

How To Preserve Patient Access in Germany – a Performance Analysis of Products That Are no Longer Available on the German Market



Dr. Lara Schröder, Malte Glüsen, Lukas Heinrich Schoppmeyer, Heike Kielhorn,
Univ.-Prof. Dr. med. Matthias P. Schönermark | SKC Beratungsgesellschaft mbH

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OBJECTIVES

The **AMNOG process in Germany** evaluates the added benefit of all reimbursable drugs with new active ingredients. Some drugs that have undergone the AMNOG process are **no longer available on the German market**. This analysis examines the **performance factors** (e.g. evidence provided in the dossier, claimed benefit, launch price) within the AMNOG process and the subsequent price negotiations that could **prevent a drug’s withdrawal**.

METHODS

As of **October 2024**, 1,002 completed AMNOG procedures have been analyzed. Of these, the **drugs from 83 procedures were withdrawn** and the **drugs from 919 procedures are available** on the German market. In this analysis, all AMNOG procedures related to drugs currently available on the German market are compared with those related to withdrawn drugs with respect to the results of the **benefit assessment and price negotiations**.

RESULTS

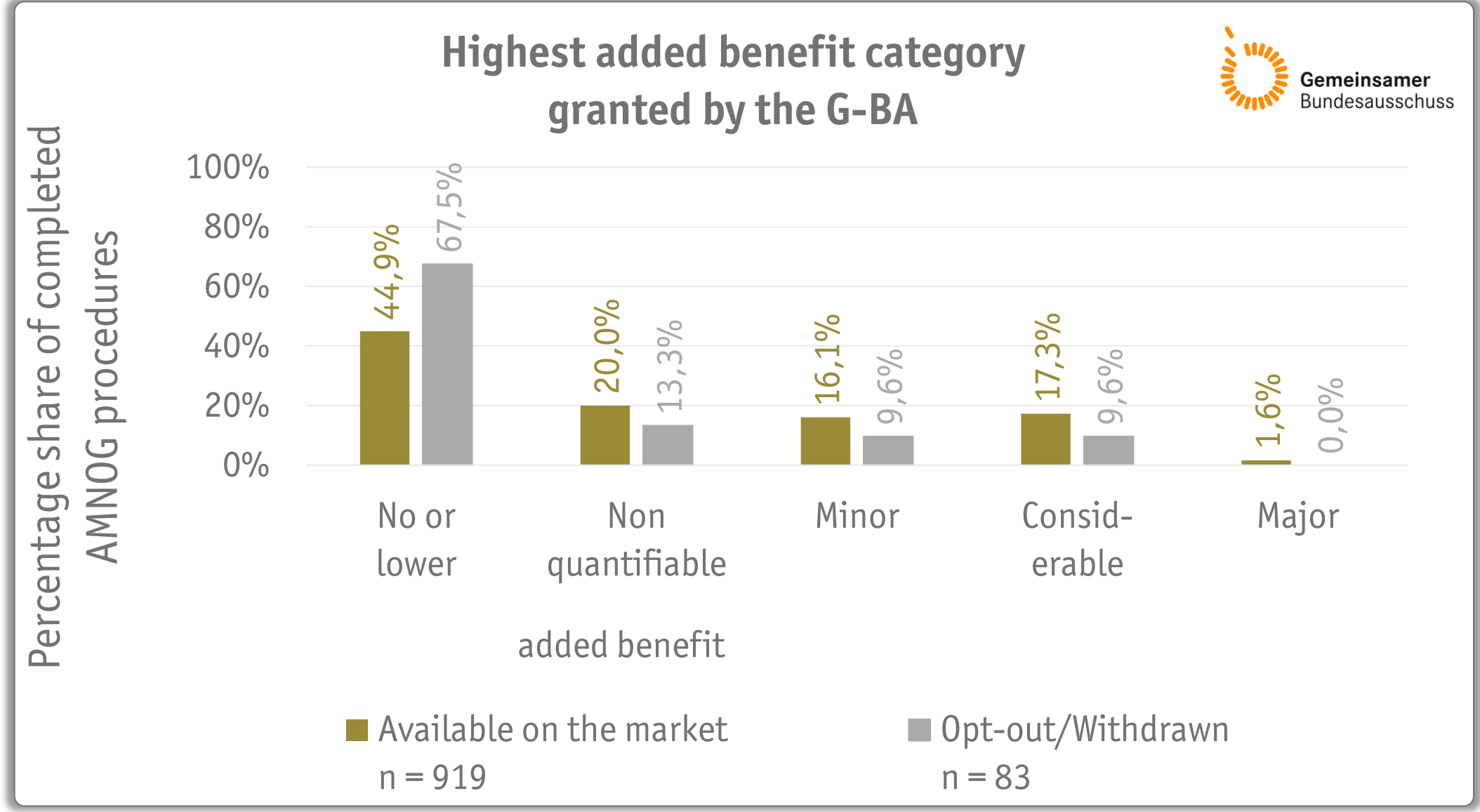
As of October 2024, 31 of 83 withdrawn products have a negotiated reimbursement amount

Overview of relevant AMNOG procedures

	Total	Available on the market	Withdrawn from the market
Number of started AMNOG procedures	1,125	1,042	83
Number of completed (benefit-assessed) AMNOG procedures	1,002	919	83
Number of AMNOG procedures with a negotiated reimbursement amount	834	803	31

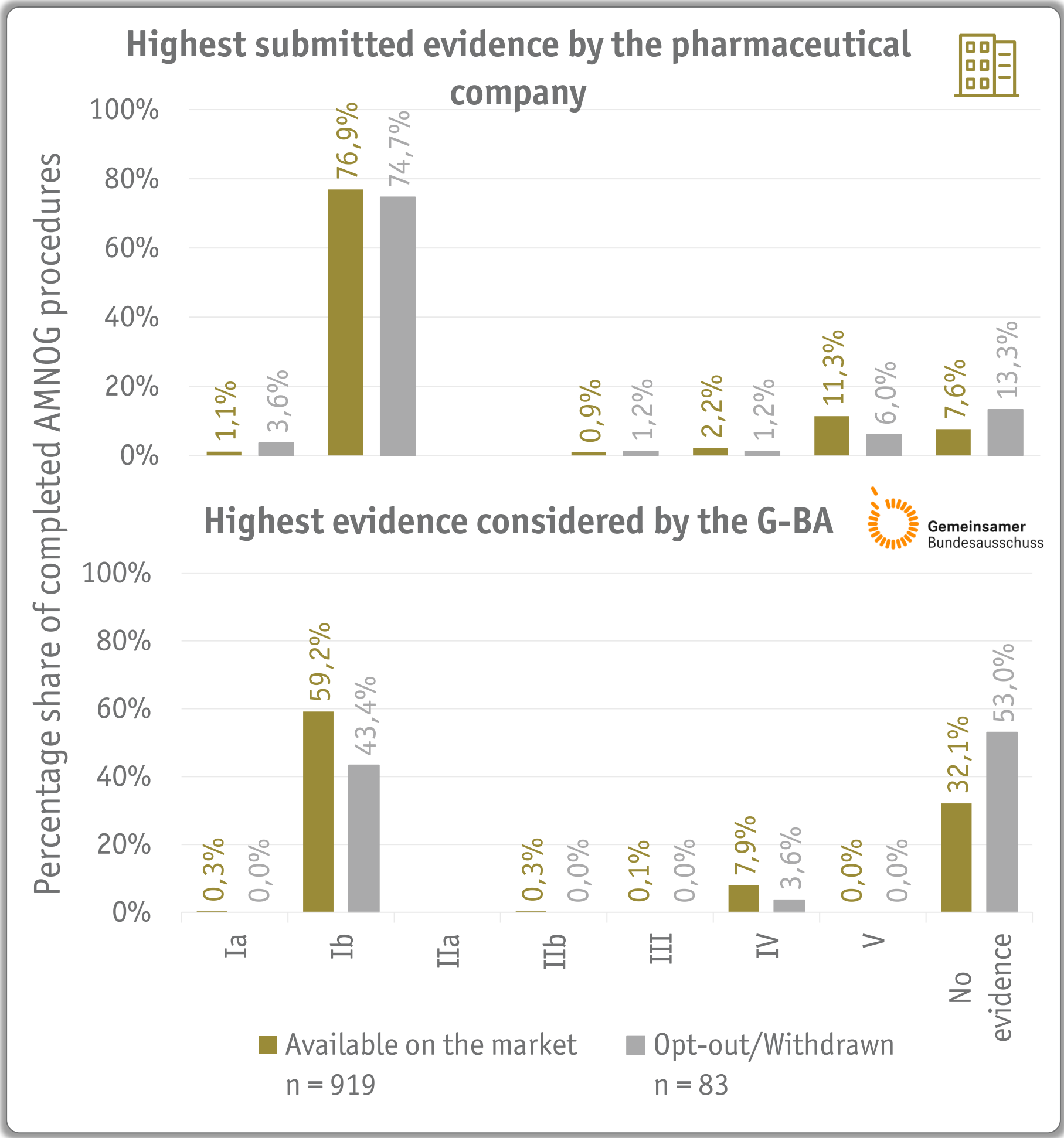
- As of **October 2024**, 1,125 AMNOG procedures have been initiated and 1,002 procedures have been completed.
- The reimbursement amount for the drugs of **834** benefit-assessed procedures has already been **negotiated** with the German association of SHI funds or determined by the arbitration board.
- While drugs from 919 benefit-assessed procedures are available on the German market, **drugs from 83 procedures have been withdrawn**.
- Of the 834 negotiated procedures, **the drugs from 803 procedures are still available while 31 are no longer on the market anymore**.

The added benefit granted by the G-BA is higher for AMNOG procedures for drugs still available on the German market.



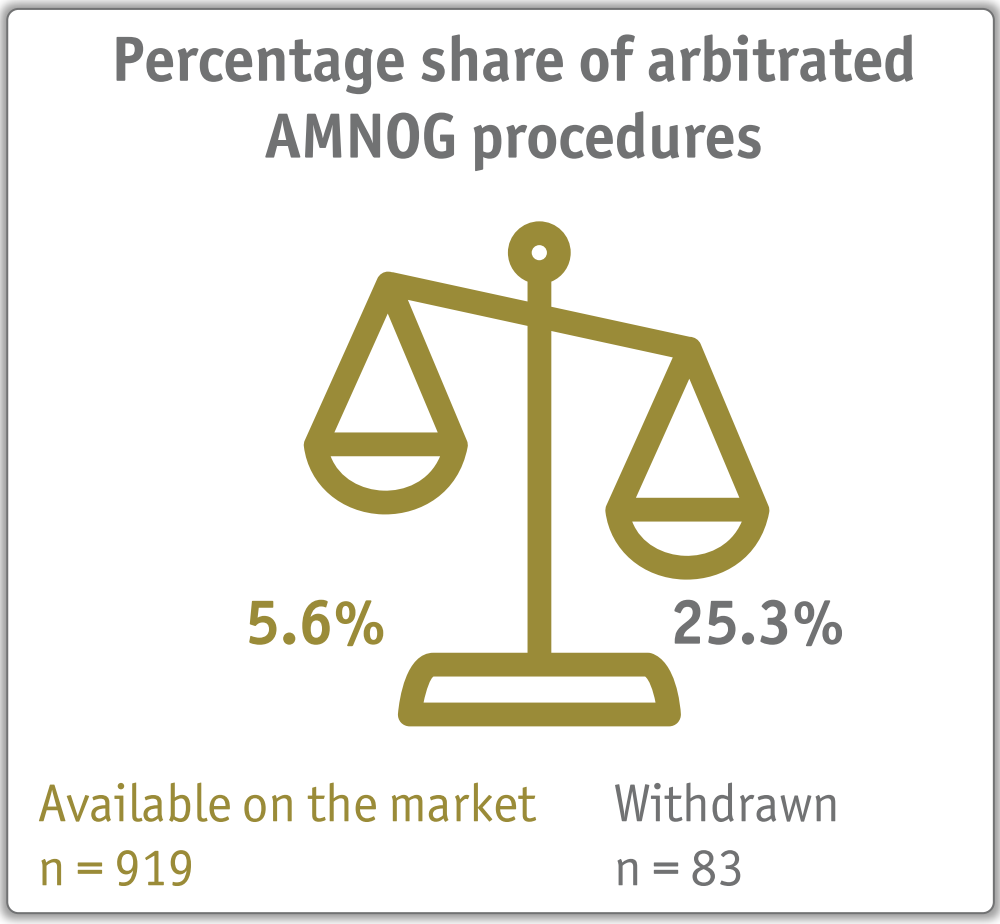
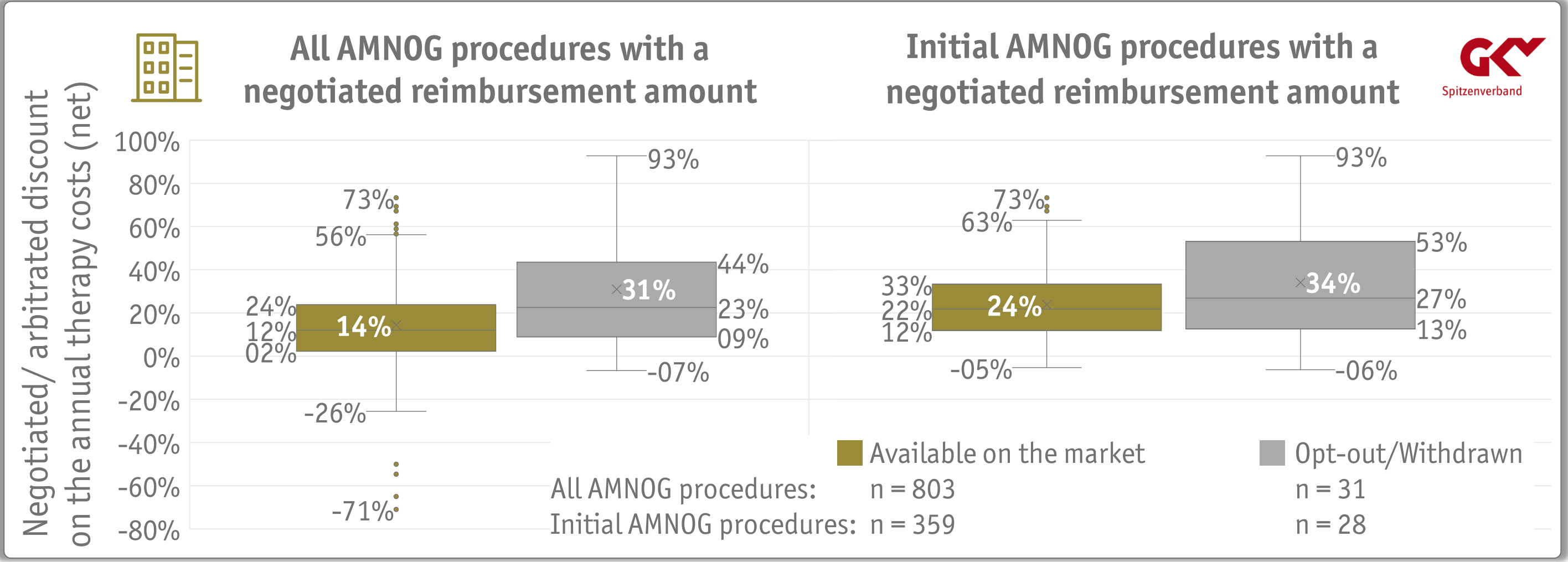
- For withdrawn drugs, the **proportion of procedures with no added benefit is significantly higher: 67.5% vs. 44.9%**.
- In addition, the **proportion of procedures with at least a considerable added benefit is significantly higher for drugs still available on the German market: 18.9% vs. 9.6%** (there are also relatively more procedures with a non-quantifiable or minor added benefit).

While the evidence submitted is comparable for both groups, there are differences in the evidence considered by the G-BA.



- The level of **evidence submitted** by pharmaceutical companies was **comparable** for both: marketed and withdrawn drugs.
 - Evidence classified as level Ia & Ib **78.0% vs 78.3%**
- The G-BA considered **level Ia or Ib evidence in 59.5% of the procedures for marketed drugs**. For only **43.4% of the withdrawn drugs RCTs were considered** by the G-BA to derive an (added) benefit.
- For **53.0% of the procedures of withdrawn drugs no evidence was considered** by the G-BA compared to only **32.1% of procedures of marketed drugs** (e.g. due to incorrect comparator or insufficient study duration).

The negotiated/arbitrated discount is lower for drugs that are still available on the market compared to drugs that are no longer available on the German market.



- The **average discount** on net annual therapy costs for AMNOG procedures for drugs that are still on the market is **14.4%**. In contrast, the **average discount for procedures for drugs that are no longer on the market is 31.0%**.
- A similar picture emerges if only **initial AMNOG procedures** are considered: The average discount for drugs still on the market is **23.8%**. For drugs no longer on the market, the **discount is 34.1%**.
- In addition, the **proportion of arbitration proceedings is significantly higher** for drugs that have been withdrawn from the market (25.3% vs. 5.6% for drugs still available in Germany).
- Given the high proportion of drugs no longer on the market with low launch prices (<€10,000; 36.3% vs. 18.4% for available drugs; not shown), significant discounts likely impact the business case, making opt-out or withdrawal inevitable.

CONCLUSION

Our analysis indicates that lower ratings by the G-BA significantly reduce the likelihood of securing appropriate reimbursement, leading to significant number of products exiting the market before price negotiations (“Opt-out”). Successful benefit ratings depend on the quality of submitted evidence, the choice of comparator, and a sound pricing strategy. Discrepancies between the evidence submitted by pharmaceutical companies and the evidence considered by the G-BA often result in downgraded benefit ratings. A high proportion of withdrawn drugs had no evidence considered in the G-BA’s assessment, often due to the G-BA’s preference for an Ia or Ib level of evidence. Poorer benefit assessments for drugs no longer on the market also negatively impact the discounts achieved in price negotiations with the GKV-SV.

SKC is a strategic consultancy focused on the increasingly challenging market access environment of innovative drug products based in Germany. We support the successful market access both on a strategic and an operational level. For nearly 20 years, our highly experienced team has been supporting our clients in solving their strategically complex questions.

SKC joined the MAP group, thereby broadening further the group’s European platform and combining crucial local expertise to drive our client’s global success. The MAP Group is a pan-European specialist strategic consultancy for pharmaceutical and biotechnology that has established operations across the UK, Ireland and Benelux, and has served more than 200 clients in 20 markets.

All analyses have been generated by data from SKC's proprietary MAIS (**Market Access Intelligence System** = MAIS) database. This database contains and links information on completed and ongoing benefit assessments according to §35a SGB V of the German Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA). The MAIS-database records and evaluates relevant information from the dossier, the benefit assessment by IQWiG or the G-BA, the G-BA resolution as well as the Lauer-Taxe. It also contains an up-to-date overview of all procedures and their status.