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Short report

Pricing schemes for new drugs: A welfare analysis

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ABSTRACT

Drug price regulation is acquiring increasing significance in the investment choices of the pharmaceutical sector. The overall objective is to determine an optimal trade-off between the incentives for innovation, consumer protection, and value for money. However, price regulation is itself a source of distortion. In this study, we examine the welfare properties of listing through a bargaining process and value-based pricing schemes. The latter are superior instruments to uncertain listing processes for maximising total welfare, but the distribution of the benefits between consumers and the industry depends on rate of rebate chosen by the regulator. However, through an appropriate choice, it is always possible to define a value-based pricing scheme with risk sharing, which both consumers and the industry prefer to an uncertain bargaining process.

Introduction

Public health care expenditure growth is a major concern for policymakers, especially in the current period of global recession. In Europe, where approximately 75% of pharmaceutical expenditure is reimbursed by public funds, price dynamics place budgetary pressure on governments that respond with more stringent price regulations (Carone, Schwierz, & Xavier, 2012; OECD, 2011; Panos, Taylor, Manning, & Carr, 2010).

The aim of these mechanisms is to find an optimal trade-off between the incentives to investments in innovation, consumer's protection, and better value for money in the use of public funds. However, regulations and restrictions are themselves a source of distortion. Pharmaceutical data shows a sharp decrease in the productivity of R&D spending measured in terms of newly approved drugs. Di Masi, Hansen, & Grabowski (2003) estimate that pharmaceutical companies invested more than US$ 33 billion in R&D worldwide compared to approximately US$ 13 billion just a decade earlier; however the number of New Molecular Entities (NMEs) approved for market entry by the Food and Drug Administration (FDA) in the US has declined from 53 in 1996 to only 26 in 2010 (PhRMA, 2011). This decline may well be determined by stringent price regulation such as reference price (Bardey, Bommier, & Jullien, 2010; Pammolli, Magazzini, & Riccaboni, 2011).

Despite the increasing interest, little is known of the welfare properties of alternative regulatory schemes. The aim of this article is to partially fill this gap by studying two alternative mechanisms: uncertain bargaining and value based pricing schemes. We show that bargaining through an uncertain listing process is not optimal from a welfare viewpoint. Value based pricing schemes with risk sharing are superior instruments, but the distribution of the benefits between consumers and the industry depends on the rebate that should be paid if the drug fails to reach a specific effectiveness target. The model proposed shows that if the regulator want to design a scheme that increases both consumer surplus and the industry profit the rebate has to be inversely related to the cost of the new drug.

Drug price regulation

In public health care systems, the price of new drugs is strictly controlled by Government agencies. After their approval drugs can be sold in the market, but they will be available for free (or through co-payment) only if listed in the formulary of reimbursed drugs. The scheme used to list a new drug is a country-specific mechanism, but shares some essential features: the outcome is uncertain and the probability of success depends on the cost effectiveness of the new drug (usually measured through its Incremental Cost Effectiveness Ratio—ICER, which is the ratio of change in costs to incremental benefits) and on the expected budget required to treat potential patients. This system has several drawbacks: it lacks transparency; its outcome depends on the bargaining abilities of the actors; it may lead to relevant differences in the payment for a unit of cost effectiveness across drugs; it may lead regulators to delay listing in order to reduce uncertainty and obtain better value for money (Griffin, Claxton, Palmer, & Sculpher, 2011).

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In the recent past, several innovations have been introduced in price regulation. Here, we focus on value-based pricing and risk sharing. Value-based schemes aim at reducing uncertainty in the listing process by setting a price that is directly related to the effectiveness of the drug; in other words, prices are determined on the basis of the expected benefit of the drug to the patient and not on the basis of the cost of producing the product. In this case, the listing process changes: the regulator identifies the maximum willingness to pay for a unit of cost effectiveness and each drug is priced according to the level of expected cost effectiveness derived from randomised clinical trials. However, there is no consensus in existing literature on the desirability of this pricing scheme. Those in favour indicate that the scheme allows reimbursement of the true value for money; opponents show that the system may inflate prices and result in poor value for money if ex post effectiveness falls below the expected value (Claxton et al., 2008, Claxton, Sculpher, & Carroll, 2011; Danzon, Towse, & Mestre-Ferrandiz, 2012; Jena & Philipson, 2008).

In the quest to reduce the cost of new drugs, regulators have also introduced risk sharing systems, where the industry pays back a part of the price through rebates if the ex post effectiveness falls below a specific threshold, or if the quantity sold is "too high" (Adamski et al., 2010; Barros, 2011; Cook, Vernon, & Mannin, 2008; Zaric & Xie, 2009). The literature does not agree on the desirability of risk sharing: for example, Towse and Garrison (2010) argue that these schemes will reduce profits, while Cook et al. (2008) are less pessimistic. Lilico (2003) shows that these schemes may improve welfare when patients are risk averse while Barros (2011) and Antonanzas, Juarez-Castello, and Rodriguez-Ibeas (2011) argue that administrative costs are the key issue since they may outweigh the benefits of these schemes.

In this study, we propose a very simple model that compares the welfare properties of listing through an uncertain bargaining process and value-based pricing schemes. From an ideal First-Best world, we show how these schemes alter welfare and its distribution between consumers and the industry.

The model

Let us consider a society that consists of a mass of individuals, normalised to one. Each of them has a fixed exogenous income Y in the support $(0, Q)$ and the average income is Y_M. We assume the existence of a public health care system that supplies drugs for free to patients and finances the cost using a linear income tax at rate τ. Patients utility is additive in income and benefits from health care. A new drug is about to be commercialised and its effectiveness E may vary in the range $[0, A]$. For the sake of simplicity, all the values are assumed to be equiprobable. Then, the expected effectiveness of the new drug will then be $A/2$. The drug is appropriate to treat a fraction v of patients for whom there are no other treatment alternatives. The expected utility function for a patient with income Y can be written as:

$$EU = Y(1-\tau) + \begin{cases} \lambda \int_0^A E \frac{1}{A} \mathrm{d}E = \lambda \frac{A}{2} & \text{treatment is appropriate} \\ 0 & \text{treatment is not appropriate} \end{cases} \quad (1)$$

where λ is the money utility equivalent gain from treatment with the new drug. If the drug is made available, the total expenditure pv will be financed by the following linear tax

$$t = \frac{pv}{\int_0^Q Yf(Y)dY}.$$

The drug is produced by a profit maximising firm at cost c. The profit of the firm can be written as:

$$\Pi = (p-c)v. \quad (2)$$

In the absence of the new drug, people use their income to buy commodities and the aggregate consumer surplus can be written as:

$$CS_0 = \int_0^Q Yf(Y)\mathrm{d}Y = Y_M. \quad (3)$$

The benefits from introducing the new drug are represented by the increased utility that society enjoy from health care. Each unit of effectiveness increases utility by λ, the drug can produce an effectiveness in the range $(0, A)$, and it is appropriate for a fraction v of patients. This implies that the expected benefit can be written as $\lambda v\,(\int_0^A E/A\mathrm{d}E)$ and that the expected consumer surplus derived by the introduction of the new drug is:

$$ECS = \int_0^Q Y(1-t)f(Y)\mathrm{d}Y + \lambda v\left(\int_0^A \frac{E}{A}\mathrm{d}E\right) = Y_M(1-\tau) + \lambda v\frac{A}{2}. \quad (4)$$

In this context a benevolent regulator should decide whether to list the new drug. The decisions will be made on the basis of the price and expected effectiveness of the new drug. In other words the regulator evaluates the difference $ECS - CS_0$ and decides whether to reimburse it.

First best solution

Let us now consider an ideal world where information is complete and symmetric and the regulator sets the price for the new drug. A benevolent regulator would set an "equitable" price by sharing the benefit deriving from the new drug between the industry and consumers. As done in the classical regulatory problems (Laffont & Tirole, 1994), the regulator maximises welfare that is defined as a function of consumer surplus and profit:

$$W = g(ECS) + f(\Pi)$$

where Π are the profits of the firm, g(.) and f(.) are two concave, double differentiable functions. For the sake of simplicity, let us assume a log-linear form for welfare:

$$W = \alpha \ln\left(\lambda v\frac{A}{2} - pv\right) + (1-\alpha)\ln v(p-c)$$

where α is the relative weight that the regulator assigns to consumer surplus. The maximisation of the above function yields the following definition of the optimal price as:

$$p^* = \alpha c + (1-\alpha)\frac{\lambda A}{2} \quad (5)$$

For $\alpha = 1$, the regulator simply maximises consumers surplus and sets $p_L = c$; for $\alpha = 0$ the regulator maximises the industry profit and the price will be equal to $p_M = \lambda A/2$. When the regulator is equally concerned about the two, $\alpha = 1/2$ and $p_{EQ} = 1/2(\lambda A/2 + c)$.