Reimbursement and promoting additional R&D in the pharmaceutical sector: An analytic framework

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Abstract

In publicly funded health care systems decisions have to be taken about whether or not pharmaceuticals should be reimbursed and included in the budget-constrained public insurance system. Within this context, an iterative framework could be used to distinguish the conceptually separate decisions of whether a pharmaceutical should be reimbursed in a specific moment in time from the decision of whether to fund and promote additional R&D in a therapeutic area. Within this framework, decision analysis could be used to determine (1) whether a particular pharmaceutical should be reimbursed in a specific moment in time; and (2) the specific reimbursement for different patient groups. In other words, the presented framework links reimbursement decisions and future R&D investment to therapeutic value of pharmaceuticals.

Keywords: pharmaceuticals, reimbursement.

1. Introduction

In publicly funded health care systems decisions have to be taken about whether or not pharmaceuticals should be reimbursed and included in the budget-constrained public insurance system. Reimbursement may cover the entire cost of the treatment or only a part, in which case the patient may have to contribute the outstanding cost.

According to economic theory, the optimal reimbursement should equal the externalities that arise due to the consumption of the good or service. In such cases it may be difficult to vary the reimbursement between different pharmaceuticals and between different patient groups according to the way in which the size of the externality varies, mainly because it is extremely complex to quantify the externality. Additionally, it may for instance be difficult to vary the amount of reimbursement over time, depending on the size of the externality.

Decision theory provides a valuable framework that could be used to distinguish the conceptually separate decisions of whether a pharmaceutical should be reimbursed in a specific moment in time from the decision of whether to fund and promote additional R&D in a therapeutic area.

This article presents a framework that addresses the two sets of decisions thorough the employment of value of information (VOI) analysis to support efficient reimbursement of pharmaceuticals. Within this iterative framework, the preceding model informs each subsequent stage, updated to incorporate information acquired to date. Hence the framework becomes the updated vehicle for efficient decision making, managing and directing future R&D efforts on an iterative basis.
This article is structured as follows. Section 2 reviews the different approaches proposed in the literature to regulate the pharmaceutical industry. Section 3 presents the methodological background for VOI analysis and cost-effectiveness acceptability curves, together with an illustrative application of VOI analysis. Section 4 analyses the selective reimbursement for pharmaceuticals according to the peculiarities of different patient groups. Section 5 discusses main policy implications of adopting the suggested framework and section 6 concludes.

2. Regulation in the pharmaceutical industry

There is a widespread agreement that an unregulated pharmaceutical market would not produce socially desirable outcomes, either in terms of safety or access to life enhancing pharmaceuticals. Hence, different strategies have been proposed to regulate prices and profits in the pharmaceutical industry[1].

From a societal point of view, optimal regulation of a pharmaceutical firm requires optimal investment by the firm and at the same time optimal consumption of the medicines resulting from that investment. To achieve these objectives Kremer[2] suggests a mechanism in which a firm that has patented a new chemical entity would be bought out of the patent by the government, which could either produce the good at marginal cost or make the new product available to any firm without charge.

Loeb[3] proposes that pharmaceutical prices should not be directly regulated but that it should be paid a tax-financed subsidy equal to the consumer surplus generated by its chosen price. The firm will choose its price to maximise willingness to pay less cost and it will price at marginal cost.

Laffont[4] explores an optimal regulation scheme that explicitly models asymmetric information and investigates the mechanism that induces pharmaceutical firms to provide the regulator with its private information.

Guell[5] claims that the government should buy patents and distribute them. Because, under his argument, R&D expenditures are too low he calls for a mark up over the expected net present value of the monopoly profits which he establishes using an auction.

These theoretic approaches to optimal regulation in the pharmaceutical industry have never been put in practice due to the difficulties faced in its implementation and because it is assumed that pharmaceutical firms would accept offers from the government greater than the expected net present value of the monopoly profits[5].

Most innovative drugs are available only by prescription because it is believed that individuals can not assess the suitability of each medicine which may be appropriate for a medical condition. Another reason is that the available range of medicines is so vast and complex that information failures abound. Consequently, most governments recognise that information failures require regulation on safety, therapeutic efficacy and third party reimbursement to consumers on the grounds that access to life enhancing medicines should not be related to ability to pay.

Furthermore, public funded pharmaceutical expenditure has been rising substantially over the past several decades and is likely to continue to rise in the future[6]. This appears to be largely due to the growth of new pharmaceuticals[7,8]. While improvements in health are highly valued[9], evidence from diverse methodological perspectives suggests that many technologies may have little value at the margin[10-12]. It seems to be that cost effectiveness analysis and other methods for health technology assessment may be used to address this important problem. In this sense Sculpher[13] explains that the analytical framework of cost effectiveness analysis is important because it addresses two fundamental questions about new pharmaceuticals under conditions of uncertainty: First, is the product expected to be cost-effective on the basis of existing evidence? Second, is additional research concerning the product itself cost-effective? In addressing these questions, the analytical framework can establish when sufficient evidence exists to sustain a claim for a new pharmaceutical to be cost-effective.

Hence, one of the most important aspects of regulation is the way that government decides to include pharmaceuticals in a reimbursement list.