Last Resort for Reimbursement of New Drugs in Germany: When the Arbitration Office Must Decide

Glüsen M[1], Rehkopf J[1], Martyniszyn-Eiben A[1], Kielhorn-Schönermark H[1], Schönermark MP[1,2]
[1]SKC Beratungsgesellschaft mbH, Hannover, Germany, [2]Medizinische Hochschule Hannover, Hannover, Germany

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Objectives

After the benefit resolution of the German health technology assessment (AMNOG) for new drugs, the pharmaceutical companies negotiate with the Sickness Funds about reimbursement amounts and general conditions. If no agreement is achieved, an arbitration procedure must be initiated, and the reimbursement amount is determined by the arbitration office. The aim of this study was to analyze the arbitration procedures regarding benefit assessment ratings, rebate outcomes, and market exit after arbitral verdict to examine the impact on and of the arbitration process.

Methods

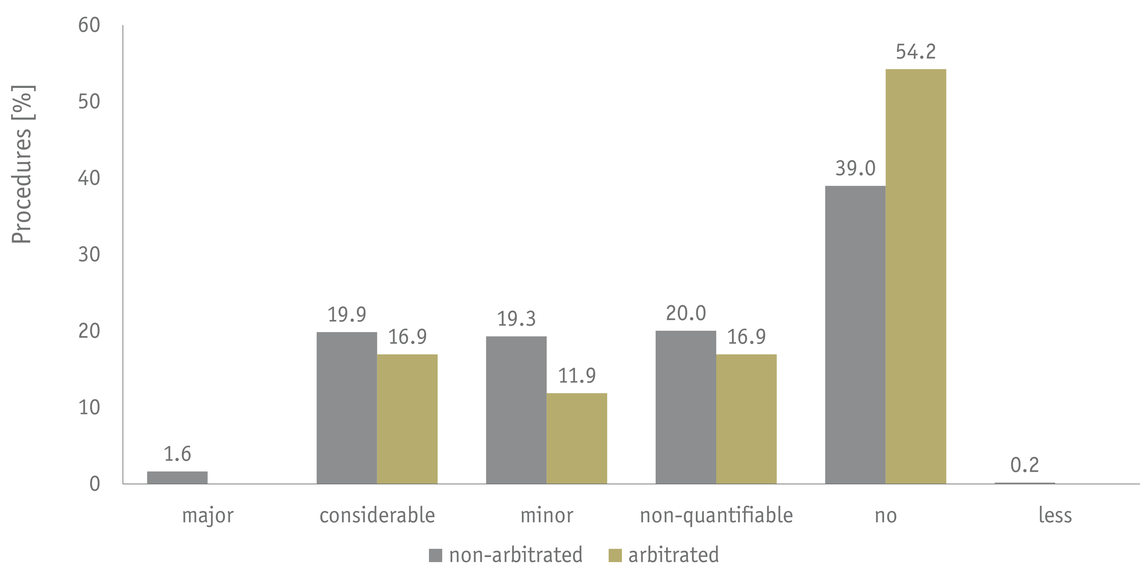
The results of AMNOG procedures with a subsequent arbitration process on reimbursement amounts were compared with all other AMNOG procedures without an arbitration process utilizing our MAIS database, containing information on dossier content, benefit assessment, G-BA resolution, prices and negotiated rebates of all AMNOG procedures ever performed. Using the Lauer-Taxe, drug prices and availability on the German market were verified. For this analysis we had access to 55 arbitration verdicts, in which the price was arbitrated. We make no claim to the completeness of the arbitration verdicts. Data cut-off was the 10th October 2022.

Results

The level of additional benefit is decided by the G-BA as part of the AMNOG benefit assessment. There are six types of additional benefit levels that can be designated by the G-BA: Major, considerable, minor, non-quantifiable, no and less. The arbitration office must include the additional benefit defined by the G-BA in its decision on reimbursement amounts. For our analysis the net box rebate was calculated by the reimbursement amount of the box plus manufacturer's discount without value added tax divided by the launch price. Accordingly, a lower box rebate reflects a lower price discount for the pharmaceutical manufacturer.

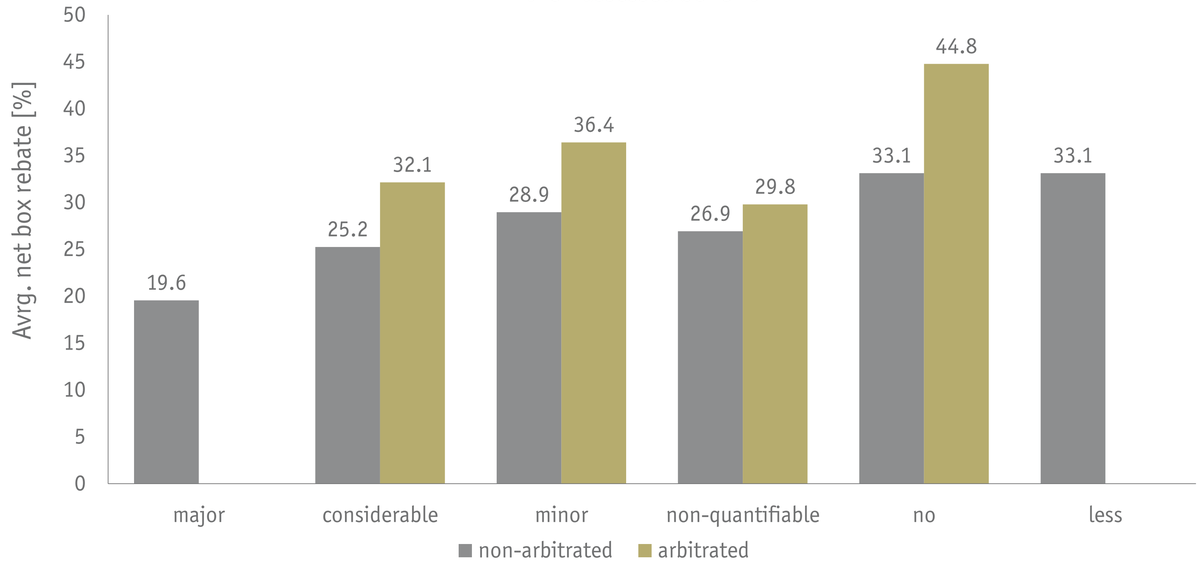
No relevant differences in the distribution of benefit levels between AMNOG procedures with (n = 59) and without arbitration (n = 549) process could be identified.

Figure 1 Additional benefit ratings for arbitrated and non-arbitrated AMNOG procedures



Net box rebates were on average higher after an arbitration process, both for procedures with and without added benefit (arbitrated n = 59; non-arbitrated n = 549).

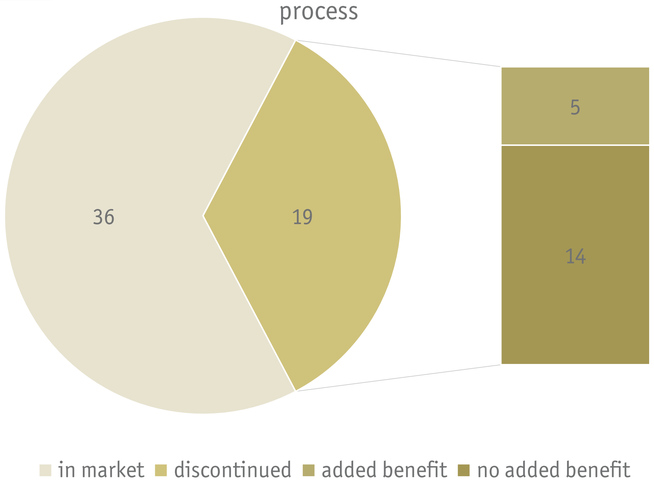
Figure 2 Average net box rebate of arbitrated and non-arbitrated AMNOG procedures in relation to their assessed benefit



If a drug or a box size is no longer economically viable through an arbitrated or negotiated price, the pharmaceutical manufacturer can withdraw their drug from the market at any time. A relaunch with a new box is possible. In a single arbitration process, more than one AMNOG procedure can be arbitrated.

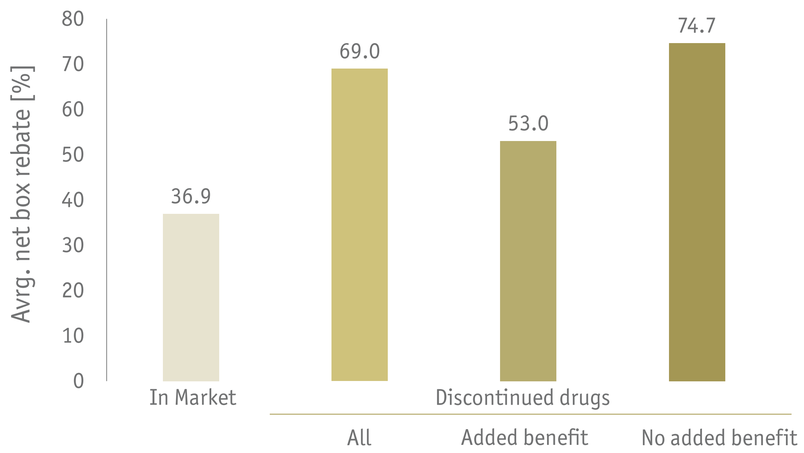
In 19 out of 55 arbitration processes, the drug exited the German market after arbitral verdict. 14 of those 19 drugs did not receive an additional benefit in the benefit assessment.

Figure 3 Market status of arbitrated drugs after the process



The average net box rebate for the discontinued drugs is 69.0% and 36.9% for the drugs that are still in the market. However, the average net box rebate of the discontinued drugs assessed with an additional benefit is 53.0% and without a benefit 74.7%.

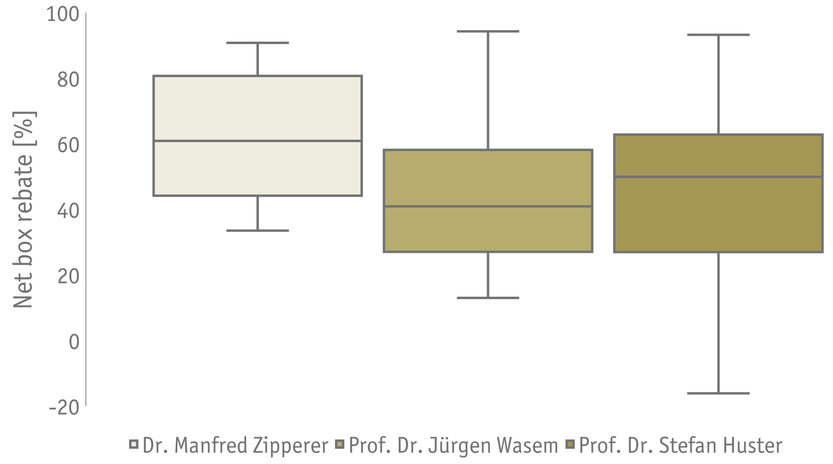
Figure 4 Average net box rebate of arbitrated drugs after arbitration



Dr. Manfred Zipperer was the chairman of the arbitration office from 01.07.2011 to 30.06.2015 and Prof. Dr. Jürgen Wasem from 01.07.2015 to 30.06.2019 . Prof. Dr. Stephan Husters tenure started 01.07.2019 and will end on 30.06.2023.

Arbitrated net rebates show minor differences correlated with the chairman of the arbitration office; Dr. Zipperer (n = 12, md = 60.8%), Prof. Dr. Wasem (n = 28; md = 40.9%), Prof. Dr. Huster (n = 15; md = 49.8%).

Figure 5 Net box rebate after arbitration



Conclusion

- The appointed level of benefit for a drug in the G-BA resolution had no influence on whether the arbitration office was involved. However, undergoing the arbitration process leads on average to higher rebates for drugs, i.e., arbitration processes seem to be decided to the disadvantage of pharmaceutical manufacturers.
- The high rebates lead to a remarkable high withdrawal rate of arbitrated drugs from the German market. Since the benefit level is the most relevant price anchor for reimbursement amount assessment, these high rebates correlate with low benefit levels.
- The minor differences in rebates between the different chairmen could indicate an influence of the personnel composition on the rebate level, which points to the complexity lying behind the arbitration process decision making.

schönermark kielhorn collegen

SKC Beratungsgesellschaft mbH | Hannover | Germany |
www.skc-consulting.de | Fon: +49 511 64 68 14-0
Email: gluesen@skc-beratung.de

All analyses have been conducted with our own comprehensive MAIS database that contains and links AMNOG information of all completed and ongoing benefit assessment procedures according to §35a SGB V of the German Federal Joint Committee (G-BA).