOH/Treasury discussions. In 1993 the pharmaceutical industry was far from universally liked within the wider DOH. “It was easy and fashionable for health people to take the view that the pharmaceutical industry were fat cats creaming off profits from exploiting innocent patients,” noted a senior politician.⁷⁴²

⁷⁴¹ Interview, DOH civil servant 27

Through the dual role of the DOH, the procurement and industrial policy aims of government are unified far earlier in the policy process, at the sub-departmental level, rather than inter-ministerially as would otherwise be the case. The head of division within the Department of Health has overt and formal responsibility for unifying these two objectives before policy proposals are put to ministerial examination. “There is merit in civil servants, even behind Chinese walls, being aware of the range of issues that are affected in a single area of policy,” noted a senior politician. And the situation seemed to improve: “Gradually the status and recognition of that function within the Department of Health increased, although it was something of a battle.”⁷⁴³

The makeup of the wider department is crucial to judging the likely effect on policy outcomes if the sponsorship function were removed: “Other areas of the Department tended to be very suspicious of the pharmaceutical industry – they were far more focussed on value for money in the NHS – but it was an objective that ministers had,” said a senior civil servant.⁷⁴⁴

6.8.5 The role of the DTI

There is evidence that the role of the DTI was important in the 1993 negotiations even with its limited role. The DTI bolstered the arguments of the DOH in exercising its sponsorship function:

“I persuaded Michael Heseltine [Secretary of State for Trade and Industry] to write me a letter accusing me of being too brutal with the industry, because I really was worried that if I was asked to take even more out by the Treasury that it would actually damage the industry. Michael Heseltine duly wrote this letter, which got circulated to all departments in Whitehall, suggesting that Mrs. Bottomley was being *ruthless* to the industry – ruthless and reckless! Then the Treasury backed off and decided that I was just to settle.”⁷⁴⁵

⁷⁴² Interview, Government minister 17

⁷⁴³ Interview, Government minister 17

⁷⁴⁴ Interview, DOH civil servant 27

⁷⁴⁵ Interview, Government minister 17

For the most part, it seems that industry spokespersons regard the DOH's role as having been significant in the 1993 negotiations. One industry spokesperson noted that "Every time the government is horrible to us some argue that the DTI would be a more effective sponsor," and that the PPRS negotiations are bound to be a time of relative tension. There can be a tendency then for some within the industry to object to the role being placed with DOH. But the alliance between the Department of Health and DTI seen in 1993 is one that is based on the DOH having this role. Without it, the same industry source maintains, "There would be no bar on the Department of Health following normal government procurement rules and driving the lowest possible price they could."⁷⁴⁶

Industry did use the DTI as a 'back door' to the DOH regarding the PPRS. The ABPI had expressed concern to the DTI about the 'export disincentive' in the PPRS and a new interdepartmental group focused on exports was set up under the auspices of the DTI to look at export promotion in industries not sponsored by the Department, including pharmaceuticals.⁷⁴⁷ So where direct DTI concerns were at issue, foremost exports, the industry could rely on some DTI representation within government.

If the DTI played some active role in the 1993 negotiations, under its limited remit, then the sponsorship role of the DOH can be seen as an additional source of industry support within government rather than an alternative one. The real importance of the role of the DOH is in the balance of power that exists between these three departments. "The most difficult negotiations were within government, not between government and the pharmaceutical industry, and the key player in our interdepartmental steering committee was the Treasury."⁷⁴⁸

⁷⁴⁶ Interview, industry executive 9

⁷⁴⁷ *Scrip* No 1776, 4 December 1992, p.4.

⁷⁴⁸ Interview, DOH civil servant 27

6.8.6 The role of the Treasury

The key relationship according to commentators on both sides is between the DOH as a procuring department and the Treasury. “The real warriors were the Treasury, who always, whatever the outcome was, wanted another 5%. Whatever happened, the Treasury were always greedy and never satisfied; they never congratulated you,” noted a senior DOH politician.⁷⁴⁹

The recent history of pharmaceutical expenditure would ensure that the Treasury had a significant part to play in the negotiations about the PPRS within government: “The growth in the drugs bill of 12%+ rang alarm bells in the Treasury, where expenditure changes are always incremental,” said a senior civil servant.⁷⁵⁰ He also suggested that the PPRS was an important piece of regulation for the Treasury, representing a large chunk of public expenditure. They devote significant effort to its renegotiation.⁷⁵¹

The Treasury could interfere in the various elements of a department’s budget and nowhere more so than in areas such as the pharmaceutical services within the NHS. “The Treasury always made other matters within the departmental budget conditional on taking an arm and a leg out of the pharmaceutical budget, noted a senior politician.⁷⁵² A senior civil servant explained its importance for the Treasury: “Aside from social security, this is probably the biggest chunk of government expenditure that was, at the time, demand led rather than cash limited and the Treasury were very hands on.”⁷⁵³ Indeed the Treasury, in the shape of Treasury Secretary Michael Portillo, had fired a shot across the bows of the industry in a public pronouncement about the rising drugs bill, prior to the 1993 spending review and during the PPRS negotiations.⁷⁵⁴

⁷⁴⁹ Interview, Government minister 17

⁷⁵⁰ Interview, DOH civil servant 27

⁷⁵¹ Interview, DOH civil servant 27

⁷⁵² Interview, Government minister 17

⁷⁵³ Interview, DOH civil servant 27

⁷⁵⁴ *Scrip* No 1795, 16 February 1993, p.2.

The power of the Treasury is the key factor in the judgement of industry commentators that the DOH is the most beneficial place to site the sponsorship function. "Ultimately the government's position has to be agreed by ministers, which effectively means the Secretary of State for health and the Chancellor, but the Chancellor is always more important than the Secretary of State for health, and so he effectively had a veto."⁷⁵⁵ Despite the presence of DTI in policy making groups that discussed the PPRS, the key bargaining with government was between Health and Treasury and the importance of the sponsorship function arises because without it Treasury pressure would meet little resistance.

Both the chief civil servant in the Department of Health and the Secretary of State noted that the key sticking points in government's internal decision making process occurred because the Treasury insisted on a higher level of savings.

The Treasury's influence meant that the price cut was one of the more important parts of the agreement for government as a whole and this was communicated to industry, albeit indirectly: "We didn't start off negotiations by saying we are looking for savings of 200 million or whatever. We went in saying that our objective is to improve the operation of the scheme but implicit in that was that we would also be saving a lot of money for the Treasury."⁷⁵⁶

6.8.7 Conclusions

The progress of the negotiations and the contextual events of 1993 suggest that the sponsorship role of the DOH was central to the outcome of the scheme. The Treasury in 1993 was particularly vociferous in seeking a saving on the pharmaceutical budget, which they saw as rising far too quickly. The focus of the Secretary of State for Health on non-procurement issues appears to have been decisive in her pursuit of a 'fair deal'.

⁷⁵⁵ Interview, DOH civil servant 27

⁷⁵⁶ Interview, DOH civil servant 27

Furthermore, the key point that the DTI does not cease to have any role but can bolster a sponsorship function of the DOH was demonstrated overtly by Michael Heseltine's 'recruitment' to the cause, effectively lining up two cabinet ministers against the Treasury's position. The Treasury was widely regarded as having little concern other than cash savings in the 1993 negotiations and the broad ranging competence of the DOH, specifically its sponsorship role, was therefore central to the maintenance of the PPRS policy community.

Chapter 7

Conclusions

7.1 The pharmaceuticals market

7.2 The global context

7.3 The co-operative state

7.4 The role of Parliament

7.5 Role of the Department of Health

7.6 Understanding government-industry relations in the pharmaceutical sector

7.1 The pharmaceuticals market

The negotiations of 1993 and 1999, as well as the passage of the 1999 Health Bill left the market for pharmaceuticals largely unchanged. The PPRS does not impinge directly on all the features of the market identified here as characterising its structure. The NHS is the basic structural feature of the market, concentrating purchasing power to the point of monopsony. But while this concentration of public purchasing power yields clear bargaining resources for the government, the empirical research here also shows that this concentration has yielded regulatory goods for industry. It provided clear advantages for the process of clinical trials, a fact recognised by the government: "We had the success of the NHS which meant an exceedingly good basis where drugs could be evaluated, tested and developed."⁷⁵⁷ And as one industry commentator pointed out, it provides a stable market for the industry's goods: "If you argue for a free market, understand what you mean by a free market – you live in a market now where, before NICE, it's virtually compulsory for the customer to buy your products. If you have a free market, it's not compulsory for the customer to buy your products."⁷⁵⁸

The NHS itself can therefore be seen as a basic structural asset for both government and industry. It enables a symbiotic relationship and facilitates the balancing and *satisficing* – even the *optimising* – of their respective policy aims.⁷⁵⁹ The 'network interdependence' identified by Wright⁷⁶⁰ was something that was maintained despite the potential for crisis in 1999 and was clearly a desired outcome of both sides.

⁷⁵⁷ Interview, Government minister 17

⁷⁵⁸ Interview, industry executive 13

⁷⁵⁹ Wilks, S. and Wright, M. (1987), p.298; Simon (1957), pp.204 ff; March and Simon (1958) pp.48 ff

⁷⁶⁰ Wright. M. (1988b), p.402.

All the factors that characterise the British marketplace for drugs can be seen as contributing to the ability of both sides to achieve an acceptable level of 'goods' from the two PPRS agreements. Yet the government throughout the 1990s had concerns about the developing nature of the industry and its potential budgetary impact. The research exemplifies the importance of these issues: part of the motivation for government to examine a range of policy possibilities in 1993 was the perceived shift to more expensive products – a shift that was proved by the DOH's research into the causes of growth in the drugs bill over preceding years. In 1999 the Health Bill introduced explicit mechanisms of control to augment the PPRS and the issue of 'blockbuster' products had been increasing in importance through the decade: other mechanisms were used, including Schedule 10 of the GMSR. But in the end, the restraining features of the market – including the conservative prescribing habits of GPs and the wide use of generics – kept this threat sufficiently in check and any belief in a serious threat of a 'shock' to the policy community from this quarter cannot be deduced here.

In the end however, the key regulatory goods that were sought by industry were maintained and a facilitator of this was the context of the PPRS in a relatively conservative market.

Nevertheless, some liberalisation within the PPRS can be identified across the decade – most importantly through the large extension of the MOT in the 1999 scheme. Even the 1993 scheme (which can be characterised as more strict in its narrowing of the margin of tolerance on the ROR) was inclined to exaggerate the tendencies of the scheme and further reinforce the costs and benefits of it to both sides.

Furthermore, both sides had to gauge the costs and benefits of the PPRS in the absence – given its five decades of operation – of certain knowledge about how the market would later behave without the scheme, or if significant changes

were made to it. “You can never know the counterfactual,” noted a senior civil servant in this regard.⁷⁶¹

In judging the benefits of the market for the taxpayer, while keeping one eye on industrial policy aims, the PPRS had to be judged within the framework of the NHS and the monolithic nature of medicines purchases. In this context the breadth of choices seemed to the politicians involved to be limited: “Until there was a different system of health care funding, I wasn’t able to identify an alternative practical structure,”⁷⁶² said a senior politician.

The particular shape of the NHS market provided a known and relatively risk free context in which to continue the co-operative regulatory regime and is a clear example of a policy community as Wright would have it, where actors “share a common identity or interest,” and will ‘transact’ with each other, exchanging resources in order to balance and ‘*optimise*’ their mutual relationships.⁷⁶³

7.2 The global context

The global nature of the industry and the national structure of its markets create special dynamics in the government-industry relationship. Given the industrial policy aims of government, the mobility of global firms lends them increased bargaining resources in their negotiations with the government over regulation. This is likely to be an increasingly important factor in all types of government-industry relations over coming years as trade barriers continue to diminish and as firms become more global in their organisation, their markets and their outlook.

⁷⁶¹ Interview, DOH civil servant 27.

⁷⁶² Interview, Government minister 17

⁷⁶³ Wilks, S. and Wright, M. (1987), pp.298-9.

This is a key point in underpinning the strategic aims of both sides and the international competitiveness of the industry is explicitly recognised in the aims of the PPRS. It is therefore an institutional factor that defines the *policy aims* as well as the *negotiating resources* of both sides: government's industrial policy aims are mirrored by the bargaining resource of industry to invest according the most conducive regulatory environment.

The consolidation of firms in the sector and their increasingly global focus has been accompanied by a definite shift in its investment from Europe to the United States. Given the dominance of American based firms in the global marketplace, the conditions of the American market stand as an example to American executives in Europe and they are the ones most likely to push for liberalisation and accept least strict regulation. This was the case in 1993 but became far more pronounced in 1999: arriving at an industry position within the ABPI necessitated placating considerable pressure from some American firms for more liberalisation of the market (in the end underpinning the PICTF process).

All three studies here again indicate that the global structure of industry provided a context that both necessitated and enabled the aims of each side – as constituted following their internal discussion – to be balanced within the PPRS to a degree acceptable to each.

The global structure of the industry significantly defined the relationship between government and industry, because the government's industrial policy aims enabled industry to gain important concessions in their cost containment aims. The value of the industry to government was demonstrated by the willingness of the Prime Minister to meet the CEOs of the major British firms in the run up to the 1999 PPRS negotiations, to discuss broad issues about the UK as a pharmaceutical industry location.

Furthermore, this important structural feature of the industry was identified by a key civil servant as a potential problem for the regime, in operational terms, in the future: “There’s a difficulty of having a return-on-capital scheme in a global business. It’s alright when the assets are all in this country, but when they are spread around the world it makes it more difficult and this is something that’s happening through mergers ... it is a question for the future.”⁷⁶⁴ A potential ‘shock’ to the policy community in the future – or perhaps at least a rising pressure – might prove to be the globalisation of firms and the increasing difficulty of assessing their national operations in relation to their national sales.

7.3 The co-operative state

The approach of the state to the control of pharmaceutical prices has been a key factor in the persistence of the PPRS as a mode of regulation. The role of the state is defined by its ambition: it has not sought to regulate strictly the activities of the sector and has confined its cost control aims to the context of the NHS and a good deal for the taxpayer within it. That is to say, broader aims for control of the sector have not been pursued and industrial policy aims have been to facilitate a globally successful industry (meaning both success for British firms on the world stage and success for the UK as a pharmaceutical location). This attempt to balance different aims rather than to develop a ‘strategic’ approach from a blank piece of paper is one seen by Middlemas as bringing industry into decision making as part of the ‘extended state’.⁷⁶⁵ Industrial policy aims can therefore be seen as having underpinned the close working relationship between government and industry in the PPRS.

The industrial culture of the UK – the conception of the role of government in the economy – has predisposed the government to this limited involvement in the

⁷⁶⁴ Interview, DOH civil servant 5

⁷⁶⁵ Middlemas, K. (1986), p.348.

sector.⁷⁶⁶ The historic role of the state was as an overseer of private business activity.⁷⁶⁷ A comprehensive public health care system has complicated this relationship but in the aspects of the NHS that create relationships with industry the more liberal tendency has prevailed. Co-operation can be seen as a core value of the policy community that was instrumental to re-establishing the balance in it in 1999, following the crisis of the early part of the negotiations and the Health Bill.⁷⁶⁸

The three studies show that this is the case. In neither the negotiations of 1993 or 1999 did the government seek stricter control of the industry. Even the 1999 Health Bill, which sought greater legal control in several areas, did so within the context of the PPRS: that is to say that while a different form of control was sought in it, the content was to remain the same. In any case, and accepting that the form of regulation was also a crucial factor for industry, many of the original aims did not progress to the Act. 'Negotiated compliance' was certainly preferred to strict enforcement, and regulators wish to avoid taking legal proceedings to enforce regulation, which necessitated the balancing of various interests.⁷⁶⁹ Co-operation was certainly a regulatory good for the government in both 1993 and 1999. It was also a means to the regulatory good of investment, as companies cannot be regulated into investing easily in a globalising economy.⁷⁷⁰

The studies show a desire on the part of government to continue with a co-operative regime rather than an inability to regulate in any other way. Indeed in other areas of regulation the government has acted decisively to control costs and to regulate the industry: not least through continued increases in demand side controls and the introduction of the National Institute for Clinical Excellence (NICE).

⁷⁶⁶ Wilks, S. and Wright, M. (1987), p.278; Wilks, S. (1983), pp.132-137.

⁷⁶⁷ Balogh, T. (1959), p.109.

⁷⁶⁸ Wright, M. (1991).

⁷⁶⁹ Middlemas, K. (1986), p.348.

Indeed, the government did perhaps come close to upsetting the nature of the government-industry relationship – not least because of other events happening at the same time. Principally this consisted of the introduction of NICE, which could undermine the main benefits of the PPRS from the industry's point of view.

Yet in the PPRS, the negotiations show the government's clear preference to keep industry 'on-board' and to listen to its commercial concerns. In this sense, the state, in this sector, cannot easily be defined as 'weak' given the connotations of that term, although some of the features of the 'weak state' identified by Atkinson and Coleman may be present – most obviously here the government's own perceived need to have information provided by industry, compromising its ability to act.

Industry showed a similar inclination. Despite their initial consternation at being presented with legislation in 1999, industry actors soon came round to defending the government-industry relationship. Large parts of industry gave some support to attempts by government – through the Bill or the PPRS – to ensure better compliance with the scheme. The role of industry actors in discussing detailed amendments to the Bill was so overt that they effectively became a part of the legislative process, albeit informally.

This reticence by both parties to undermine their mutual agreement underlined the nature of their relationship as one identified by Grant as an *exchange relationship*, in which government gains the information required to conduct policy, and an *exchange process* to implement it.⁷⁷⁰ Co-operation between the two sides is overtly recognised as a *core value*, in Wright's terminology, as well as clearly discernable from their strategies and actions. The acceptance of a negotiated agreement underpins policy that is, in the terms of Wilks and Wright and of Simon, about *optimising* and *balancing*.

⁷⁷⁰ Hancher, Leigh and Moran, Michael. (1989), p.275.

⁷⁷¹ Grant, Wyn. (1993), pp.46-65.

The traditional 'Treasury view' of the role of the state is one that does not sit easily with the largest remaining part of the Beveridge welfare state: the NHS is not a state-minimalist system. Furthermore, the 'sponsorship' element of the PPRS is one that allows the sort of free pricing of new medicines that costs the exchequer money: the scheme is not the most robust of regimes for keeping costs to a minimum. Yet the 'Treasury view' of the minimalist state has informed policy in this area: the acceptance of higher-than-possible prices has at all PPRS negotiations been accepted in the end. The Treasury, in both 1993 and 1999 the driving force behind the government's bargain hunting, has been persuaded of the need to give industry the freedom to succeed in international markets. In 1999 Treasury officials were adamant that enabling a successful industry was a Treasury aim as well.

The modern welfare role appears to set up another anomaly in analysing government-industry relations. The Victorian laissez-faire state was one, according to Vogel,⁷⁷² that had an adversarial relationship with industry: it was explicitly not mercantilist. A co-operative state-industry relationship is the reverse of laissez-faire in these terms. Yet this dichotomy can be seen to have evolved significantly long before the post-war welfare states were inaugurated. Government's 'enabling' of successful industry, albeit by keeping out of its way, was an established feature of Anglo-American thinking by the late nineteenth century. '*Industrial culture*'⁷⁷³ – the conception of the proper role of the state in the economy, and the extent to which intervention by government is acceptable – remained minimalist but the relationship was not necessarily adversarial. The co-operative relationship emerges because the choices facing government are shaped by the welfare state – in this case the NHS. The government by definition has a close relationship with industry as its primary customer. The

⁷⁷² Vogel, David. *National Styles of Regulation: Environmental Policy in Great Britain and the United States*. Cornell University Press, 1986. Chapter 6. pp.226-263.

⁷⁷³ Wilks, S. and Wright, M. (1987), p.278; Wilks, S. (1983), pp.132-137.

choice is therefore between a co-operative relationship that fulfils mutual aims or an adversarial one which does not.

7.4 The role of parliament

The three studies present mixed evidence for the extent of Parliament's role in the procurement of medicines for the NHS. On the one hand, Parliament has no explicit role in the negotiation of the PPRS or in examination of its execution. It has however sought to scrutinise the general implementation of the scheme and judge its value for money, asking the National Audit Office to conduct a report into it in 1993. This proved to be a significant report and many of its suggestions shaped the agenda for reform in 1999.

Furthermore, explicit power over the area was given to Parliament in 1999 through the process of legislating for the back-up 'statutory PPRS' that sought to enforce the voluntary agreement on those who signed up to it and to provide an alternative means of control for any companies that didn't.

The studies show that, as in 1984 and the debacle over the Limited List, Parliament's role is enhanced when there has already been some breakdown in the relationship between government and industry. Both sides have sought to engage Parliament to their own advantage at some times and both have been successful to some degree. The Health Bill and the PPRS negotiations each show that Parliament can be a crucial player in instances of policy innovation or overhaul. Formal and informal parliamentary contacts made a crucial difference to the ability of industry to gain back some of the ground it felt it had lost because of the government's thorough preparation for the 1999 negotiations. Equally, it was (and, by definition, is) the mechanism – through proposed legislation – by which the government can exercise its key resource as a lawmaker.

Parliament has become a central actor at such key moments but there is no evidence that this position can be sustained by it separately from the desire of government and/or industry for it to play that role. The exception to this state of affairs, as the 1999 PPRS in particular has demonstrated, is in the influence Parliament has had over the negotiating agenda, which has to a significant degree been driven by Parliamentary scrutiny and criticism. Even here, however, Parliament's minimal grasp of the PPRS and minimal involvement in it has limited its criticism to suggestions for reforms to the existing regulatory regime.

There is a general point of accountability, which at key times becomes of central importance, as one senior industry commentator noted: "Eventually Parliament has got to feel happy that the way in which medicines are handled is acceptable. Perceptions in parliament are important."⁷⁷⁴

The Department of Health and the ABPI do not seek a wider policy community except, as Wright would have predicted, when there are problems present in their close co-operative relationship. Parliament has a 'look-in' and has examined the efficiency of the PPRS but it has not been a central player of its own accord. This role is encouraged by the limited ability of industry to lobby Parliament on an abstruse issue which MPs do not see as central to their constituents concerns. Only MPs with particular industrial interests (pharmaceutical investments in their constituencies) have an obvious motive for taking a substantial interest in the PPRS. The opaque nature of the scheme to outsiders was sited as a problem for their discussion of it in the 1999 Health Bill. In 1984-5, when Parliament had been engaged in the Limited List debate, the issue here was far simpler for MPs – access for patients to medicines. The debate about NICE has followed this pattern because there is a direct effect on constituents of blocking a new drug for general NHS use and this can fill a

⁷⁷⁴ Interview, industry executive 6

substantial part of MPs' post bags. The pricing of pharmaceutical has been a proxy for wider concerns but not a central issue of concern in itself.

7.5 Role of the Department of Health

The role of the Department of Health in 'sponsoring' the pharmaceutical industry is one factor that sets the British system apart from its continental neighbours: "Crucial to the evolution of a community ... was the concentration of legal authority and policy jurisdiction (regulation *and* sponsorship) in one department."⁷⁷⁵ There has been an increased focus on supporting new medicines in some European countries in recent years – notably France – in recognition of the success of the PPRS in supporting an innovative industry. And indeed the sponsorship function of the DOH has facilitated a forum for dialogue between government and industry and enabled the latter to impress upon government its evolving concerns.

The 'balanced' view of the Department of Health as a whole, represented by the head of the IID (now MPI) in the PPRS negotiations, is one that has proved decisive in shifting the DOH's approach to the scheme. As a senior civil servant in the Department remarked, "There are 5½ thousand people working in the Department of Health. All of them bar one want to screw the pharmaceutical industry as hard as they possibly can. One person who's got to be aware of something a bit wider than that is the Head of the Division that's negotiating the PPRS."⁷⁷⁶ It is the role of the Head of Division, informed by both the procurement and sponsorship motive of the DOH, to face down any one-sided procurement concerns that the Treasury and the wider DOH may have. There is also evidence that in both 1993 and 1999 the Secretary of State for Health shifted towards the sponsorship concerns during the process of the negotiations:

⁷⁷⁵ Wright M. (1991), p.513.

⁷⁷⁶ Interview, DOH civil servant 10

as the person ultimately responsible for signing off the agreement, this is evidence of the influential role of the sponsorship function.

The government's interests here are, in the words of Allison, "competitive, not homogenous."⁷⁷⁷ As the Treasury is the dominant force among British government departments, it is inconceivable that a DOH that did not have its approach influenced significantly by the sponsorship role would not drift towards a far more procurement-focused approach. While the DTI's role has had some influence, not least in 1999 as a facilitator of discussion when relationships between the DOH and industry had been soured, it cannot be seen as decisive vis-à-vis the Treasury and it is unlikely to have either been altered or bolstered by possessing a sponsorship function while the DOH was the lead department, formally responsible for the scheme. Because there was no diminishment in the forcefulness with which the DTI aimed to represent the pharmaceutical industry, in comparison with any other industry, the DOH sponsorship function can be seen as an addition to, rather than a replacement of, the DTI's role. Both the DOH and the DTI face the Treasury as industry 'sponsors' (formal and informal).

The sponsorship role of the DOH has therefore significantly affected the outcome of PPRS negotiations: a key aspect in fact of the 1999 scheme was the incorporation into it of a unique and wide-ranging review of the commercial and scientific interests of the industry in the British marketplace and economy.

7.6 Understanding government-industry relations in the pharmaceutical sector

Government-industry relations in the pharmaceutical sector in the UK are defined by various factors, outlined throughout this thesis. The particular form of

their relationship through the PPRS is one that was defined as early as the modern pharmaceutical industry itself, during the war years when government's relationship with industries of all kinds was shaped by the need for public procurement of essential goods. The organisation of the industry at that time enabled an amicable and co-operative relationship between the two to emerge and prosper. The trauma of setting up the NHS and subsequent economic problems that focused the government's attention on the balance of trade, combined to underpin a relatively 'light-touch' form of price regulation of pharmaceuticals in considerable contrast to alternative systems that developed throughout the rest of Europe.

Despite the transformation of the industry in the intervening years, the basic framework devised in 1957, the VPRS, with its development during the 1970s, still constitutes the basic framework for regulation today. Nevertheless, the hypotheses developed here enable an assessment of the likely determining factors of both continuity and change and, crucially, the *direction*, if not the detail, of any such change in the years ahead. Fundamental among those factors is the British government's conception of its own role, in the context of the vital importance of the pharmaceutical industry in the UK's industrial performance in a changing 'knowledge' economy. That is to say, the conjunction of the British government's broadly liberal approach to industrial regulation combined with the industrial importance of the industry, is likely to continue to prioritise the industrial policy dimension of pharmaceutical regulation to a sufficient degree to offset any perceived increased need for cost containment in health care at a time of potentially profound demographic and social change. The prioritisation of industrial policy has arguably been leant a helping hand by the peripheral role of the legislature in framing regulation, where it might be considered to have focused to a greater degree on purely procurement concerns, which is to say, value for money in the short term. In addition, the changing corporate shape of the industry has raised clear operational questions

⁷⁷⁷ Allison (1971) p.146

over the long term viability of the PPRS because of the increasing complexity of corporate organisation across countries.

The PPRS negotiations of 1993 and 1999, and the drama of the Health Bill, can be seen to represent the latter chapters in the story of the PPRS. It was quite clear that the PPRS was not seen as an 'ideal' form of regulation so much as one that already existed alongside few obvious alternatives. More importantly, what the cases of government-industry negotiation here show is a future direction of policy, rather than its precise form or content. The difficulties in moving from the PPRS to another form of more direct price regulation firmly suggest that any inadequacies of the PPRS will be met in the future by moves towards more liberal rather than stricter regulation of the industry. The government has thoroughly explored and rejected 'off-the-shelf' options for price regulation over a sustained number of years, through administrations of varying political colours, and the freeing up of the market for pharmaceuticals in the UK is the most likely direction of reform for the coming years. And nor is the industrial policy vs. procurement concerns a clear dichotomy: the changing shape of health care is likely to mean that medicines come to be yet more central to the delivery of health care to an older, wealthier population, in which primary care is charged with an ever greater portion of the responsibility for delivering world class health care accessible to all.

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Appendix 1: Interviewees

Name	Type	Date	Role/position
Jim Attridge	Industry executive	May 2001	Corporate Affairs, AstraZeneca; ABPI Advisory Team
Michael Bailey	Industry executive	23 February 2000	Glaxo Wellcome Corp. Affairs; Chairman ABPI; ABPI Negotiating Team
Jack Barnes	DOH civil servant	19 April 2000	Head, DOH International and Industry Division (IID)
Kevin Barron MP	Parliamentarian	19 March 2001	MP (Labour), Chairman of Pharmaceutical APPG
Rt. Hon. Virginia Bottomley MP	Government Minister	01 August 2001	Secretary of State for Health 1993
Alistair Bridges	Treasury civil servant	March 2001	Head, Treasury Health Team, Public Services Directorate
Mike Brownlee	DOH civil servant	06 February 2000	Head, DOH PPRS Branch
Rt. Hon. Kenneth Clarke MP	Government Minister	Letter: 23 May 2000	Minister of Health 1984 (Secretary of State for Health 1986)
Lord Tim Clement-Jones	Parliamentarian	16 January 2001	Lords (LibDem), Health Spokesman, LibDems
Monica Darnbrough	DTI civil servant	23 August 2000	Head, DTI Biotechnology Directorate
Derek Davis	DTI civil servant	26 March 2001	Head, DTI Chemicals Directorate
Rt. Hon. Frank Dobson MP	Government Minister	19 September 2000	Secretary of State for Health 1999
Jim Furniss	DOH civil servant	April 2001	Head, DOH PPRS Branch 1993
Iain Gillespie	DOH civil servant	18 October 2000	DOH Sponsorship Branch
Dr. Evan Harris MP	Parliamentarian	24 October 2000	MP (LibDem) Standing Committee
David Hill	Industry executive	05 February 2000	Leo Pharmaceuticals Corp. Affairs; ABPI Negotiating Team 1993 & 1999
Earl Frederic Howe	Parliamentarian	September 2002	Lords (Con), Opposition Leader on Health
Trevor Jones	Industry executive	13 January 2000	Director General, ABPI
Chrissie Kimmons	Industry executive	8 March 2000	Corp. Affairs SmithKline Beecham; ABPI Advisory Team
Till Medinger	Industry executive	11 September 2000	Corp. Affairs AstraZeneca; ABPI Negotiating Team
John Middleton	DOH civil servant	18 October 2000	Head, DOH Sponsorship Branch
Louise Rickitt	Treasury civil servant	March 2001	Treasury, NHS improvement unit
Baroness Margaret Sharp	Parliamentarian	March 2001	Lords (LibDem), Main LibDem Health spokesman in debates
Sir Richard Sykes	Industry executive	April 2001	Chairman, GlaxoSmithKline / CEO Glaxo Wellcome
Mike Wallace	Industry executive	05 April 2000	Corp. Affairs, Schering; ABPI Advisory Team
Lord Walton of Detchant	Parliamentarian	March 2001	Lords (Crossbencher); significant participant in debate