Pharmaceutical politics in OECD countries

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Chapter 9: Pharmaceutical policy and politics

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Introduction

Perhaps the key difference in the practice of medicine at the beginning of the twenty-first century compared to a hundred or even fifty years previously is the prescription and use of therapeutic drugs. With this change, health politics has changed, too.

For health care is a problem of political economy. When health care states were established, this problem took the form of the distribution of its costs between capital and labour, employers and employees. And in most countries and systems, the burden of insurance premia has been divided between the two. As far as pharmaceuticals are concerned, however, what is consumed in one part of the economy is produced in another. There is a trade-off to be made between benefits to doctors and patients in the health care state, and those which accrue to firms and shareholders in the health care industry.

For the health care state, as Michael Moran has famously explained, is not only a welfare state but also an industrial capitalist state, as well as a liberal democratic state (Moran 1995, 1999). As such, it is faced with dilemma and compromise at every turn. In respect of pharmaceuticals, this takes the following form. To guarantee access to health care means ensuring the availability of medicines, and doing so means addressing familiar distributional issues of who gets what, when, how. Governments and providers want to improve the quality of treatments they offer to citizens: they are concerned to promote therapeutic innovation, but also to protect patients from possible associated risks. Meanwhile, major pharmaceutical firms are emblematic of national economic success: they provide employment of high quality and often high volume, their production generates considerable added value, and they are a principal source of foreign export earnings. In this context, the government interest is both to sponsor and to discipline industry, to maximise its possible earnings and its possible contribution to health but to minimise its potential cost. This dilemma – a 'quadrilemma', in Weisbrod's (1991) phrase - is the more difficult in democratic states, where the decision making process is subject to powerful lobbying on the part of producer interests and subject to electoral approval (or otherwise) on the part of consumers. Furthermore, as Burton Weisbrod suggests, it has an accelerating, dynamic quality: the market for new drugs is predicated in large part on public coverage of much of their costs, which in turn feeds new and increased demand (Weisbrod 1991).

Yet things are more complicated still. More than other elements of health care systems, pharmaceutical research, production and marketing are unusually internationalised. This has been a feature of the industry since it first developed in its

modern form in the later decades of the nineteenth century, and contrasts markedly with the predominantly national organisation and regulation of the medical profession, for example. National economies and health systems are exposed to the global market in pharmaceuticals to different degrees and in different ways, though all are subject to changes in an environment essentially beyond their control. While attempts at the international regulation of that market began in the 1990s, it remains dominated by global networks of global producers.

Across OECD countries, total expenditure on pharmaceuticals amounts, on average, to slightly more than 1.3% of GDP (table 1, below), and to around 17.5% of all health spending (OECD 2006).[ii,iii] In most countries, more than half of pharmaceutical expenditure is reimbursed by public funds, such that public spending on pharmaceuticals represents something like 13.8% of GDP (table 2). At the same time, the average share of GDP devoted to pharmaceuticals has increased in most OECD countries by around 50% since 1970, in line with increases in health spending. Even in countries with relatively moderate health expenditure growth, such as the UK or the Netherlands, the growth of the share of pharmaceuticals in GDP has been significant.

[table 1 here]

[table 2 here]

Public expenditure on pharmaceuticals (table 2) tends to be highest in countries which combine extensive coverage with high levels of consumption, such as Japan,

Germany and France. In the US, where public coverage is limited, public expenditure on drugs is low although total pharmaceutical spending is at the OECD mean. Pharmaceutical expenditure levels per head of population tend to be lower in northern European countries, where doctors are paid mainly by salary and capitation. They are highest in Japan, the United States, France, Belgium and Germany.

The distribution of pharmaceutical production is disproportionately concentrated in five to ten countries. The United States remains the major producer: although its market share declined between 1970 and 1980, when other countries showed relatively stronger growth, it has remained stable since then. The US position has been sustained partly by the very strict requirements for market entry in the pharmaceutical sector, and partly by high levels of domestic consumption. Of course, pharmaceuticals are manufactured goods, often originating from countries like the US, Sweden, Switzerland, Germany and the UK which have high living standards and high labour costs. This means that pharmaceutical expenditure tends to be a relatively heavier burden for health care systems in poorer countries. Hence, pharmaceutical spending as a proportion of GDP is highest in countries such as Portugal, Greece, Hungary and the Czech Republic, and much lower in countries such as Denmark, Norway, Luxembourg, Switzerland and the Netherlands.

A ranking of standard trade balances underlines the strong position of countries with a research-based pharmaceutical industry, such as Switzerland, Germany and the United Kingdom, though it is notable that, in relative terms, the United States is not a big exporter of pharmaceutical goods. Belgium, Sweden, Denmark and Ireland also have a significant surplus, while the French surplus is relatively small in comparison to its

overall domestic production. At the other extreme, Japan is the biggest importer of drugs, which reflects the limitations of its own industry (Balance et al 1992, Thomas 1995). Adjusting trade performance to the size of the domestic market underlines the success of the Scandinavian exporting countries, Denmark and Sweden, as well as of the United Kingdom and Germany. By contrast, some European countries such as Greece, Finland, Portugal and Norway have large deficits. Australia, Canada and Austria also import a significant share of their therapeutic drugs.

Not surprisingly, those countries which enjoy a strong international position are also the home countries of large multinational exporting companies. This is particularly true for Switzerland (Roche, Novartis), the United Kingdom (GlaxoSmithKline), Sweden (AstraZeneca) and Germany (Bayer). The United States (Merck, Pfizer, Johnson & Johnson, Bristol Myers Squibb, Lilly) ranks highly in international terms simply due to the size of the US market (which is around a third of the total OECD markets, and which also means that US-based firms control roughly half of pharmaceutical production in the OECD area).

In sum, pharmaceutical spending represents a small but significant share of the GDP of most OECD countries. Pharmaceuticals absorb a significant share of health expenditure and, critically, an increasing share of public spending on health. There is evidence that pharmaceutical spending, like health spending in general, is closely associated with national wealth, but also that it is subject to specific institutional effects. The next section of this chapter discusses the range of regulatory instruments used by the governments of OECD countries to steer the production, trade and use of medicines.

Policy instruments

Given the range of objectives governments have in formulating pharmaceutical policy, it is inherently unlikely that they will find a single measure or 'magic bullet' to meet their needs or cure all ills. Instead, they deploy a range of instruments, targeted at various aspects of demand and supply, in something like a policy variant of combination therapy.

Defining the market

One of the first functions of pharmaceutical policy is to define the scope and extent of the market itself. This involves setting rules for market entry, such as establishing the efficacy and safety criteria which must be met before a given drug may be sold or distributed. Such tests are administered by the FDA in the United States, and its equivalents in other countries.

Where medicines are covered by public schemes, as for example by social insurance in Germany and the Netherlands and by the NHS in the UK, a second task is to define the basket of goods which will be eligible or listed for reimbursement. Adjusting and updating this list is the most immediate way governments influence demand: in most OECD countries lists are revised several times a year, either by the relevant Ministry (usually Health) or by a specific body in charge of pharmaceuticals such as PHARMAC in New Zealand. Sometimes lists are subject to more extensive revaluation as in France, where the government also conducted an extensive revaluation in 1999, and in Germany, where the government excluded over-the-counter drugs from reimbursement in 2004.

However, not all countries provide universal coverage for pharmaceuticals. Where this is the case, as in the United States and Canada, each insurer has to draw up its own list or formulary, as do HMOs in the US, for example. In Canada, while Medicare does not cover pharmaceuticals, the federal government provides drug coverage to specific groups (Vandergrift and Kanavos 1997). For their part, provincial and territorial governments subsidise the cost of prescription drugs for at least some sectors of the population, notably seniors, social assistance recipients, individuals with specific disease conditions, and in some cases, home and community care recipients.

Patient copayments

The very function of insurance is to separate immediate financial considerations from others concerning access to services. But where demand is not regulated by price, as is the case with pharmaceuticals covered by a public scheme, there is a risk of over-consumption (which is much greater for pharmaceuticals, for example, than other elements of health care such as hospital stays). In practice, therefore, almost all insurance schemes, both public and private, set some level or type of copayment (or deductible) a patient must make for pharmaceuticals. Even the tax-funded NHS in the United Kingdom introduced copayments soon after it was established, extending them significantly in the early 1980s.

Copayments certainly have an effect on drug consumption, and seem to be more efficient when related to the price of the drug rather than set at a fixed rate per prescription; maximum efficacy in terms of reducing consumption seems to be reached at rates of about 25% (Newhouse 1993), though this figure may be country- and context-

specific. Cross-national evidence suggests that limiting the level and scope of patient reimbursement inhibits the use of essential as well as non-essential drugs. This means that while such measures may reduce public spending, they may also reduce the cost-effectiveness of drug use (Freemantle and Bloor 1996).

Because the distributional effects of direct payments by patients are regressive, lower income groups and those with chronic and serious illness tend to be disproportionally affected by them. Many OECD countries counter this problem with extensive exemption schemes and safety nets: in the UK, for example, almost 50% of the population is virtually exempt from copayments on prescription drugs (though the eligible list of such drugs is more restricted than in Germany or France). On the other hand, some countries have copayment policies which may appear more illusory than real. In France, for example, most of the population has supplementary insurance which reimburses most or all of the copayments set by the principal public schemes. Germany and the Netherlands, meanwhile, like Japan and some other countries, have banned this kind of cost-shifting by reinsurance, precisely because it erodes the incentives put in place elsewhere in the system.

Physician prescribing

Often, governments first move in seeking to contain public spending on pharmaceuticals is to increase the financial responsibility of patients by introducing or extending copayments. Targeting providers comes second. Most western European countries as well as managed care schemes in the United States have implemented some sort of monitoring of physician prescription, supplemented by various tools intended to

influence prescribing in particular ways, including auditing, the use of guidelines and fixing drug budgets.

The United Kingdom has long made considerable efforts to influence doctors' prescribing behaviour (Rochaix 1993, GAO 1994b). Information benchmarking their patterns of prescription against those of their colleagues has been made available to doctors for a long time in the form of the Prescribing Analysis and Cost (PACT) data collected by the Prescription Pricing Authority. France, too, has long had a periodic review of physicians' individual prescribing activity, the *Tableaux Synthétiques d'Activité des Praticiens* or *TSAP*. In the NHS in the UK, targets and budgets have been used to constrain GP prescribing. Savings seem to have been achieved through doctors' greater willingness to prescribe generic rather than branded drugs, and to a greater receptiveness to the use of computerised prescription management systems. Although direct evidence of the impact of these initiatives is scarce, UK prescription patterns in general appear to be rather more cost-efficient than those of other countries, with lower rates of unnecessary prescribing and of the use of relatively expensive drugs.

Prescription guidelines have been in place in most OECD countries since the mid-1990s (Mitchell 1996). They can be either positive, indicating generally appropriate prescribing policies or negative, as in France, where they state what should not be done and set possible sanctions. Meanwhile, global pharmaceutical budgets have been set for the physicians' association of each regional state in Germany, under the terms of health reform legislation passed in 1993. Budgets were introduced in a similar fashion in France under the Juppé Plan of 1996 (in both cases, financial penalties for over-supply may apply to pharmaceutical companies, too). Finally, where prescribing and dispensing

functions are held jointly, as they have been in Japan and to a limited extent in the Netherlands, there are clear incentives for doctors who also dispense medicines to over-prescribe. In both countries, in consequence, governments have been concerned to separate these essentially different tasks (Seo 1994 , Japanese Ministry of Health and Welfare 1996).

One problem underlying all attempts to modify doctors' prescribing behaviour is that evidence of what determines it in the first place remains scant. Budgetary and other incentives appear to have more effect than the simple provision of information, though few of these various methods have been subject to rigorous testing (Bloor and Freemantle 1996). Information and guidelines collected, collated and issued by providers and public authorities compete with information disseminated by manufacturers through advertising, sponsoring conferences and other benefits, and personal visits to physicians by sales representatives. In this respect, pharmaceutical supply is a battle between government and industry to influence doctors. Meanwhile, prescription appears to be strongly based in habit: studies in France, for example, have shown that doctors tend to remain insensitive to economic considerations as long as they do not themselves bear the cost of the decisions they make (Lancry and Paris 1995). This reveals the extent to which improving the appropriate and cost-effective use of medicines turns on the regulation not only of markets but also of the professions, and is likely to be possible only through extensive collaboration with them.

Price fixing and reference pricing

In so far as price fixing creates distortions in markets, it is not applied to many goods. For several decades, however, pharmaceuticals have been subject to extensive and wide ranging price fixing in OECD countries.[iv] Today, pharmaceutical prices are free in only a minority of OECD countries, though this minority includes some major players such as the United States and Germany. In general, public authorities become interested in price fixing when prescription pharmaceuticals are deemed intrinsic to universal health care entitlements and when patient access to drugs is to be protected against financial constraints, but public funds are limited. In Canada for example, a Patented Medicine Prices Review Board has set maximum prices for patented drugs since 1987.

Because the UK's Pharmaceutical Price Regulation Scheme (PPRS) determines an initial or 'benchmark' price for a drug, manufacturers are concerned that it be set as high as possible, in the knowledge that this launch price will subsequently be contained, if not fixed. This makes the UK a lead market, of some significance in determining how others work.

The difficulty with price fixing in the case of pharmaceuticals is that prices are fixed for what is apparently traded on the market, namely boxes, while in fact what is actually bought is a certain set of chemical substances with therapeutic properties. In the case of pricing by the box, the price-fixing mechanism is highly vulnerable to manipulation (Abbott 1995, Schönhöfer 1999): minor changes in strength, packaging, or some recomposition of the chemical formula will help to make the product appear new. This means that it can be artificially priced higher for the same therapeutic properties.

The effectiveness and appropriateness of price fixing depends, of course, on the level at which the price is fixed. OECD countries use a combination of criteria to fix the prices for drugs supplied to patients under public schemes. These include the therapeutic value of the drug, reference to existing products and/or to international comparisons, and the contribution of pharmaceuticals to the national economy. In Canada, the guidelines of the Patented Medicine Prices Review Board include several tests: for a similar chemical product, tests are performed which measure it against others with a comparable molecular structure; for breakthrough products which promise substantial therapeutic improvements, international price comparisons are made using exchange rates averaged over the previous 36 months; for similar or moderate therapeutic improvement products, a therapeutic class assessment is made with comparable medicines of comparable dosage.

Reference pricing sets a standard rate of reimbursement for specific drugs. Strictly defined, a reference price is established by comparing a branded product with its generic equivalents. In a more general sense, however, it may involve similar products of the same therapeutic class though not necessarily the same chemical formula. Reference pricing has largely been developed in countries with a large public reimbursement system and a strong, research-oriented pharmaceutical industry, mainly in Northern Europe.[v] Most extensive use of it has been made in Germany, as well as in Denmark, Sweden and the Netherlands, though it also formed a substantial part of changes made in Italy in 1996. As of 1 January 1999, reference prices for drugs in Germany may not exceed the price at the first tercile of the distribution of products within a given reference group (for drugs without reference prices, public health insurance reimburses the price of the drug

less a fixed amount). The introduction of this system led initially to very significant savings of several billion Euro a year although, over time, its effect has diminished.

In the German scheme, the difference between the branded price and the reference price of drugs with the same active ingredients or a similar pharmacology has to be borne by the patient. This should, in theory, give the patient a strong incentive to be discriminating in her use of medicines. However, when her ability to switch to generic products is limited by a lack of appropriate information, for example, this mechanism puts some patients at risk of incurring increasingly high direct, out-of-pocket costs. In this situation, it is the pharmacist who often guides a patient's decision. For this reason, reference pricing is often linked with a pharmacists' right, coupled with incentives or even an obligation, to substitute one product for another.

Profit controls

Governments use profit controls to a lesser extent than price controls, though Spain has taken costs into account in determining prices since 1991. Meanwhile, in spite of its name, the Pharmaceutical Price Regulation Scheme in the United Kingdom has specified a permitted rate of return on capital when companies submit new products for approval. Drug companies are free to set their own prices but may not exceed a predetermined profit ceiling. By the same token, prices for existing products cannot be raised. The scheme has been in operation in various forms since 1957 and covers all licensed, branded prescription medicines sold to the NHS (80% of all NHS pharmaceutical spending). Over time, the government has both lowered the rate of return and adopted a more restrictive approach as to which types of drugs should be approved.

The UK scheme (UK Department of Health 1997) has attracted much attention, not least because it seems to have combined a strong performance by UK-based firms in pharmaceutical markets with a relatively low level of domestic health spending on the NHS (GAO 1994a, GAO 1994b, Thomas 1995). In practice, however, the scheme is less than transparent (Bloom and van Reenen 1998), and seems to have been successful largely due to the ability of public authorities to establish and maintain a flexible and reliable relationship with pharmaceutical manufacturers. More recent agreements have allowed some leeway for newer products in exchange for savings on existing drugs (UK Department of Health 1997). It is notable, too, that the UK pharmaceutical industry has become one of the most concentrated in the OECD, as smaller firms have virtually disappeared.

Global budgets

Faced with both slower growth and rising spending, governments' need to preserve short term financial balance became more acute in the 1980s and 1990s. Attempts to stabilise or reduce public spending on pharmaceuticals made for unilateral price freezes and sometimes price cuts: such measures have affected countries with all types of public coverage schemes, in northern, central and southern Europe.

Global budgets have been developed by two countries with high levels of expenditure, France and Germany, which otherwise had no specific 'managed care' features, nor any stringent control of prescription. France essentially followed Germany's example (Schneider 1995): in both countries a national target for drug expenditure was set, with financial penalties to be shared by doctors and the pharmaceutical industry if

pharmaceutical expenditure should exceed a specified target. In France, penalties apply when total prescribing, whether reimbursed or not, exceeds a certain limit; in Germany, to the total payments made by sickness funds for drugs. These measures seem to have led to significantly reduced expenditure in the short term, as doctors in both countries have reduced prescribing or (in Germany) substituted cheaper drugs for more expensive ones. Such unilateral measures have generally come at the price of considerable disaffection among doctors in both countries, and were suspended in Germany in 2000.

Generic drugs

In the majority of OECD countries, there are now explicit policies to promote the use of generic drugs. Generics are sets of drugs with the same chemical compound and the same International Common Denomination. Once products are off-patent, they can be sold as generic drugs at a much lower price than branded alternatives. In recent years, with the time limit on patents expiring for an increasing number of products, as well as the need to generate savings, the interest in generic drugs has grown.

The rising number of patent expirations and the declining number of effective years of patent protection first prompted a reaction from national authorities in the United States. Its purpose was to restore appropriate protection for future drugs, allowing for high initial returns on innovation in large part by decreasing the return on older existing products through the promotion of generics. In 1984, the Drug Price Competition and Patent Term Restoration Act, also known as the Waxman-Hatch Act, repealed existing laws that prohibited substitution, and tried at the same time to ensure that savings were passed on to consumers (Grabowski and Vernon 1992, Congress Budget Office 1998).

Other countries followed suit at the end of the 1980s, mainly those European countries with sophisticated regulation systems and high prices such as Germany, Netherlands and the United Kingdom.

Special rapid approval processes make it possible for generic drugs to enter the market, although additional legislation, or some deregulation of antisubstitution provisions, has been necessary to effectively promote their use. In the United States, by 1989, all states had passed drug product substitution laws that allowed pharmacists to dispense a generic drug instead of the prescription brand original. Meanwhile, the pressure of buyers (below) has often been the most efficient way to speed up the diffusion of generics.

Increased use of generic drugs may be encouraged by providing either information or economic incentives, or often some combination of the two. Information may take the form of advice to patients or guidelines for physicians (above), as for example in Germany, New Zealand, Sweden and Switzerland. Countries differ, however, in the extent to which guidelines are backed by financial incentives. Simple budget constraints serve as one way to increase the prescription of cheaper generics, as has been the case for the United Kingdom, as also in France, Germany and the Netherlands. Economic incentives may also be directed at the consumer, in the form of reference pricing, for example, which can increase the use of generics. On the whole, generic drugs appear to have gained ground only where strong financial incentives have been provided, whether to patients, pharmacists or physicians.

Managed care and changed distribution systems

In the United States, managed care organisations have done much to keep pharmaceutical costs down. Instead of specifying a standard copayment for all drugs, for example, HMOs differentiate between types of drug (generic or non-generic), and they use positive lists and reference pricing for reimbursement purposes. They have also fostered the emergence of more aggressive buyers such as Pharmaceutical Benefit Management companies (PBMs), which were a response to the combination of high prices and relatively high distribution costs prevalent in pharmaceutical retailing. They began by drafting formularies and negotiating rebates on them from manufacturers, which then put them in a position to offer cheaper, integrated delivery service and payment systems to major purchasers such as health plans and HMOs. This changed market dynamic has led to a pattern of implicit cross-subsidy among customer categories. Private customers in retail pharmacies now pay more in order to compensate producers for those sales for which prices have been bargained down.

In addition to PBMs, and partly linked to them, new forms of delivery have developed through mail-order pharmacies, which cover around 10% of the US market and are particularly important for those with chronic illness and older patients (Kane 1997). Mail order is also important in Australia and New Zealand, but remains relatively uncommon in most European countries. However, its growth may be stimulated by the increasing use of electronic commerce.

In some countries, distribution systems remain a full part of the public system, as in Sweden, where all pharmacies were nationalised in 1970 to form the *Apoteksbolaget*, a public agency. In others, meanwhile, chainstores specialised in health related products have begun to transform over-the-counter (OTC) drug markets. They may be seen as a

response to restrictive listing on one hand and a rising demand for health care products on the other.

In all of this, pharmaceutical companies themselves have remained far from passive, adopting two key organisational strategies. Horizontal integration has meant merging with or acquiring other companies, partly in order to capture a larger share of the market but also to build on a wider portfolio of research and development. In Europe, for example, Novartis is the result of a merger between Swiss companies Sandoz and Ciba-Geigy; Sweden's AstraZeneca is a merged firm, as is Aventis (between the German firm Hoechst and the French Rhone-Poulenc), while GlaxoSmithKline is the result of a merger between the already merged firms Glaxo Wellcome and SmithKline Beecham. The critical synergetic effect of such alliances lies in acquiring compounds for a company's own pipeline, or in reducing the time-to-market for new drugs (de Wolf 2000). Vertical integration, meanwhile, has meant buying up or contracting with one or more agents operating downstream, in order to obtain better conditions of access to the distribution system. In short, pharmaceutical companies have either acquired rivals or generics companies in order to gain new market shares for their products, or specific organisations such as PBMs to control their distribution.

Research and development

In an important sense, the whole pharmaceutical industry may be viewed as a product of the patent system, and in the past, countries without such a patent system have been unable to develop a significant innovative pharmaceutical industry. This is because developing new drugs is extraordinarily expensive, and in order to make innovation

worthwhile, innovators must be allowed not only to recover their costs but also to make higher than normal profits, at least in the short term. The patent system works by conferring temporary monopoly power on successful new drugs which pass the regulatory tests of safety and efficacy.

The use of scientific methods to develop new drugs is fairly recent and has been largely influenced by the regulatory process (Scherer 1997). The drug approval process in the United States was initiated with the setting up of the Food and Drug Administration in 1938 and strengthened in 1962 by the Kefauver Harris Act, which required the FDA to certify that new drugs were not only safe but efficacious. Organisations seeking to test a new product now have to obtain an 'Investigation of New Drug' authorisation, based on tests of its innocuousness on animals, before human testing may begin. Clinical trials comprise three phases, including blind tests and long-term toxicity tests, lasting for a period of 6 years. In some cases, a fourth phase can be required by the FDA (and some countries also require a test of cost-effectiveness).

The regulation of pharmaceutical R&D in Europe and Japan has been strongly influenced by the American example, especially in the United Kingdom and Germany (Thomas 1995). By setting high standards for market entry for new drugs, these countries forced their domestic drug firms to target the development of drugs of superior efficacy. This strong filtering of market entry by regulating product safety and efficacy has had an impact not only on costs and prices, but also on quality and the competitiveness of the industry as a whole. In France, by contrast, regulation was for a time much less strict, making for shorter admission times. But by the time formal market authorisation was strengthened at the end of the 1970s, the French pharmaceutical

industry had lost much of the comparative advantage it had had when very successful in the early 1960s (Thomas 1995, Barral 1995).

It is important to distinguish 'breakthrough' and 'me too' development in pharmaceutical products. Where research incentives are weak and when market entry is relatively easy, the industry may tend to concentrate on what are known as 'me too' products, for which innovation at the margin (in packaging, for example) plays a key role. In countries with strictly regulated prices, 'me too' innovation has been used as a tool to bypass price controls while contributing only marginally to therapeutic improvements (Jacobzone 1998). In all countries, there is a certain balance to be struck between 'breakthrough' and 'me too' innovation. It is the role of health technology assessment and clinical evaluation agencies, such as the National Institute for Clinical Excellence (NICE) in the UK, the Institute for Quality and Economy in Healthcare in Germany, or the Transparency Committee in France, to quantify the therapeutic value of health care products, including pharmaceuticals and to advise governments accordingly.

OECD countries differ greatly in their respective interest in pharmaceutical R&D. A recent study for the US Congress, for example, argued that price controls in other OECD countries slowed the rate of innovation in the US by reducing returns on patented drugs (US Department of Commerce International Trade Administration 2004). While some have a large research-based industry, and benefit in part from the higher prices it commands, others, without such a research base, are inclined to refuse to pay prices which do not promote their own scientific and production systems. In Australia, payments for R&D are allocated to the industry through the factor F scheme, introduced in 1988 and now called the Pharmaceutical Industry Investment Program (PIIP)

(Australia Pharmaceutical Benefits Pricing Authority 1997). The scheme grants additional support to companies which locate part of their R&D activities in Australia. Although trade rules mean that similar policies cannot be developed in the EU, government decisions in many European countries have implicitly tried to offer higher prices in return for location decisions in favour of their own country. In Canada, improvements in patent protection were made contingent on industry commitments to increase R&D spending from 5% to 10% of sales. In short, OECD governments are often ready to allow prices to reflect the high investment costs of R&D if doing so will benefit their own economies.

Supranational regulation

The EU's regulation of pharmaceuticals is derived principally from its concern with trade and industry, rather than with health and welfare. It was the Commission's Industry Directorate which, in 1996-1998 convened roundtables with working groups on a single market for pharmaceuticals. Its communication (COM(1998)588) reviewed the principal policy options for pharmaceutical markets, discussing price controls, profit controls and contractual policies. It supported the increase in the provision of generic drugs, also advocating least-cost purchasing both by providing prescribers with more comparative information on drug costs and, where necessary, requiring prescribers to share the cost of expensive practice.

Because Europe represents such a large share of the world market, what the EU does has a significant impact on pharmaceutical activity worldwide. In 1989, a European

Council Directive (89/105/EEC) took up the issue of the transparency of measures regulating drug prices and entitlements in national health systems. Meanwhile, European Monetary Union has had some indirect effect on pharmaceutical trading by increasing the transparency of price comparisons. More specifically, provision for a Supplementary Protection Certificate (SPC) has extended patent protection at the European level (Regulation 1768/92).

Drug licensing systems, of course, were first developed independently by different European countries (above). Since then, under EC Regulation 2309/93, a European Medicines Evaluation Agency (EMEA) has offered a centralised procedure for gaining marketing approval.[vi] Since January 1998, firms have been able to apply for drug licences either country-by-country or on a pan-European basis. The pan-European license saves time and resources in bringing a drug to the market, as well as harmonising the conditions for which the drug is licensed. This legislation also covers product classification, advertising, good manufacturing practice and provisions relating to labeling and wholesale distribution, though it does not address the provision of drug safety information either to health professionals or the public (Mossialos 1998, Earl-Slater 1997, Kanavos and Mossialos 1999). Importantly, the EMEA is not subject to freedom of information legislation in the way the US FDA is.

The organisation and financing of health care, however, remain the responsibility of national authorities. In this way, Europe escapes some of the dilemma (introduction, above) which confronts national governments. Though it has been able to develop standard licensing arrangements, its pro-competition industrial policy leaves it no basis for action on common pricing (Regulation 2309/93). Only at national level does

monopsony power continue to provide opportunities for price regulation, meaning that the enlarged EU still comprises 25 different pharmaceutical pricing and reimbursement systems. This makes for a picture of the EC 'coordinating divergence', in which a single market in medicines seems unlikely to emerge (Hancher 2004, Permanand and Altenstetter 2004).

One effect of Europeanisation has been that discussions between national authorities and providers in some countries over pricing and reimbursement policies have increasingly appealed to European rules (Earl-Slater 1997, Kanavos and Mossialos 1999). The European Court of Justice has ruled in favour of parallel imports, for example, and has also permitted patients to buy over-the-counter drugs more cheaply other member states, provided that they are for personal use and the product is authorised in their home country.[vii]

Meanwhile, in 1990, on the initiative of the producers' International Federation of Pharmaceutical Manufacturers' Associations, representatives of both industry and regulatory agencies began to meet under the auspices of the International Conference in Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This constitutes a higher level of regulation and coordination again: it includes the regulatory agencies of the EU, USA and Japan, and its guidelines are invariably endorsed and adopted by them. The purported logic of harmonization of this kind is to bring drugs more quickly and more efficiently to larger markets. However, while both industry and regulators employ a discourse of improved safety and enhanced innovation, compromise between different standards in competing jurisdictions is invariably made down rather than up. The relaxation of toxicological standards this

entails seems to favour, at least initially, the interests of those developing innovative products over those who might use them (Abraham and Reed 2002).[viii] Meanwhile, in so far as ICH seems likely to make it difficult for large generics manufacturers in developing countries to enter the market, its effect is to insulate established firms from competition (Timmermans 2004).

Few accounts of this increasingly sophisticated and extensive regulation of pharmaceutical supply suggest any decline in the corporate power of producers (Abraham and Lewis 2000, 2002), which seems to beg the key question of what regulation as such is for. It was effectively implemented in Germany and the UK after the sedative Thalidomide had been found to cause foetal abnormality in the early 1960s; to the extent that Thalidomide damaged public trust in the pharmaceutical industry, the origins of regulation lay in the need to restore and protect it (Abraham and Reed 2002). In most countries, medicines regulation is essentially corporatist, reflecting the interdependence of government and industry, while the consumer or patient interest is repressed or marginalised. Meanwhile, through the 1980s and 1990s, the neo-liberal position adopted by the 'competition state' tends to have made state and industry interests more rather than less congruent.

This pattern is reinforced in supranational regulation, especially in Europe. This is in part because Europeanisation removes regulation even further from the limited opportunities for participation in national policy making. But it is also due to the way in which national regulators compete to carry out assessments on behalf of the EU, which they do by speeding up the process, adopting revised criteria which suit producers before patients (Lewis and Abraham 2001).

Discussion: regulation and learning

The regulation of pharmaceuticals is a domain in which governments in OECD countries – states with Moran's three faces (Moran 1995 and introduction, above) - must pursue multiple goals. Some of these are complementary, some susceptible to reasonable trade-offs, others barely compatible. In choosing and advancing these various goals, governments are playing not one multi-level game but several.

A key consequence of this is that it is difficult, for its constituent actors as much as for the analyst, to make sense of what is going on. As a recent review of the field put it, pharmaceutical regulation seems to offer 'little new, and much that is unconsciously replicated, with scant recourse to the evidence base' (Maynard and Bloor 2003, p 39). Yet it is precisely here, in a domain which is highly internationalised, which is comprised of powerful and autonomous actors such as nation-states, transnational corporations and international agencies and in which competitive advantage is at a premium, that we might expect to find evidence of learning (even if not from 'evidence').

Some of this learning is familiar from other chapters in this volume. The development of innovative organisational forms like PBMs in the United States has often been used as a sort of *in vivo* social experiment by other countries, to the extent that many, if not most of the regulatory instruments in use in the OECD area have been influenced by policies originating in the US. In Europe, the UK represents a lead market, which makes UK institutions and initiatives of Europe-wide significance.

That said, simple learning in pharmaceutical regulation is inherently unlikely. The dilemmas of government are such that they lend themselves to no single or perfect solution. Though they draw on a common set of instruments, governments select and apply them in different ways. Each seeks to address different combinations of interests and institutions, including different ways of thinking about the relationship between government, industry and welfare. And because they are used in bundles with different local adaptations, the effect of any single regulatory initiative is specific to circumstance and difficult to test comparatively. Governments simply cannot take up the tools used by others, at least not to any equivalent purpose or effect (Mossialos, Walley and Mrazek 2004, Permanand and Altenstetter 2004, Mossialos and Oliver 2005).

At the same time, learning appears to be limited by the particular technical complexity of pharmaceuticals, both in themselves and in respect of the policy issues (principally licensing and pricing) they raise.[ix] This certainly mitigates against public participation in debate and discussion, and probably also limits government appreciation of what it might or should do. The information and research resources of industry outstrip those of government not only in respect of pharmacology but also public policy: corporations often understand the respective behaviour of different national and international markets better than governments do, and are consistently able to predict and manipulate the consequences of different regulatory interventions. Indeed, it is quite literally their business to do so.

Government appreciation and action is further constrained by divided (and sometimes competing) ministerial competences: between trade and industry on one hand and health and social affairs on the other. This holds at European level, too: EMEA

works to the Directorate-General for Enterprise and Industry, not Health and Consumer Protection. Though the UK is generally notable in comparative discussion for its relative institutional strength, it is worth specific mention again here. For it generates the greatest volume of what might be described as state-sponsored information about pharmaceuticals, including the *British National Formulary* and the *Drug and Therapeutics Bulletin* as well as PACT data, the National Prescribing Centre's *Effectiveness Bulletins* and other material generated by standards and monitoring agencies such as NICE.

Beyond that, there is much to suggest that learning is in process within and between public and private sectors as much as across countries. It is driven largely by competition, among firms, among governments and then between networks of each. Pharmaceutical companies are skilled, resourceful agents which depend on acquiring and using cross-national, comparative knowledge about pharmaceutical markets. As a combination of science and commerce, the industry as a whole is perhaps uniquely equipped for the diffusion of both hard and soft knowledge about new products, markets and ways of relating one to the other. This generates an isomorphic response on the part of governments, which must equip themselves similarly with some multilateral awareness of business strategies and ways to respond to and influence them. What regulatory transfer takes place is not the result of a collaborative undertaking among governments to face down industry, but of competition between states for economic and industrial advantage both at home and abroad. In terms of price control, for example, governments' interest may lie in transferring price-setting instruments. Yet the point is not to achieve

common pricing, but to set prices which trade off the interests of domestic pharmaceutical producers and consumers to maximum specific advantage.

At bottom, the multilevel and multilateral game played between states and pharmaceutical companies is one which reflects their reciprocal interdependence. Governments want firms to produce therapeutically effective products, but not at levels or prices which put the viability of public health coverage at risk. Firms want governments to provide them with markets and income streams (which is what licensing and public coverage do), but not on terms which offer them limited return. Innovation and regulation, in both policies and products, are bound up together.

Pharmaceutical regulation is a game both government and industry must play, though it would suit neither to win outright. It is, moreover, a complex game in which the rules are constantly changing, including those which govern the authority of the rules. The way to stay in the game is to learn, to adapt to new products, policies, firms and agencies as they appear. The situation is very like the one described by Heclo thirty years ago: 'What one learns depends on what one does… In both its self-instruction and self-delusions, the cobweb of socioeconomic conditions, policy middlemen, and political institutions reverberates to the consequences of previous policy in a vast, unpremeditated design of social learning' (Heclo 1974, p 316).

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Table 1: total spending on pharmaceuticals, % GDP, selected OECD countries, 1970-2000

	1970	*1980*	*1990*	*2000*
Canada	0.6	0.6	1.0	1.4
Germany	1.0	1.2	1.2	1.4
Netherlands		0.6	0.7	0.9
United Kingdom	0.7	0.7	0.8	1.1
United States	0.9	0.8	1.1	1.5
OECD 17 mean	0.81	0.84	0.95	1.25
OECD 30 mean				1.34

source: OECD (2006)

Table 2: public spending on pharmaceuticals, % public spending on health, selected OECD countries, 1970-2000

	1970	*1980*	*1990*	*2000*
Canada	0.3	2.8	5.1	8
Germany	14.1	12.5	13.7	12.3
Netherlands	10.2	7.7	9.5	10.8
United Kingdom	10	9.7	10.8	12.6
United States	1.9	1.9	2.9	5.1
OECD 17 mean	13.1	9.9	10.9	12.4
OECD 30 mean				13.8

source: OECD (2006)

[i] This chapter is based on Jacobzone, S (2000) *Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goals,* Labour Market and Social Policy Occasional Papers no 40, Paris: OECD; <http://www.olis.oecd.org/OLIS/2000DOC.NSF/LINKTO/DEELSA-ELSA-WD(2000)1>. I am grateful to Peter Schönhöfer for comments on an earlier draft, and to Achim Schmid for supplying the data used in tables 1 and 2. Mistakes and misconceptions which remain are my own.

[ii] The expenditure patterns described and analysed here do not include pharmaceuticals in hospitals. Drugs in hospitals are estimated to represent roughly 10 to 15 % of the total pharmaceutical market, and in most budgets are included under inpatient care. While innovative patented drugs play a more important role in inpatient settings, trends for hospital drugs are similar to those observed for drugs used in ambulatory care.

[iii] In both tables 1 and 2 here, Netherlands 1970 figures are in fact taken from 1972, and UK 2000 figures from 1997. OECD 17 countries are Australia (1970=1971), Belgium (2000=1997), Canada, Finland, France, Germany, Greece, Iceland, Ireland, Luxembourg, Netherlands (1970=1972), New Zealand (1970=1971), Norway, Portugal, Sweden, United Kingdom (2000=1997) and the United States.

[iv] For a recent review of price regulation in the EU, see Mrazek and Mossialos (2004).

[v] For a discussion of the possible application of reference pricing in the US, see Kanavos and Reinhardt (2003).

[vi] For description and discussion of the workings of the EMEA, see Garattini and Bertelè (2004).

[vii] In Europe, the effect of parallel imports on prices seems minimal, since such drugs tend to be priced just below those from original sources. Generics are much more important in price competition (Kanavos and Costa-Font 2005).

[viii] That said, patient interests are perhaps less than obvious. The key achievement of 'treatment activists' in respect of AIDS, especially in the US, has been to speed up the release of experimental drugs, overcoming established requirements for medical trials (Epstein 1996).

[ix] For discussion of the fundamental methodological challenges of price measurement, see Jacobzone (2000, pp46-48); on measuring policy outcomes, Kanavos et al (2004).