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COMMENTARY

How Far is Germany From Value-Based Pricing 10 Years After the Introduction of AMNOG?

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1 Value-Based Pricing (VBP)

In pricing policy, the 3-C's model for pricing strategy is referred to as cost-based, competitor-based, and customer-based pricing, whereby the former can be defined as a profit mark-up on costs, the second as positioning in relation to competitors, and the latter as the value of specific benefit attributes from the customer's point of view (otherwise 'value-based pricing' [VBP]) [1]. There is a broad consensus that pricing based on value from the customer's perspective and their willingness to pay can positively influence a company's pricing power in terms of higher pricing compared with the other two Cs [2].

Value-based pricing for pharmaceuticals was not a German novelty and has already being pursued in some European healthcare systems [3, 4] and is currently being introduced in Japan, the second largest pharmaceutical market worldwide [5]. However, both criteria and measurement of the value of drugs can differ relatively widely depending on the healthcare system or stakeholder perspective [6, 7]. Its theoretical origins for health services can be found in the well-known Harvard competitive strategist Porter [8, 9], and in pharmaceutical supply, its precursor can be seen in Sweden after 2002 at a time when the term was not yet broadly used [10].

2 Paradigm Shift

In their reflections on the changing face of German pharmaceutical policy, Gerber, Stock, and Dintsios [11] asked 10 years ago how far Germany was from VBP after introducing the 'Act to Reorganize the Pharmaceuticals' Market in the Statutory Health Insurance System' (AMNOG) [12], which came into effect in 2011, leaving the question somewhat open. Synoptically, the AMNOG can be described as a regulation that aims for VBP via the preceding appraisal by the decision-making federal joint committee (G-BA) based on the assessment of the available study evidence by its contract institute, the Institute for Quality and Efficiency in Health Care. This appraisal serves for achieving a time-shifted reimbursement amount subsequent of the market launch of new drugs with free pricing for 1 year on the basis of negotiations with the National Association of Statutory Health Insurance Funds (GKV-SV). As the GKV-SV is negotiating new drug reimbursement amounts also for private insurance schemes, it acts as a monopsonist, being at the same time a constituent stakeholder of the G-BA (Fig. 1). Conversely, this means that the manufacturer will pursue the cost-based or competition-based pricing strategy, whereby they can achieve a temporary monopoly position through the time-limited patent protection for genuine drug innovations within the framework of free pricing. Under the AMNOG, however, the latter only applies for the first 12 months after market entry, as mentioned above.

3 Expectations on VBP

Gerber et al. [11] stated that as there is no way to determine an appropriate maximum reimbursable amount on the basis of the submitted dossier for the benefit assessment of new drugs by the manufacturer, it will become rather difficult to balance protection of statutory insured from unsubstantiated costs for new drugs and rightful claims of a manufacturer

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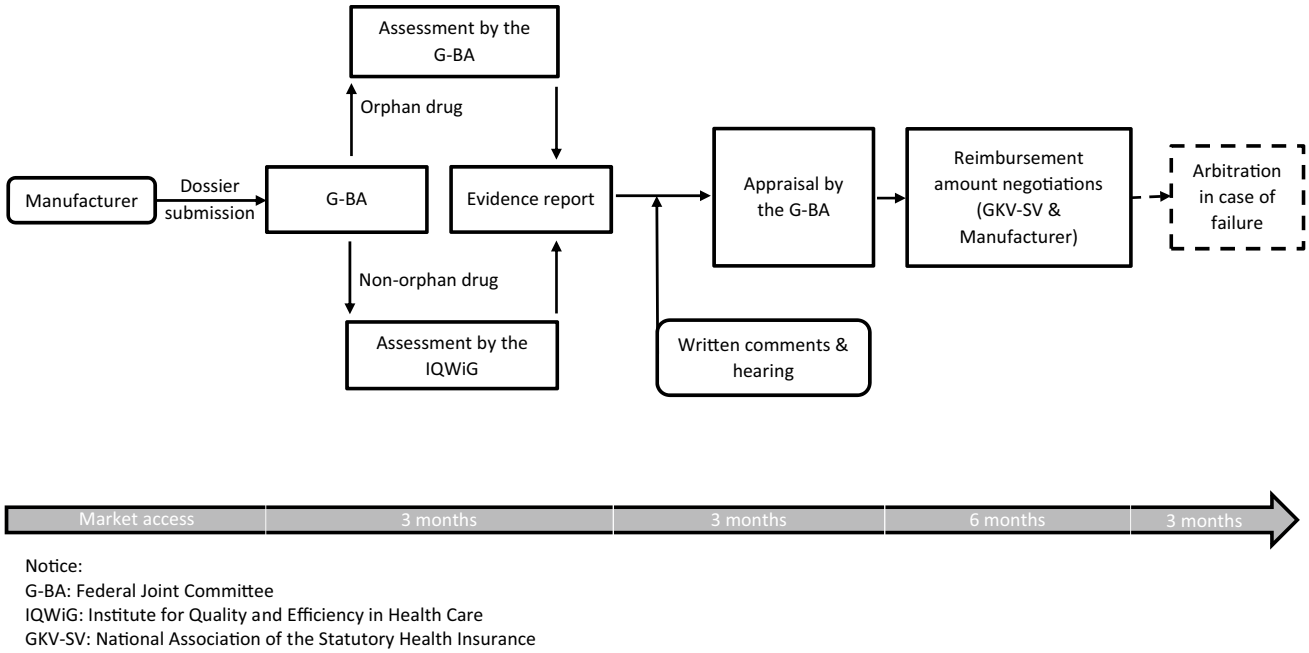

Fig. 1 Complete AMNOG ('Act to Reorganize the Pharmaceuticals' Market in the Statutory Health Insurance System') process. *G-BA* Federal Joint Committee, *GKV-SV* National Association of Statutory Health Insurance Funds, *IQWiG* Institute for Quality and Efficiency in Health Care

that launches a real innovative drug with a relevant difference in benefit. Subsequently, they concluded that as the premium for new drugs should depend on their level of benefit vs current standards under VBP principles, it seemed that Germany had taken an indeterminate step with the AMNOG towards VBP. Ten years later, a conclusive answer can be given to the question on how far Germany is from VBP.

Because in the context of German drug pricing GKV-SV acts as a demand side for patients consuming healthcare products and using services, representing the interests of its insured and not explicitly that of the patients, in terms of the AMNOG, VBP can be seen as an ex-post pricing by determining the value added of an offer for the GKV-SV or by empirically determining the willingness to pay of the GKV SV and thus stipulating the resulting profit contribution for the manufacturer.

4 Implementation of VBP

As depicted in Fig. 1, after the appraisal of new drugs by the G-BA, price negotiations between the GKV-SV and the manufacturer on the reimbursement amount begin. These negotiations are based on the framework agreement, signed by the GKV-SV and the relevant pharmaceutical companies' unions [13]. The main points to consider within the negotiations according to the framework agreement are: (1) the annual therapy costs of the comparator, (2) the extent of the added benefit, (3) comparable pharmaceuticals within the authorized indication(s) of the new drug, and (4) European prices in the referenced countries adjusted at purchase power parity and weighted by the respective sales volumes. The European countries, which are looked at while comparing the prices, are included in a specific basket that includes the following countries: Belgium, Denmark, Finland, France, Greece, UK, Ireland, Italy, the Netherlands, Austria, Portugal, Sweden, Slovakia, Spain, and the Czech Republic. The choice of countries was based on three criteria: (1) countries from all states of the European Economic Area, (2) countries with an additive population of 80% of the European Economic Area (excluding Germany), and (3) countries with a similar economic performance compared to Germany. The framework agreement clarifies that the negotiations follow a premium pricing philosophy in the sense of a mark-up calculation on the annual cost of the comparator. Furthermore, the reimbursement amounts are derived by considering every subpopulation particularly [14, 15]. Drugs that are not granted an added benefit are assigned to a reference price group if available or priced with the price of the comparator as an upper limit. If no agreement is reached, an arbitration board is called [16].

5 Not an Ideal-Typical VBP

Following the taxonomy of Sussex et al. [17], AMNOG is to be assigned to the VBP approach in the broader sense and, according to Jommi et al. [3], it fulfills the criterion of taking

into account the value of a new drug (additional benefit) as well as the second-order condition of taking into account the budget impact. However, apart from descriptive information on the envisaged regulations regarding drug price negotiations, little is known from the international literature about their actual implementation [3]. If one takes a closer look at the framework agreement, it becomes evident that, in addition to VBP per se, elements of internal reference pricing by considering the prices of comparable drugs in the indication of interest and external reference pricing (ERP) [18] via the European prices are implemented as well. For the positive and negative effects of ERP on drug spending and supply and a comparison of the short-term and long-term effects of VBP and ERP, see Kanavos et al. [19, 20]. In practice, there is enough evidence that next to VBP, internal reference pricing and ERP is implemented as well in the negotiations of the manufacturers with the GKV-SV [21] or the decisions of the arbitration board [16].

6 Impact of VBP in a Monopsonistic Pharmaceutical Market

As the first aim of AMNOG was cost containment, the expectation of an increased pricing power for manufacturers by VBP [2] has simply turned to the opposite as they have to negotiate with a monopsonistic purchaser (GKV-SV). The cost-containment target pursued with the AMNOG (Eur 2 billion [22]) was not achieved until 2018, 7 years after the law was passed, with savings of EUR 2.65 billion [23].

It is well known from the standard microeconomic literature [24] that for monopsonists, marginal expenditure is higher than average expenditure, which means that equating marginal value with marginal expenditure as a function of supply elasticity results in lower quantities at lower prices compared with the competitive market. Monopsony power leads to net welfare losses, as the level of output moves below the competitive level or, in other words, consumers with a willingness to pay higher than the marginal cost of production are denied access [25]. Faced with the dilemma of a guaranteed equilibrium quantity of the competitive market at a lower price or no purchase at all of new drugs according to the 'all or nothing' model in a monopsonistic pharmaceutical market [26], producers will not reduce the equilibrium quantity, at least in the short run. This is mainly because producers in order to survive in the market will reduce their prices until their producer surplus is completely depleted. This may even lead to lower prices than in the monopsony without an 'all or nothing' supply, with innovative producers with higher average costs exiting the market in the long run, as it has been already the case with some market withdrawals of drugs in Germany after the introduction of AMNOG [27]. From this behavior of the (absolute) monopsonist, reduced and delayed introductions of drug innovations are postulated despite a temporary monopoly position owing to time-limited patent protection [28]. Although the creation of countervailing market power through a bilateral monopoly or a monopsony monopoly market can lead to a Pareto optimum as under full competition [29], such a pharmaceutical market cannot be organized because of substitutional competition (relative monopolies). Empirically, Danzon [30] was able to show for the European Union that drug prices are far away from optimal Ramsey prices, i.e., a second-best solution for regulating natural monopolies via mark-ups on marginal cost prices calculated inversely proportional to price elasticity for the best possible allocative efficiency due to parallel trade and monopsonistic market structures. Finally, we can conclude that Germany is close to VBP, but the features of VBP in the German pharmaceutical market are definitely not compatible with the expected ones from the 3-C's model for pricing strategy.

Declarations

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