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EDITORIAL

Limiting Free Pricing of New Innovative Drugs After Launch: A Necessity for Payers?

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1 Introduction

Given the high costs of new innovative drugs, most EU countries have introduced policies to control the prices of innovative medicines over the past decade [1]. Two kinds of policies have become popular: value-based pricing (VBP) and international reference pricing (IRP). According to a recent Organization for Economic Cooperation and Development (OECD) paper [2], VBP refers to regulation of reimbursement or pricing of pharmaceuticals on the basis of their therapeutic value. Thus, the following EU countries use a VBP pricing/reimbursement policy: the Netherlands, Norway, Sweden and the UK, based on formal economic evaluation; Belgium, France and Germany, based on added medical benefits categorization; Italy, based on its system of innovation rating used in price negotiations and an advanced practice of performance-based agreements; and Denmark and Spain, because they use some elements of VBP in their decisions. A more narrow definition of VBP exists whereby economic evaluation is used not only for reimbursement but also for pricing decisions [1]. According to this definition, only Sweden and the UK use VBP [1].

In Germany, new legislation regulating the reimbursement of new innovative drugs within the statutory healthcare system (Arzneimittelmarktneuordnungsgesetz) was introduced on 1 January 2011 [3]. According to this law, new products are subject to an assessment to determine whether there is sufficient evidence of added clinical benefits compared with appropriate therapeutic alternatives. If such added benefits are confirmed, manufacturers and representatives of the statutory health insurance (SHI) are expected to agree on an appropriate reimbursement price within 6 months, starting from the completion of the benefit assessment by the German Federal Joint Committee. If drug makers and health insurers cannot agree on the price, a final decision on the reimbursement price will be made by an arbitration body. If one of the parties involved wishes so, the Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen; IQWiG) will be commissioned with a formal evaluation of costs and benefits of the product in question. Regardless of the mode of determination, the reimbursement price in Germany is 'value-based' given the definition of the OECD paper mentioned above [2]. It is applied starting from the 13th month of launch.

That the manufacturer is able to freely set a (profit-maximizing) price for the first 12 months after launch and receive full coverage has led to heated discussions. Those who are against this policy (e.g. payers) typically argue that the manufacturer is able to circumvent price regulation starting from the 13th month of launch by charging higher prices for the first 12 months in compensation.

From a policy-maker's perspective, the question then is whether value-based prices in Germany should indeed apply retroactively, thus reducing the window for free pricing. The purpose of this article is to analyze this question. The analysis will focus on truly innovative drugs, i.e. those that have demonstrated added health benefits over existing treatments. For drugs that have not demonstrated added benefits, prices should, in fact, be the same as for

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existing treatments. In this case, retroactive pricing at the level of existing treatments seems to be reasonable.

While this paper makes particular reference to the German healthcare system, the answer to the above question is relevant to any jurisdiction that regulates reimbursement prices through some form of VBP. That is, in jurisdictions where VBP is based on a formal economic evaluation, the question of whether value-based prices should apply retroactively is also relevant. Take the UK, for example: a drug may take 6–9 months from launch to a decision from the National Institute for Health and Care Excellence (NICE), as to whether it is cost effective for the national health service (NHS) [4]. If the decision is positive, it is then included in the formularies of local NHS bodies and must be made available within 3 months [5]. In all, the process could take up to a year [5]. The question with reference to the UK is then whether the UK government should allow for free pricing and coverage up to the point where the value-based price begins.

2 Should Value-Based Prices Apply Retroactively?

Obviously, applying value-based prices retroactively reduces drug expenditures of payers for the period in question. Yet, the potential for payers to achieve savings is limited: assuming a remaining patent duration of 10 years by the time the drug comes to market and a time period x for which prices apply retroactively, relative savings s over 10 years are calculated as follows:

$$s = \frac{x}{10} \times d$$

where d is the relative discount of the value-based price compared with the price freely set by the manufacturer (i.e. the profit-maximizing price). Average discount d across all drugs has been 23 % in Germany, based on the 25 highest selling drugs until 2013 [6]. Assuming 1 year for x, savings over the remaining patent period amount to only 2.3 % of total expenses for payers. Take the example of sofosbuvir (brand name, Sovaldi), which is used in combination with other drugs for the treatment of hepatitis C virus (HCV) infection and has been subject to intense discussions around its price. The European Commission granted marketing authorization in 2014. In Germany, manufacturers and representatives of the SHI thereafter agreed on a price of approximately €43,500 for a 12-week treatment. As the market entry price set by Gilead was €56,576, the resulting discount was 23 %. Yet, based on the above equation, avoiding free pricing will result in a mere 2.3 % reduction of total payer expenses over 10 years. Such a calculation for sofosbuvir and other drugs may even be conservative considering that the patient population in the first year after launch may be smaller than in the following years due to slow uptake. On the other hand, approval of other new drugs may reduce future market sales.

The limited potential for savings by applying value-based prices retroactively even needs to be traded against potential market entry deterrence of manufacturers. That is, a manufacturer may falsely assume a too-low retroactive price and therefore not enter the market. Only if the manufacturer has a correct expectation about the value-based price, then not launching—per definition—will not result in a loss of value or welfare for payers (but perhaps for patients). Moreover, manufacturers may not launch because of the spillover effect of a low price on the price in countries using IRP [7]. That is, the lower the price in a VBP country, the lower the price in IRP countries. Note that the German government has recently announced its intention to keep negotiated prices confidential to mitigate this effect [8].

Furthermore, in countries where value-based prices are determined based on efficient price negotiation, payers are able to translate foregone savings from free pricing into larger price discounts. Yet, this presupposes sufficient bargaining power on behalf of payers. Retroactive price regulation should thus be considered only if payers have less bargaining power than manufacturers (e.g. in the case of a breakthrough innovation or a life-threatening disease [9]) and hence are not able to translate higher (undiscounted) prices in the first year into higher discounts for the remaining years. Given potential market entry deterrence of retroactive price regulation, a compromise may be 'limited retroactive VBP', which does not extend to the time of launch. Yet, when negotiation power of payers is low, retroactive pricing may also backfire: manufacturers may use lower prices at market entry as an argument to limit overall price discounts.

In jurisdictions such as the UK, where VBP is based on a formal economic evaluation, foregone savings due to free pricing can be similarly accounted for: value-based prices can be (formally) adjusted downward for free pricing in the period before.

3 Discussion

Any jurisdiction using VBP can account for free pricing of manufacturers for a limited period after launch by lowering the value-based price in the period thereafter (i.e. by increasing the discount on the free price). Payers may want to avoid free pricing only if VBP is based on negotiations and payers have less bargaining power than manufacturers. Hence, by arguing to remove free pricing, payers in Germany indirectly acknowledge the lack of efficiency of

current agreements and their limited bargaining power. This poses a dilemma for payers: either the price negotiation is efficient and able to account for higher prices immediately after launch or it is not efficient, therefore requiring additional regulation.

In any case, as this paper shows, the potential for savings through avoiding free pricing is limited. In the case of the recently approved anti-HCV drug sofosbuvir, predicted savings are less than 3 % of total sales in Germany and thus much smaller than those from conducting a formal economic evaluation, which were estimated to be in the range of 30 % [10]. That is, even if negotiated prices applied retroactively, the optimal strategy for payers would have been to avoid agreement on price negotiation and commission a formal economic evaluation [11]. Hence, by trying to avoid free pricing, payers try to reduce failure from a regulatory approach (i.e. reliance on negotiations) that can lead to questionable and irrational prices in the first place.

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Compliance with Ethical Standards

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