ARBITRAL AWARDS ON REIMBURSEMENT PRICES SINCE 2019 IN GERMANY: WHAT WE CAN LEARN?

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BACKGROUND

According to the German AMNOG procedure, price negotiations between the pharmaceutical company and the National Association of Statutory Health Insurance Funds (GKV-SV) begin after completion of the benefit assessment. During four negotiation rounds, an agreement is to be reached on the reimbursement of drug costs. If the price negotiations fail, both parties usually enter an arbitration procedure (**Figure 1**). The decisions of the arbitration board (**Figure 2**) are made publicly available as so-called arbitral awards.

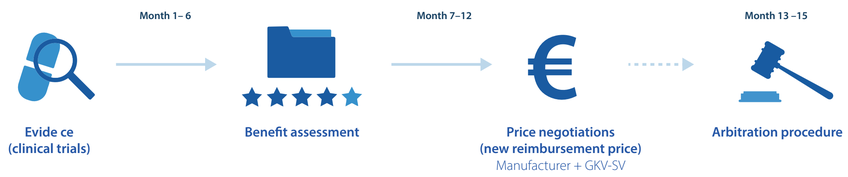

Figure 1: The AMNOG procedure. In case the reimbursement price negotiations fail, the parties enter an arbitration procedure.

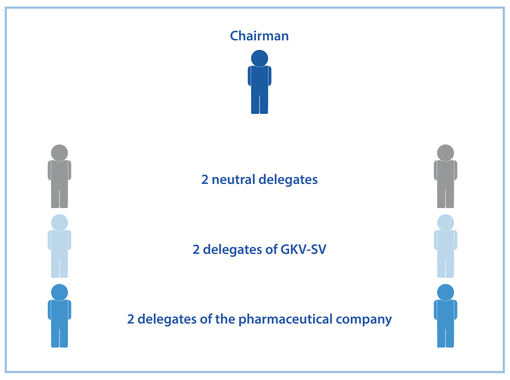

Figure 2: The members of the arbitration board. The arbitration board is constituted by the chairman, two neutral delegates, as well as two delegates from GKV-SV and from the pharmaceutical company.

OBJECTIVE

We aimed to raise knowledge from the arbitral awards which can support companies in successful reimbursement price negotiations for their products with an added benefit rating. Therefore, we intended to identify quantitative recurring decision focal points of the relevant arbitral awards concerning reimbursement.

METHODS

All arbitral awards since 2019, when Prof. Stefan Huster became chair of the arbitration board, were collected and systematically preprocessed in the co.value arbitral award data bank. In our quantitative analysis of the resulting reimbursement prices, we focused on identifying recurring influencing factors that were used by the arbitration board to set the price. Furthermore, we evaluated the impact of each identified factor concerning the final reimbursement price.

RESULTS I

The main topic in the arbitral procedures

From 2019 until January 2023, 20 arbitral awards were issued (**Table 1**).

Proprietary name	Active substance	Pharmaceutical company
Libtayo	Cemiplimab	Sanofi-Aventis Deutschland GmbH
Jemperli	Dostarlimab	GlaxoSmithKline
Vazkepa	Icosapent-Ethyl	Amarin Pharmaceuticals Ireland Limited
Retsevmo	Selpercatinib	Lilly Deutschland GmbH
Fintepla	Fenfluramine	Zogenix GmbH (jetzt: UCB)
Dupixent	Dupilumab	Sanofi-Aventis Deutschland GmbH
Lynparza	Olaparib	AstraZeneca GmbH
Amikacin liposomal	Arikayce liposomal	Insmed Germany GmbH
Forxiga	Dapagliflozin	AstraZeneca GmbH
Jyseleca	Filgotinib	Gilead Sciences GmbH
Zynteglo	Betibeglogene autotemcel	bluebird bio (Germany) GmbH
Rapiscan	Regadenoson	GE Healthcare Buchler GmbH & Co. KG
Esperoct	Turoctocog alfa pegol	Novo Nordisk Pharma GmbH
Kigabeq	Vigabatrine	Desitin Arzneimittel GmbH
Skyrizi	Risankizumab	AbbVie Deutschland GmbH & Co. KG
Erleada	Apalutamide	Janssen-Cilag GmbH
Epidyolex	Cannabidiol	GW Pharmaceuticals plc
Xofigo	Radium-223-dichloride	Bayer Vital GmbH
Ofev	Nintedanib	Boehringer Ingelheim Pharma GmbH & Co. KG
Tecfidera	Dimethylfurmarate	Biogen GmbH

Table 1: From 2019 until January 2023, 20 arbitral awards have been issued. In the table, the proprietary name, the active substance and the pharmaceutical company distributing the drug in Germany are given.

With an amount of 80% (16/20), most of the arbitral awards were issued on the reimbursement price: 35% (7/20) concerned drugs with added benefit, 30% (6/20) referred to drugs without added benefit, and 15% (3/20) related to drugs which received more than one benefit assessment with varying results. Only 20% of the arbitral awards have been issued on topics other than the reimbursement price.

RESULTS II

Added benefit of drugs with arbitral awards

The 20 arbitral awards were analysed for the outcome of the preceding benefit assessment **(Figure 3**). Strikingly, it became apparent that no arbitral award was issued for a drug with a major added benefit under the chairmanship of Prof. Huster. While 8 awards were issued on drugs without added benefit, 12 awards concerned drugs with an added benefit.

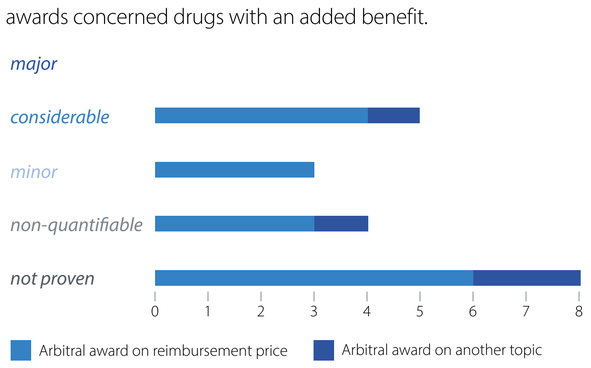

Figure 3: Analysis results for arbitral awards according to the outcome of the preceding benefit assessment. In case several outcomes were issued for a drug due to different indications or target populations, the highest benefit rating was applied for categorization.

RESULTS III

Arbitration awards according to therapeutic area

We analysed the 20 arbitral awards for the therapeutic area of the active substance (**Figure 4**). It became clear that most awards were issued in oncology. Another area in which price negotiations often failed and resulted in arbitration concerned the diseases of the nervous system.

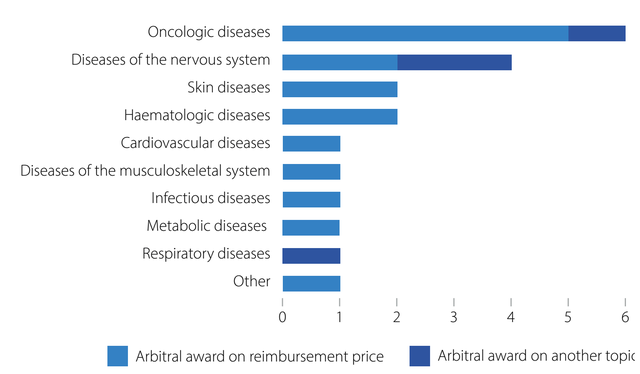

Figure 4: Analysis results for arbitral awards according to the therapeutic area of the active substance.

RESULTS IV

Decision focal points for drugs with added benefit

For drugs without an added benefit, the price of the appropriate comparator therapy is decisive according to the German legislation. However, for drugs with an added benefit, other factors become relevant, namely, the monetization of the added benefit, the European prices of the drug, and the costs of comparable drugs.

We analyzed the decision focal points on these recurring influencing factors and their effect on the reimbursement price for those drugs with an added benefit (minor, non-quantifiable or higher). Thereby, we observed that the arbitration board weighted

+ **the monetization of the added benefit at 50–90% in setting the reimbursement price,**
+ **followed by the European prices, which were weighted at 5–30%,**
+ **and costs of comparable drugs, which were weighted at 0–35%.**

CONCLUSIONS

Although each arbitral award is a case-by-case decision, important learnings can be derived from each decision for future reimbursement price negotiations in Germany. Currently, reimbursement prices are strongly limited by the legislator, and for drugs without added benefit, the costs of the appropriate comparator therapy are decisive. However, for drugs with an added benefit, the recurring influencing factors identified in this work should be used in a targeted argumentative manner to increase the possibility for a higher reimbursement price. Thereby, the focus of the argumentation efforts should be especially on the monetization of the added benefit.

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