Pharmaceutical Price Regulation
A Study on the Impact of the Rate-of-Return Regulation in the UK

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Abstract

Objective: This work carries out an empirical evaluation of the impact of the main mechanism for regulating the prices of medicines in the UK [the Pharmaceutical Price Regulation Scheme (PPRS)] on a variety of pharmaceutical price indices. The article also discusses to what extent the rate-of-return (ROR) regulation has encouraged UK-based pharmaceutical firms with patented products to diversify into markets in which products face strong competition.

Design and setting: The article starts with some background on the PPRS and the way firms behave under ROR constraints. The article goes on to explain the cointegration methods used and the results obtained. Finally, it offers some discussion and some conclusions related to the evidence and the incentives of UK pharmaceutical firms under the PPRS constraint.

Main outcome measures and results: The results obtained show that, according to only some cointegration tests carried out, the aggregate price indices of medical preparations and the price index of some therapeutic areas are cointegrated with the time series of ROR caps between 1980 and 1994. Additionally, a 1% change in the ROR cap has produced only a 0.15% change on the aggregate medicine price index.

Conclusions: These results suggest that changes in the ROR cap have had little or no impact on medicine prices and that, at best, the impact of the ROR has also differed significantly across major therapeutic areas. Finally, it is argues that the UK regulation of prices might have encouraged firms to diversify into competitive medicine-regulated markets and into uncontrolled markets.

This study aims to offer an insight into the effects of the so-called Pharmaceutical Price Regulation Scheme (PPRS) on the dynamics of drug prices in the UK. The PPRS is the main mechanism for regulating the prices of prescribed drugs covered by the National Health Service (NHS) in the UK. The study of drug price regulation in the UK is especially interesting because the pharmaceutical industry is one of the few UK 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 it has developed a large research and development industry capacity serving the world pharmaceutical industry.[1]

Government price regulations on the UK market for medicines has been the topic of inquiry in many research works. Hancher[2,3] has approached medicine price regulations in the UK and France from an institutional and legal perspective; Sargent[4,5] Macmillan and Turner[6] and Howells and Neary[7]
used the government-industry studies approach; Reekie\textsuperscript{8-10} from regulation economics perspective; and Taggart\textsuperscript{11} from the international business point of view.

Additionally, the PPRS has been the specific topic of inquiry in research by authors such as Luce,\textsuperscript{11} Teeling Smith\textsuperscript{12} and Towse,\textsuperscript{13} or it has been analysed in articles which deal with the history of government measures to control medicine expenditures in the UK, like that of Griffin.\textsuperscript{14}

However, there has been little research on analysing the long term impact of rate-of-return (ROR) regulation on the dynamics of UK pharmaceutical prices. One of the more suggestive studies on the dynamics of drug prices was that carried out by Hudson.\textsuperscript{15} He modelled the price dynamics by therapeutic submarket for the pharmaceutical markets in the US, UK, Germany and France between 1982 and 1988 using a set of variables which took into account the degree of government intervention in the price-setting dynamics. 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.’\textsuperscript{15} However, the model did not analyse how governments have affected the dynamics of medicine prices.

The study presented in the current article tries to measure the impact of the UK ROR regulation on drug price dynamics. Additionally, the article discusses to what extent 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 article starts with some background on the PPRS and the markets for medicines in the UK. Second, the paper explains the methods used to evaluate the impact of the ROR regulation on the drug price dynamics in the UK between 1980 and 1994. Third, it shows the results of the evaluation carried out. Finally, it offers some discussion related to the evidence under study.

### Background

In the UK, the main mechanism for regulating the prices of prescribed medicines covered by the NHS since the 1950s has been the PPRS. Although it has changed significantly over time, since the 1960s the PPRS has been a regulation mechanism based on a ROR cap on the capital employed by UK-based pharmaceutical firms to produce the medicines prescribed by the NHS health professionals to the public.\textsuperscript{1} It is a government-industry arrangement which differs greatly from other European regulations because it not only tries to contain the growth of the NHS drug bill, but also is in charge of the promotion of the UK pharmaceutical industry.

The PPRS regulates the way price negotiations are conducted between the pharmaceutical companies and the Department of Health (DoH) with respect to the sales of drugs prescribed and covered by the NHS. Under the PPRS, launch prices for new medicines can be freely chosen, while pharmaceutical firms have to seek price increases from the DoH for those products already on the market. In any case, the DoH annually assesses whether the profits earned by the pharmaceutical firms on its NHS operations exceed a zero profit figure calculated from allocating the costs of production of the products covered by the NHS. The assessment of costs includes the allocation of a rate of return (agreed between the DoH and the Association of the British Pharmaceutical Industry (ABPI)) on the capital employed by the firms as capital costs for the production of drugs covered by the NHS. The DoH and the ABPI agree on a ROR range, and each firm negotiates with the DoH its final permitted ROR figure. Capital costs are calculated by multiplying the rate of return on each firm’s capital allocated to NHS operations.