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Arbitration Board Setting Reimbursement Amounts for Pharmaceutical Innovations in Germany When Price Negations between Payers and Manufacturers Fail: An Empirical Analysis of 5 Years' Experience

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ABSTRACT

Background: In Germany, an arbitration board is setting reimbursement amounts for drug innovations when price negations between payers and manufacturers fail. **Objective:** To empirically analyze all arbitrations since the reform of Germany's Act to Reorganize the Pharmaceuticals' Market in the Statutory Health Insurance System came into effect. **Methods:** All available relevant documents up to January 2016 were screened and the identified contentious issues between the negotiation parties extracted. Reimbursement requests of both the negotiating parties and the arbitrations were transformed into a comparable format on the basis of defined daily doses and then contrasted among each other. **Results:** In the given period, 16 arbitrations took place. The arbitration board is implementing the same criteria used in the negotiations between manufacturers and payers. Almost all arbitrations dealt with generic appropriate comparative therapies. Reimbursement amounts set by arbitration were on average 38.4% less than the mean of negotiation parties' requests (69.2% less than the manufacturers' requests). The corresponding prescription volumes were arranged rather centrally. All but one arbitration refer to a 1-year contract period. The arbitration board rarely decided on further technical contentious points. Hence, no heuristics referring to them were derivable. **Conclusions:** There is some evidence for a quasi-algorithmic approach of the arbitration board, even though it is legally determined that it has to decide while taking the peculiar conditions of each case into due consideration, including the characteristics of the respective therapeutic area. The balance of interests proved to be within a very narrow space albeit it concerns in principle discretionary decisions. Thus, the purpose of arbitration seems not to be achieved sufficiently.

Keywords: AMNOG, arbitration board, early benefit assessment, price negotiations, reimbursement amount.

Introduction

Over the last few decades pharmaceutical expenditure has been rising in the member countries of the Organisation for Economic Cooperation and Development [1], although the recent financial crisis led to cuts in health care expenditure especially in Southern European countries [2,3]. Interestingly, differences in price across European countries seem not to be necessarily in line with their economic situations [4]. National policymakers apply different pharmaceutical cost containment measures for new drugs so as to curb growing expenditure, the most prominent of which are more or less external price referencing [5–7] and negotiations of reimbursement contracts [8], and to some extent value-based pricing [9]. Recently, there has been a call for differential pricing [10] in the European Union (EU) [11]. Germany was one of the few EU countries where until 2011 pharmaceutical companies have been largely free to set prices for new drugs.

AMNOG—Paradigm Shift

The German parliament passed the Act to Reorganize the Pharmaceuticals' Market in the Statutory Health Insurance System (AMNOG) on November 11, 2010, and brought a paradigm shift in the use of drug innovations in Germany [12]. This was preceded by a number of legal reforms with approaches of cost containment but without the intention of implementing a benefit assessment of pharmaceuticals. Before the adoption of the AMNOG, exaggerated deficit estimates were available. These estimates of €7.4 billion for 2010 and €11 billion for 2011 have induced the legislature to carry out a reform. A price freeze has been introduced so that prices of prescription drugs keep the same price level as of 2009 until the end of 2017. Moreover, manufacturer discounts, oscillating since 2003 between 6%, 16%, and at present 7%, have been realized.

In the last three decades, the dominant approach of health care reforms has been an attenuation of cost increases. This was

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mainly achieved through simple mechanisms of cost control such as price freezes and budgeting. As a result, it can be emphasized that the cost expenditures borne by the Statutory Health Insurance (SHI) account for 6% of the gross domestic product in the last 15 years [13].

Before the AMNOG only a few cases were excluded or cost-neutrally distributed. This applies, for instance, to rapid-acting insulin analogues being subject to a benefit assessment review, which was initiated by the decision-making Federal Joint Committee (FJC) and realized by the Institute for Quality and Efficiency in Health Care (IQWiG) [14].

Health economic evaluations as a basis for maximum reimbursement amounts were planned but not implemented because of time-consuming processes and a controversial methodology development. The respective pilot report G09-01 of the IQWiG constitutes an exception [15]. The report, however, examined only the feasibility of the suggested method, without demonstrating relevant consequences for the reimbursement.

Arbitration—Course of the Procedure

The day of the placing of a newly authorized pharmaceutical on the market marks the start of the early benefit assessment. Pharmaceutical manufacturers have to submit a benefit dossier to the FJC, the key legal institution of the self-administration within the German health care system, before the medicine is made commercially available. Within 3 months of the submission, the dossier is evaluated in most cases by the IQWiG. The IQWiG evaluation results in a recommendation regarding the added patient-relevant benefit of the investigated drug (assessment). Three months after IQWiG's recommendation, the FJC concludes the benefit assessment by making a final decision regarding the added benefit (appraisal). In the case of an acknowledged added benefit, this benefit can vary to different extents (major, considerable, and minor; or not quantifiable in the case of a not determinable added benefit). Furthermore, the benefit can be classified as not available or less in comparison with the appropriate comparative therapy. In addition to that, the evidence base of the (added) benefit is differentiated between a hint, an indication, and a proof [16].

After the FJC decision, price negotiations between the National Association of SHI Funds and the manufacturer on the reimbursement amount begin. This reimbursement amount is valid for SHI and private insurers. The price negotiations must be finalized within 6 months. If no agreement is reached in this time, an arbitration board is called. This board must come to a retrospective valid final pricing decision within 3 months, although an agreement between the negotiation parties is also possible during the arbitration process. Therefore, the arbitration board plays a key role in the whole process of the early benefit assessment, whenever the negotiation parties have recourse to arbitration (Fig. 1).

Subsequently, both contracting parties can apply for a cost-benefit assessment to the FJC, which is again conducted by the IQWiG. Moreover, they can take legal actions, but neither the cost-benefit assessment nor the legal actions have delaying

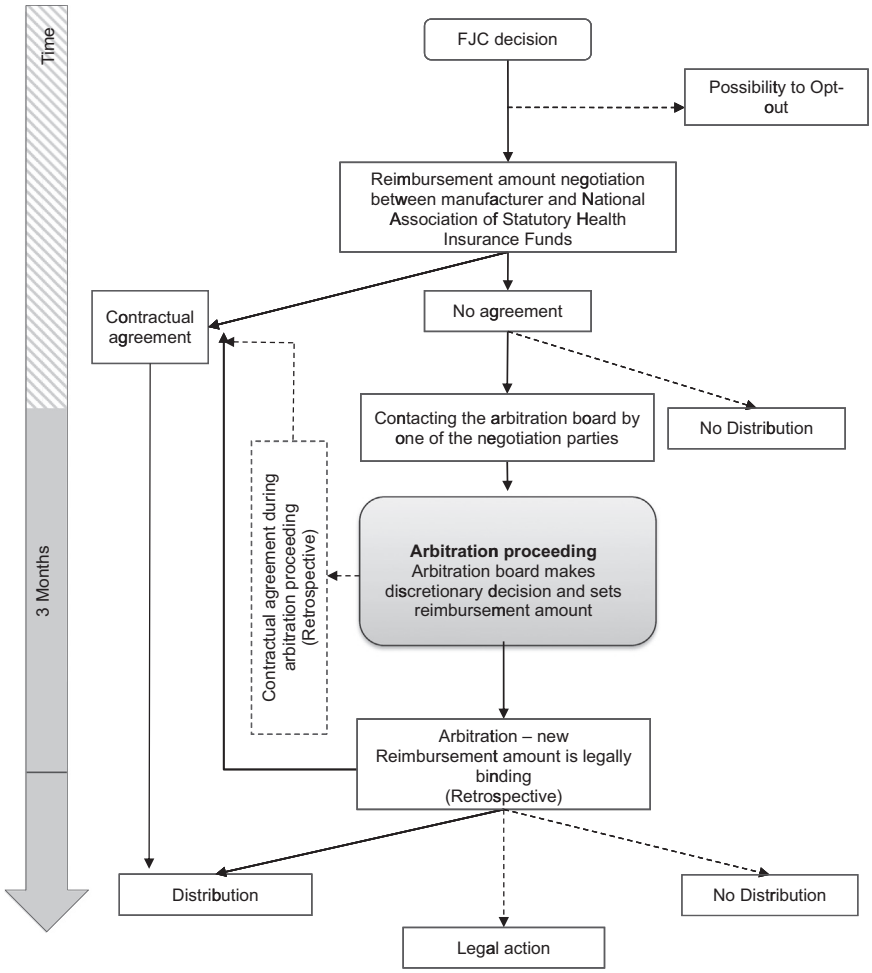

Fig. 1 – Arbitration proceeding. FJC, Federal Joint Committee.