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PRICES OF MEDICINES : A CASE-STUDY ON THE IMPACT OF THE RATE-OF-RETURN REGULATION IN THE UNITED KINGDOM

Joan-Ramon Borrell [@]

Adreça correspondència:

Departament de Política Econòmica i Estructura Econòmica Mundial

Grup de Recerca de Qualitat 'Anàlisi i Avaluació de Polítiques Públiques'

Facultat d'Econòmiques - Universitat de Barcelona

Avda. Diagonal 690 - 08034 Barcelona

Tel: 34.3. 4021945 Fax: 34.3.4024573 e-mail: borrell@eco.ub.es

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Abstract

This work carries out an empirical evaluation of the impact of the main mechanism for regulating the prices of medicines in the UK on a variety of pharmaceutical price indices. The empirical evidence shows that the overall impact of the rate of return cap appears to have been slight or even null, and in any case that the impact would differ across therapeutic areas. These empirical findings suggest that the price regulation has managed to encourage UK-based firms' diversification in many therapeutic areas.

JEL codes: Government Expenditures and Health (H51);
Government Policy, Regulation, Public Health (I18);
Innovation and Invention: processes and incentives (O31).

Resumen

En este trabajo se lleva a cabo una evaluación empírica del impacto del principal mecanismo de regulación de los precios de los medicamentos en el Reino Unido sobre un conjunto de índices de precios farmacéuticos entre 1980 y 1994. La evidencia empírica muestra que la incidencia de la tasa de retorno máxima sobre los precios ha sido muy moderada o nula y que, en cualquier caso, el impacto difiere entre áreas terapéuticas. Estos resultados empíricos sugieren que la regulación de precios ha fomentado la diversificación de las empresas farmacéuticas radicadas en el Reino Unido en numerosas áreas terapéuticas.

Códigos JEL: Gasto Público y Sanidad (H51);
Política Económica, Regulación y Salud Pública (I18);
Innovación e Invención: procesos e incentivos (O31).

PRICES OF MEDICINES : A CASE-STUDY ON THE IMPACT OF THE RATE-OF-RETURN REGULATION IN THE UNITED KINGDOM

Joan-Ramon Borrell

(Universitat de Barcelona)

Introduction

This case-study aims to offer an insight into the effects of the main mechanism for regulating the prices of the medicines prescribed and covered by the National Health Service (the so-called Pharmaceutical Price Regulation Scheme, PPRS) on the drug price dynamics in the UK. The study of the British medicine price regulation is especially interesting because the drug industry is one of the few British high technology industries manufacturing high value-added products which has succeeded in competing in the international market. It has become one of the largest manufacturing contributors to the UK balance of trade, and which it has developed a large research and development industry capacity in the UK serving the world pharmaceutical industry.[1]

Although the British pharmaceutical industry has been the matter of inquiry by many scientists[2], there are very few studies on the incidence of

[1] Taggart (1993, 232) has argued that 'the existence and vigorous development of the nationally based pharmaceuticals business had led to substantial benefits in employment, investment and (perhaps most important of all) in the nation's technological capacity'.

[2] Hancher (1989-1990) has approached the study of the British pharmaceutical industry from a comparative legal perspective; Sargent (1981 and 1987), Macmillan and Turner (1987) and Howells and Neary (1995) from a political science perspective; Reekie (1975, 1979 and

domestic price regulations on the dynamics of medicine prices. However, the impact of the rate-of-return regulation on the dynamics of British pharmaceutical prices has been a matter of debate since the creation of the PPRS. These debates have mainly centred on studying the extent to which the regulation has allowed British prices to become higher or lower than the prices in other countries.

By contrary, there has been little research on analysing the long-term impact of rate-of-return regulation on the dynamics of British pharmaceutical prices. One of the more suggestive studies on the dynamics of medical preparation prices was that carried out by Hudson (1992). He modelled the price dynamics by therapeutic sub-market for the US's, the UK's, Germany's and France's pharmaceutical markets between 1982 and 1988 using a set of variables which took into account the degree of government intervention in the price setting dynamics.[3] However, this model does not analyses how governments have affected the dynamics of medicine prices.

This case-study tries to test the hypothesis that *the impact of the British rate-of-return regulation on drug price dynamics has been slight.* If this hypothesis is tested positively, we may argue that the UK domestic regulation of drug prices has encouraged UK-based pharmaceutical firms to diversify into many therapeutic markets. In so doing, it would have also shaped a rather successful policy outcome in terms of the performance of the UK-based pharmaceutical firms in the international market.

This paper starts with some background on the PPRS and the markets for medicines in the UK. Secondly, the paper moves on explaining the methods

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1995), Teeling Smith (1992) and Hudson (1992) from an economic perspective; and Taggart (1993) from the international business point of view.

used to evaluate the impact of the rate-of-return regulation on the drug price dynamics in the UK between 1980 and 1994. Thirdly, it shows the results of the evaluation carried out. Finally, it offers some concluding remarks derived from the evidence under study.

1. Background

In the UK, the main mechanism for regulating the prices of the medicines prescribed and covered by the National Health Service (NHS) since the 1950s is the Pharmaceutical Price Regulation Scheme (PPRS). Although it has changed strongly over time, since the 1960s the PPRS is a regulation mechanism based on a rate-of-return cap on the capital employed by pharmaceutical firms to produce the medicines prescribed by the health professionals of the National Health Service (NHS) to the public. It is a Government-Industry arrangement differing strongly from other European regulations because it has two goals: the NHS drug bill contention and the industry promotion.

The Pharmaceutical Price Regulation Scheme (PPRS) regulates the way price negotiations are conducted between the pharmaceutical companies and the DoH with respect to the sales of drugs prescribed and covered by the National Health Service (NHS) and provided whether by pharmacists or by hospitals. Under the PPRS, the prices set for new products are free while pharmaceutical firms have to seek price increases from the Department of Health (DoH) for the products already established on the market. In any case, the DoH annually assesses whether the profits earned by the pharmaceutical firms on its NHS operations exceeds a zero profit figure calculated from allocating the costs of

[3] One of the most significant conclusions which this work draws is that 'in the three European countries [...] there has been increasing downward pressure on price growth, although this is only significant in the UK' (Hudson 1992, 110).

production of the NHS products. The assessment of costs includes the allocation of a rate-of-return (agreed between the DoH and the ABPI) on the capital employed by the firms as capital costs for the production of NHS drugs.

Since 1986 the Scheme covers only those drugs sold under brand names, and excludes those products sold under generic names. Since then, those generic drugs are subject to a mechanism of reference pricing which differs strongly from the regulation scheme for branded products. The DoH establishes the amount of reimbursement to the pharmacist of the NHS prescription drugs sold under a non-proprietary name. Pharmaceutical firms in the UK may be operating in the following business lines which may be linked to three types of markets:

1. Sales of drugs which face little competition and which are under the rate-of-return regulation: sales to the NHS of in-patent branded products and innovative branded products which its patent has expired recently but which already retain high consumer loyalty.
2. Sales of drugs which face competition and which are subject to the rate-of-return constraint: sales to the NHS of innovative out-of-patent branded products, fighting brands, and pure generics until 1986.
3. Unregulated drug sales: sales to the NHS of pure generics since 1986; sales over the counter; sales of privately prescribed drugs; and exports.

Larger pharmaceutical industries (and those who seek price increases) and the Department of Health (DoH) carry out annual assessments of firms' accounts and negotiations with respect to the following aspects:

1. Assessed revenues: firms should report their revenues from retail sales of NHS general practitioners prescribed drugs.
2. Assessed costs:

2.1. Fully allocated costs to the NHS revenues: cost of goods, distribution, promotion (restricted to a maximum figure of 7 percent of revenues), information and research (restricted to a maximum of a figure about 20 percent of revenues).

2.2. Common costs:

2.2.1. General and administrative costs: overheads are spread pro rata to fully allocated costs of sales among different business lines.

2.2.2. Capital costs: capital is spread pro rata to fully allocated costs of sales among different business lines. Capital costs are calculated multiplying the rate-of-return agreed between the DoH and the ABPI, and the capital allocated to the NHS operations.[4]

3. Outcome: the DoH assesses whether the firm has earned zero profits.

4. Price variations or repayments: individual firms and the DoH negotiate price variations according to the deviation of assessed profits and zero profits. If the trading profit is above zero profits figure, firms are expected either to reduce its prices or to make a repayment of the excess to the government. However, if the trading profits are below zero profit figure firms are allowed to compensate by increasing prices on whatever drugs desired.[5]

[4] The 1986 version of the agreement established that the rate-of-return would be related to the FT500 index. For those firms which have a large ratio sales to capital in the UK, the DoH assesses the capital costs using a rate-of-return on sales rather than on capital employed.

[5] What Sargent (1987, 26) call a 'merit league table' guides each firm-DoH negotiations. So doing, the DoH take into account the extent to which the firm has created jobs in the UK, has carried out its research efforts in the UK, has undertaken productivity improvements and so on. Additionally, each version of the agreements have established somehow a 'grey area' or 'tolerance margin' within which firms may retain profits earned above zero profit figure with respect to NHS operations.

Let us review briefly some of the terminology on the drug markets and the relevance of each type of drug market out of total pharmaceutical markets in the UK using the available data.[6] Sometimes drugs are obtained at retail pharmacies, hospitals, dispensing doctors or nurses, or other outlets under health professionals prescription. Those drug sales are known as prescription sales. But sometimes, drugs are obtained over the counter (so-called OTC products): that is, distributed through many different professional and commercial outlets without health professional prescription.[7]

Although the percentage of medicines purchased over the counter was in 1987 slightly higher than in the 12-member European Community, in the UK medicines are mainly prescribed by health professionals (around 78 percent of them in 1987 in value terms).[8]

Over-The-Counter medicines are paid by the patients. On contrary, those drugs prescribed by National Health Service (NHS) health professionals are covered by the NHS. Patients are charged a flat rate per prescription when they collect the medicine from the pharmacies, and the NHS pays the costs to the pharmacist, the wholesaler and the pharmaceutical firms.[9] Patients are not charged when drugs are dispensed by hospitals or community health centres.

[6] We have 1987 data for over-the-counter sales of drugs, 1986-1994 data on retail and hospital sales covered by the NHS, 1989 data on age and patent protection sales and 1983-1995 data on branded vs generic sales to the NHS, and only 1984 data on leading product sales by therapeutic areas in the UK.

[7] Burstall (1990, 7) has described those drugs as 'tried-and-true remedies for minor illnesses such as headaches, colds and transient intestinal upsets'.

[8] Burstall (1990, 9).

[9] Although the greater part of the prescriptions issued do not raise this charge because the elderly, the young and the poor people are exempt. According to the DoH (1996b, 2), in 1995 the number of prescriptions where the patient did not pay a charge accounted for 84 percent of all prescriptions.

The NHS has covered between 81 and 85 percent of the sales of prescription drugs in the UK between 1986 and 1994.[10]

Competition in pharmaceutical markets depend on (1) patents and (2) trade-marks as well. Some producers enjoy patent rights with respect to its innovations. Innovators of molecular entities, extensions, chemical variations and technological processes may be granted with a patent by national governments with respect to the new molecular entity (product patent), or with respect to the technological process (process patent) or with respect to both, the new entity and its process of production (product and process patent). The patent offers a temporary monopoly of manufacture and distribution to the innovator. The effective length of patent protection depends on the patent term established by law in each country and the length of time which it takes for a new medicine to be developed to the stage where it is granted market approval.[11]

Drugs may be produced by more than one firm due to one of the following reasons:

1. Because the commissioner of patents or the patent owner has issued a license for the importation or manufacture of those drugs whose patent is still extent.
2. Because the patent or monopoly of manufacture and distribution has expired.

[10] Data compiled and calculated from UK IMS Ltd. and DoH.

[11] Following claims by the industry that the patent life was being effectively shortened by the increasingly long length of the R&D stages, the patent term was extended from 16 to 20 years in 1978. With the European Commission ruling related to the Supplementary Protection Certificate effective patent life may be extended to a maximum of 15 years from the date of first market approval in Europe. According to Collins (1993, 203), almost half of the prescription medicines produced by the larger pharmaceutical firms were in-patent drugs.

3. Because the patent protects only the monopoly of the innovator on the technological process for producing the new molecular entity (*innovator brand*), and other producers have achieved to produce a molecular entity with the same therapeutic value by alternative processes (*copy brands*).
4. Because these drugs have never been granted a market exclusivity right.

There is some confusion on the use of the term *generic* for grouping pharmaceuticals produced by firms other than the innovator. Some authors use *generics* to refer to any out-of-patent drug which is marketed by any firm other than the innovator. However, those follower firms may use a *fighting brand*, and in this case the medicine is a *branded generic*, or they may use a generic or non-proprietary name, and in this case the drug is a *pure generic*.[12]

Pure generics may be grouped as well in two groups, whether *commodity pure generics* and *house-brand pure generics*. The latter are out-of-patent substances sold by well-known companies without a product-brand name but under the generic name and the company's name.

In the prescription segment of the market for medicines, the number of drugs sold under non-proprietary names has increased following the end of the patent protection terms and the policies of the public and private health insurance institutions promoting generic prescription. The number of prescriptions written generically has risen in England from 35 percent in 1985 to 55 percent in 1990 (DoH 1996, 24). However, this change in prescribing habits has had only a minor effect on the NHS drug bill. The amount of drugs prescribed and dispensed generically has risen only from 5 percent in 1983 to 11 percent in 1995 in terms of the total NHS drug bill.

[12] See Ballance *et al.* (1992, 13) who quotes UNIDO.

Encouraging generic prescription increases competition for out-of-patent drugs. In the UK case, in 1983 only 12 percent of the NHS drug bill was accounted for by products prescribed generically; however, this percentage rose to about 26 percent in 1990, and had increased to 32 percent by 1995.

Finally, pharmaceutical firms compete only within therapeutic sub-markets between which cross-elasticity of demand is considered low. Additionally, the competition within sub-markets is considered highly imperfect because the supply is dominated by very few firms. Although sales of leading products accounts for a very little share of the total sales of medicines and the total sales of each therapeutic area, it accounts for a very large share of the total sales at sub-market level.

Many authors argue that competition in the market for medicines is derived from innovation dynamics. It is contended that new products face competition from alternative treatments, mainly from their predecessor drugs or treatments which, although they cost less, are supposed to be less cost-effective. Once new drugs are considered to be major advances, they gain acceptance and may largely dominate their therapeutic sub-market.

Although, as time goes by, lead products at the therapeutic sub-market level face the competition of new products and developments of existing treatments, they enjoy temporarily a dominant position and therefore the producer may charge high monopoly prices.

Nevertheless, this product-based competitive process is argued to imply large social costs because manufacturers may devote excessive resources to promoting trivial product changes.[13]

[13] Hancher (1990,50) and Ballance *et al.* (1992, 157) have both argued that companies' laboratories are primarily concerned with 'molecule manipulations' or 'me-too drugs' which increase risk and cost unnecessarily. Stiglitz (1994, 146) even have described some R&D activity as 'nothing more than an attempt to capture rents away from some other firm' by

2. Methods

The hypothesis of this case-study that *the impact of the British rate-of-return regulation on drug price dynamics has been slight* is based on two economic models: the classic model of Averch and Johnson (1962) and the common costs model of Brageutigam and Panzar (1989). These models explain the behaviour of regulated firms which not only produce for a non-competitive market but for competitive markets as well.

Stating with the Averch and Johnson (1962) model, these authors assumed that the regulated firm produces some output (Q) for a non-competitive market (which will be denoted by number 1) and some output for a competitive market (which will be denoted by number 2). The production function for each market depends on the combination of two inputs, capital and labour (K and L). Due to the monopoly power of the regulated firm in the non competitive market, prices in this market depend on the output as it shows the inverse demand function of the non- competitive market:

$$P_1 = P(Q_1) \tag{1}$$

Contrary, the regulated firm is not able to influence equilibrium prices in the competitive market, P_2*. Therefore, if the unit costs of the capital and labour inputs are r and w respectively and the rate-of-return cap on the capital employed imposed by the regulator is s, the regulated firm maximises the profit function with respect to the output produced for each market subject to the regulatory constrain imposed by the regulator:

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inventing 'a product that is like an already existing product but not covered by the patent protecting that product'.

$$Max_{Q1,\,Q2} \quad B(Q_1, Q_2) = P_1 Q_1 + P_2^* Q_2 - w (L_1 + L_2) - r (K_1 + K_2) \tag{2}$$

$$\text{subject to} \quad P_1 Q_1 + P_2^* Q_2 - w (L_1 + L_2) - s (K_1 + K_2) = 0 \tag{3}$$

If $s > r$ to the extent that the regulated firm may earn in the non-competitive market the monopoly rents which would earn in an unconstrained scenario (*m*),

$$P_1 Q_1 - w L_1 - s K_1 = m \tag{4}$$

the regulated firm may satisfy the regulatory constrain only if she increases output for the competitive market to the extent that the following condition is satisfied:

$$P_2^* Q_2 - w L_2 - s K_2 = - m \tag{5}$$

Therefore, according to Averch and Johnson (1962) regulated firms are interested in expanding output in the competitive market which happens to be under the regulatory constrain in order to increase the capital employed and operate in the non-competitive market like in the unconstrained scenario when the rate-of-return imposed by the regulator (*s*) exceeds the unit cost of capital (*r*). If this is the case, the firm earns an extra profit for each unit of capital employed in the competitive market equals to:

$$d B / d K_2 = (s - r) K_2 \tag{6}$$

This extra profit is obtained by seeking price increases in the non-competitive markets, and therefore, the firm will expand capital employed in the competitive market until she earns in the non-competitive market the monopoly rents which would earn in an unconstrained scenario.

By contrary, Braeutigam and Panzar (1989, 390) pointed out that, among other effects, the rate-of-return regulation may induce the firm to 'price below marginal cost in a competitive market which happens to be included in the set of core markets regulated by an aggregate rate-of return constraint' even in the case that the cap rate-of-return equals the unit cost of capital ($s = r$). This may be the case if there are some common costs in the production for the competitive and the non-competitive markets subject to a regulatory constrain, and for a third market which happens to be not included in the regulatory constrain (which will be denoted by number 3).[14]

C_j *(j= 1, 2, 3)* denotes production costs fully allocated to each one of the markets for which the regulated firm produces and *Cc* the common costs to the three markets. The rate-of-return on the capital employed for producing to the regulated markets equals to the unit cost of capital ($s = r$), and the regulator uses an allocation function for calculating the common costs which will be taken into account in the constraint. This allocation function depends on the output for each one of the three markets *(f* (Q_1, Q_2, Q_3)*)*. According to Braeutigam and Panzar (1989) the regulated firm maximises the profit function with respect to Q_1, Q_2 and Q_3 subject to the rate-of-return constraint on the capital employed in the regulated markets:

$$Max_{Q1, Q2, Q3}\, B(Q_1, Q_2, Q_3)=P_1Q_1 + P_2*Q_2+P_3*Q_3 -Cc-C_1-C_2 -C_3 \quad (7)$$

$$\textit{subject to} \quad P_1Q_1+ P_2*Q_2 + \; - f\, Cc - C_1 - C_2 = 0 \quad (8)$$

[14] Braeutigan and Panzar (1989) assume that the firm is not able to influence prices in the third market. The equilibrium prices in this competitive market are denoted by P_3*.

The allocation function of the common costs has the following properties: it is increasing in output for the regulated markets, and decreasing in output for the non-regulated market.

$$df / dQ_1 > 0, \qquad df / dQ_2 > 0 \text{ but } \quad df / dQ_3 < 0 \tag{9}$$

If we assume again that the regulated firm may obtain in the non-competitive market the monopoly rents related to the fully allocated costs which would earn in a non-constrained scenario (*m*),

$$P_1 Q_1 - C_1 = m \tag{10}$$

the regulated firm can satisfy the regulatory constraint only if output for the competitive market subject to the regulation is increased to the extent that:

$$P_2^* Q_2 - C_2 - f\,Cc = -m \quad or, \qquad P_2^* Q_2 - C_2 = f\,Cc - m \tag{11}$$

Therefore, according to Braeutigam and Panzar (1989) the regulated firm is interested to expand output in the competitive market which happen to be under the regulatory constrain to increase the share of common costs which are taken into account in the regulatory constraint. So doing, the regulated firm may seek price increases in the non-competitive market subject to the regulation. The firm may allocate additional costs under the constrain when it expands the output in the competitive market which happen to be under the regulatory constrain depending on:

$$d(f\,Cc) / dQ_2 = (d\,f / d\,Q_2)\,Cc + (dCc / d\,Q_2)\,f \quad (12)$$

The firm will increase output in competitive markets until she can earn in the non-competitive market the monopoly rents related to the fully allocated costs which would earn in a non-constrained scenario.

In short, Doyle (1993, 118) argues that 'in a situation where a multiproduct ROR [rate-of-return] regulated firm may sell some of its output on competitive markets, then this may lead to pricing below marginal cost in some of those markets as a way of expanding the rate base [the capital base]'. The incentive to expand the capital base may be generated because the regulated rate-of-return exceeds the cost of capital in the Averch and Johnson model, or because expanding output in the regulated competitive sector adds to the allocation of common costs in the Braeutigam and Panzar model (Doyle 1993, 119).

According to these models, the rate-of-return caps imposed by the regulator have a weaker impact on prices in those industries which regulated firms may carry out diversification strategies either into competitive markets subject to the regulation and into unregulated markets. Due to the fact that pharmaceutical markets are very heterogeneous, it is possible that the British rate-of-return regulation encourages those pharmaceutical firms with monopoly power in some regulated therapeutic sub-markets to diversify into competitive therapeutic sub-markets which happen to be under the regulatory constrain, and to therapeutic sub-markets which are not subject to the constraint. So doing, those firms may whether increase the denominator of the profit-capital ratio or increase the common costs taken into account under the regulatory constraint. In this case, the dynamic relationship between drug prices and rate-of-return imposed by the regulator may be weaker than it otherwise would be.

We try to evaluate the impact of the rate-of-return cap on the dynamics of the price of medicines across therapeutic areas in the UK between 1980 and 1994 using cointegration procedures. The classical regression analysis based on time-series data implicitly assumes that the underlying time series are 'stationary'. A stochastic process is said to be 'weakly stationary' if its mean, variance and autocovariances are constant over time. Therefore, the regression of a 'non-stationary' time-series variable on another 'non-stationary' time-series variable often only shows spurious long-term relationships.

To avoid spurious regressions, the evidence on the long-term relationship has been tested using cointegrating procedures. The cointegration theory has been developed extensively during the last decade. According to Granger (1986), two or more time-series variables are said to be cointegrated (in mean and variance) if a linear combination of them is a 'weakly stationary' stochastic process. Additionally, Park and Phillips (1989) pointed out that the cointegrating linear combination might include a deterministic trend, in which case two or more time-series variables are said to be cointegrated in variance. The concept of cointegration in variance is actually the most used to test whether there is a long-term relationship between two or more time-series variables.

The time-series under study are the following. On one hand, Laspeyres Price Indices related to UK manufacturers' home sales for the Standard Industrial Classification's aggregate heading 'medical preparations' (i.e. medicines) and for seven major therapeutic areas.[15] These price indices have been constructed from the data published by the Central Statistical Office for

[15] The abbreviations referring to the time series of price indices are the following: MEDIC for medicines, CNS for central nervous system medicines, CVS for cardiovascular system medicines, RESP for respiratory system, ALIM for alimentary tract, MUSC for muscular and skeletal systems, DERM for dermatologics, and ANTINF for general anti-infectives. The abbreviation for the rate-or-return caps is ROR.

the sample 1980-1994. Some of them have been constructed as an average of its main therapeutic sub-markets. These indices show the price dynamics of the medicines sold by UK-based manufacturers in the United Kingdom whether covered by the NHS or privately (by patients or by private insurers). We have assumed that these price indices should not differ strongly from the price indices related to the medicines prescribed by the NHS general practitioners.[16]

On the other hand, under the Pharmaceutical Price Regulation Scheme (PPRS) two rates-of-return on capital employed caps are distinguished. One is that agreed between the Association of the British Pharmaceutical Industry (ABPI) and the Department of Health (DoH) in the every five years negotiations of the Scheme. Each version of the agreement has usually stated a range of rates-of-return, and a 'grey area' or 'margin of tolerance' within which every single company may negotiate its own permitted annual rate-of-return on capital employed to its NHS sales. The other cap is the actual aggregated rate-of-return permitted to the industry after each company annual negotiation which differs from the rate-of-return cap agreed between the ABPI and the DoH. We are mainly interested in the average actual rate-of-return permitted to the industry after the firm by firm negotiations. We have taken the return on capital employed reported by the UK pharmaceutical quoted companies compiled by Datastream as a proxy of the actual rate-of-return permitted after the firm-by-firm negotiations because the Department of Health (DoH) does not publish the aggregated figure of return on capital permitted. There is little doubt that the disclosure of the actual figures of the permitted rate-of-return would allow a much more accurate study of the impact of the Scheme on the price indices.

[16] We should remind that ethical drugs accounted for about 78 per cent of drug sales in the UK in 1987 and the NHS has covered more than 81 percent of total UK ethical sales between 1986 and 1994.

The main weakness of our empirical estimation is that it is based on just 12 degrees of freedom. Therefore, our results depend strongly on whether our estimations satisfy conventional residual assumptions.[17] In any case, the data described in table 1 shows that the price indices and the rate-of-return time-series under study appear to be 'non-stationary' variables, and therefore, these time-series may be cointegrated.[18]

Table 1
Data description

	Average	St. Dv.	Max	Min	N
MEDIC(1)	141,996	20,890	167,405	100,000	15
CNS(2)	163,700	39,149	228,724	100,000	15
CVS(3)	129,192	14,399	141,693	100,000	15
RESP(4)	174,293	36,102	209,530	100,000	15
ALIM(5)	144,317	23,023	172,629	100,000	15
MUSC(6)	116,610	8,112	126,472	100,000	15
DERM(7)	143,389	26,746	179,169	100,000	15
ANTINF(8)	108,831	3,837	115,100	100,000	15
ROR(9)	33,757	7,964	44,340	17,360	15

(1) MEDIC medical preparations price index; (2) CNS central nervous system preparations price index; (3) CVS cardiovascular system preparations price index
(4) RESP respiratory system preparations price index; (5) ALIM alimentary tract preparations price index; (6) MUSC muscular and skeletal systems preparations price index; (7) DERM dermatologics price index; (8) ANTIF general anti-infectives price index; (9) ROR rate-or-return caps.

Source: Central Statistical Office (various years) and Datastream.

3. Results

[17] Additionally, although the PPRS suffered two major changes in 1986 and 1993, the few observations available do not allow for testing any structural change in the series.

We proceeded to run the following cointegrating regressions to test whether any linear combination of the rate-of-return cap and any price index including a deterministic trend, was a 'stationary' stochastic process:

$$ln\ (Prices)_t = C + a_1\ TIME + \boldsymbol{a_2}\ ln\ (Rate\text{-}of\text{-}Return\ Caps)_{\ t} + e_t \qquad (13)$$

The error terms (e_t) from these regressions are stochastic processes which result from the linear combination of two 'non-stationary' time-series variables including a deterministic trend. We are interested in finding whether e_t are stationary stochastic processes in mean and variance across time. If any e_t is stationary, we may say that its respective price index time series and the rate-of-return cap time series are cointegrated processes in variance, and therefore, there have been a long-term relationship between them. The estimates from the long-run equations are shown in table 2.

Table 2
Estimated long-run equations †

	CONSTANT TERM	TIME TREND	ROR	R^2	Normality Test Chi (2)
MEDIC	4.18	0.02	0.153	0.97	2.98 §
	(38.74)	(13.88)	(4.61)		
CNS	4.46	0.05	0.055*	0.96	1.07 §
	(23.94)	(14.71)	(0.96)		
CVS	3.91	0.01	0.234	0.96	1.05 §
	(41.76)	(8.67)	(8.09)		
RESP	3.48	0.03	0.294	0.97	2.40 §
	(17.06)	(8.57)	(3.20)		
ALIM	4.28	0.03	0.118	0.96	0.98 §
	(31.58)	(12.60)	(2.83)		
MUSC	4.24	0.007	0.129	0.76	13.60
	(29.18)	(2.87)	(2.88)		

[18] Dickey-Fuller and Augmented Dickey-Fuller tests for unit roots confirm that these time-series are non-stationary.

DERM	4.48	0.04	0.039*	0.97	0.89 §
	(36.98)	(17.94)	(1.04)		
ANTINF	4.73	0.002*	-0.018*	0.09	0.53 §
	(33.20)	(1.08)	(-0.42)		

All variables in natural logs; † t statistic in brackets; * not statistically significant at 95 percent probability and excluded from residual analysis; § residual normality assumption is accepted at 95 percent probability.

Tables 3 and 4 show the results from the conintegration tests. These results depend on the tests used.[19] As table 3 shows, the Godfrey-Breusch test of the cointegration residuals (GBCR test) suggest that the rate-of-return cap on the capital employed on the sales of products covered by the NHS has had an impact on some pharmaceutical price indices between 1980 and 1994. According to this test, the price index of medicines as an aggregate, the price index of the cardiovascular system, respiratory system, alimentary tract and muscular and skeletal system medicines are cointegrated with the time series of rate-of-return caps because the residuals of the cointegration regressions are not serially correlated.[20]

Table 3
Stationary tests on cointegration regressions residuals

	GBCR(1)	ADF(2)CR(2)
MEDIC	0.06	-2.47*
CVS	0.13	-3.03*
RESP	0.002	-2.09*
ALIM	2.42	-3.52*
MUSC §	3.98	-2.70*

All variables in natural logs; § cointegration residuals suffer from non-normality; * residuals are not stationary, time series are not cointegrated; (1) GBCR, Godfrey-Breusch test on the Cointegration Residuals. Critical value at

[19] The Appendix contains a brief explanation of the tests used in this case-study.

[20] The estimates for the muscular and skeletal system preparations price index have to be put into question because cointegration regression residuals suffer from non-normality.

95 percent 5.89, null hypothesis is that residuals are stationary and time series are cointegrated; [(2)] ADF(2)CR, Augmented Dickey Fuller of order 2 test on the Cointegration Residuals. Critical value at 95 percent, -4.67. Null hypothesis is that residuals are not stationary and time series are not cointegrated.

On contrary, the Augmented Dickey-Fuller test of order 2 on the Cointegration Residuals (test ADF(2)CR) in table 3 shows that the residuals of the cointegration regressions are not stationary in any case, and therefore the rate-of-return cap has not had any significant impact on the dynamics of the prices of the pharmaceutical preparations between 1980 and 1994.

Finally, as table 4 shows the Coefficient of the Error Correction Model test (test CECM) depends on how we test at the same time whether the error correction model residuals are serially correlated. Using the Augmented Dickey-Fuller of order 2 test on the Error Correction Model Residuals (test ADF(2)ECMR), the impact of the rate-of-return cap on prices would have been null between 1980 and 1994.

Table 4
Statistical significance of the error correction models parameter and stationary tests on error correction models residuals

	CECM[(1)]	GBECMR[(2)]	ADF(2)ECMR[(3)]
MEDIC	-2.85	5.18	-1.68*
CVS	-3.30	4.55	-1.41*
RESP	3.40	2.32	-2.05*
ALIM	-2.09	10.02*	-2.34*
MUSC	-1.58 §	2.15	-1.53*

All variables in natural logs; § Not statistically significant at 95 percent probability and cointegration residuals suffer from non-normality; * residuals are not stationary, time series are not cointegrated; (1) CECM, t statistic of the Coefficient of the Error Correction Model. Critical value at 95 percent, 1.78; (2) GBECMR, Godfrey-Breusch test on the Error Correction Model Residuals, null hypothesis is that time series are cointegrated. Critical value at 95 percent, 5.23; (3) ADF(2)ECMR, Augmented Dickey Fuller of order 2 test on the Error Correction Model Residuals, null hypothesis is that time series are not cointegrated. Critical value at 95 percent, -4.61.

However, using again the Godfrey-Breusch test on the Error Correction Model Residuals (test GBECMR), the rate-of-return cap would have had an impact on the medicines aggregate price index, on the cardiovascular system medicines price index and on the respiratory system medicines price index.

Table 5 sums up these results. The parameter of cointegration measures the elasticity of the price indices to the changes on the rate-of-return cap because the dependent variables and the regressors are in natural logs.

Table 5
Long-term relationships between rate-of-return cap and price index time series. United Kingdom, 1980-1994
(Price-elasticity with respect to rate-of-return cap changes) [21]

	Cointegration Tests			
	GBCR	ADF(2)CR	CECM+ GBRECMR	CECM+ ADF(2)ECMR
MEDIC	0.153	0	0.153	0
CNS	0	0	0	0
CVS	0.234	0	0.234	0
RESP	0.294	0	0.294	0
ALIM	0.118	0	0	0
MUSC §	0.129	0	0	0
DERM	0	0	0	0
ANTINF	0	0	0	0

[21] Although the cointegrating parameters estimations are inefficient because the cointegrating regression does not take into account all the available information, those estimations are only biased when the statistic R^2 differ strongly from one. This is only the case of the 'muscular and skeletal system preparations' cointegrating parameter which has to be put into question.

§ Cointegration residuals suffer from non-normality.

4. Discussion

The empirical evidence support one main conclusion: the British rate-of-return regulation appears to have had little effectiveness with respect to the aim of containing the price of the medicines. According only to some of the econometric procedures used, in the best scenario a one percent change in the rate-of-return cap appear to have produced only a 0.15 percent change on the prices of the medicines between 1980 and 1994.

Additionally, the empirical evidence suggests that the impact of the regulation has differed across major therapeutic areas. Therefore, it appears that the PPRS has encouraged pharmaceutical firms to follow a strategy of setting prices which takes into account to what extent products of different therapeutic areas face competition. Firms may have been able to balance the incidence of competition on the prices of some therapeutic areas medicines by increasing prices in other therapeutic areas subject to lesser competition. Future research is badly needed for assessing whether the regulatory scheme has encouraged diversification of the UK-based pharmaceutical firms. Firms may have reduced the incidence of the rate-of-return cap by entering in many sub-markets.

Let us review briefly these results. Due to the difficulties of the Scheme in ensuring the containment of pharmaceutical prices, it may be argued that the government has had to rely on other mechanisms of price control --mainly out of the Scheme price cuts and freezes, and its ability to contain prescription costs through the functioning of the NHS. In the middle 1980s, the industry faced the real threat of having some of its branded drugs excluded from the NHS available preparations list if it did not lower its prices. By this way, the

government was able to exert a real downward pressure in the price of some products included in the PPRS, when they were little affected by its aggregated approach. [22]

The overall control of profits under the PPRS applies a limit to the aggregate prices that a company can charge for its products, including new products and products already on the market. The empirical work suggests that the PPRS also encourages an aggregated approach to price setting strategies. When the cointegration tests indicate that there is a long-term relationship between price indices and rate-of-return, the impact of the rate-of-return cap differs across therapeutic areas and many price indices remain unaffected by the dynamics of the rate-of-return.

Companies may have been carrying out price modulations to make sure that the combined effect of a set of price changes for a number of products leads to a neutral outcome with respect to the rate-of-return cap. Indeed, a reduction in the rate-of-return cap may induce firms to increase production of those products regulated by the PPRS but facing strong competition in their therapeutic sub-market. So doing, the assessment of profits would be reduced without reducing the prices of the products which happen to be enjoying a dominant position at the therapeutic sub-market level. These results might be strengthened using price indices at the therapeutic sub-market level because the aggregation in therapeutic areas probably does not offer a complete picture of the differences in the impact of the rate-of-return at the therapeutic sub-market level.

[22] Walley *et al.* (1995, 328) have argued that particularly the extension of the selected list in 1992 'acted as little more than a reference pricing system'. The extension, unlike the original 1985 list, involved prolonged discussion which led the reviewing committee to consider appropriate prices for particular therapeutic areas. This meant that: 'manufacturers were effectively forced to reduce their prices' to those considered appropriate by the reviewing committee if they wanted not to be de-listed (Walley *et al.* 1995, 328).

Finally, it may be argued that firms are encouraged to expand output in those price competitive sub-markets under the regulation (*pure generics* until 1986 and *fighting brands* during the whole period under study). By increasing the sales of these kind of products, competition in prices do not allow companies to take advantage of the whole return permitted. On contrary, this 'non used' permitted return on the price-competitive products may be argued to be used when seeking prices on those products which do not suffer price competition in its therapeutic sub-market. Further, increasing production on those markets allows firms to increase the share of common costs which are taken into account by the regulator. The large amount of the pharmaceutical firms sales for non-regulated markets (particularly export and OTC markets) implies that the amount of common costs which the regulator has to take into account for its allocation under the regulatory constrain is very large. Diversification is encouraged because the regulation allow firms to seek price increases for those products which face little competition, mainly *branded in-patent or innovative products recently out-of-patent*. Therefore, the Scheme may encourage a diversification strategy, which is particularly feasible for the larger UK-based companies which enjoy larger economies of scale and scope, and consumer loyalty.[23]

Summing up, we may conclude from this empirical evidence that the hypothesis that *the impact of the British rate-of-return regulation on drug price dynamics has been slight* has been tested positively.

Therefore, we may argue that the British regulation of the prices of medicines has encouraged UK-based pharmaceutical firms to diversify into many therapeutic markets and has offered to the pharmaceutical industry a

[23] Some evidence, like that stated by Taggart (1993, 259) that 'Glaxo's success has been largely due to an increased product range, especially in anti-ulcerants, respiratory and systemic antibiotics', appears to support these conclusions.

rather stable framework. This framework has been able to channel the public concern on the monopoly power of pharmaceutical firms, while it has included the demands of the industry in favour of mechanisms which reward research efforts (without costs-efficiency evaluation of the research expenditures) and in favour of some public policy promoting the investment in the UK of pharmaceutical firms producing for international markets. Further research should confirm whether the impact of the rate-of-return cap at therapeutic sub-market level leads to similar conclusions as those stated here, and undoubtedly, the formulation of a model of price dynamics based on the assumptions of the behaviour of the agents in monopolistic competition markets would offer more complete and rigorous results on the relation between medicine prices, market structures, firm strategies and government regulations.

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Appendix

Although a large number of methods to test for cointegration have been proposed, we have used only three of them: the Godfrey and Breusch test of serial correlation on the residuals of the cointegration regressions (GBCR test), the Augmented Dickey and Fuller test for unit roots on the residuals of the cointegration regressions (ADF(d)CR of order d test), and the test of the Coefficient of the Error Correction Model (CECM test). The Gofrey-Breusch test is similar to the well-known Durbin-Watson test which may be used in the case of having only few observations available.[24] The ADF(d)CR test is a unit root test proposed by Engle and Granger (1991) which may be used on the cointegration regression residuals. However, Kremers *et al.* (1992) pointed out that these tests impose a particular restriction on the cointegration procedure, that is, it assumes that the short-term elasticity between the variables under study is equal to the long-term elasticity. This restriction may lead to rejecting cointegration when it does in fact exists. These authors, using the Granger representation theorem which links cointegration to error correction models, argued that an error-correction-based test is preferable because it is more powerful and it uses all the available information more efficiently. The error-term in the error-correction model will be significant only if the time-series variables are cointegrated. Kremers *et al.* (1992) pointed out that when the short-term elasticity differs from the long-term elasticity between the variables under study, the t-ratio on the error term is approximately normally distributed.

[24] Godfrey (1978) and Breusch (1978).

Therefore, the significance of the error-term may be tested using the usual t-Student critical values. Hence, we proceeded to test whether there has been a long-term relationship between the permitted rate-of-return cap and each one of the price indices between 1980 and 1994 using the error-correction test proposed by Kremer *et al*. (1992).

We constructed the following error-correction models related to our cointegrating regressions to carry out the CECM tests: [25]

$$d\ ln(Prices)_t = C + b_1\ d\ ln\ (Rate\text{-}of\text{-}Return\ Caps)_t + \boldsymbol{b_2}\ (\ e_{t-1}\ ) + u_t \qquad (14)$$

The error-term, $\boldsymbol{b_2}$ will be significant only if the respective price index and the rate-of-return caps time series are cointegrated. We used the Godfrey-Breusch test and the Augmented Dickey-Fuller for testing whether the residuals of the Error Correction Models had serial correlation problems (GBECMR and ADF(d)ECMR of order d tests respectively).

[25] D before a variable denotes first difference; e_t is the respective error-term form the cointegrating regression.