

OVERVIEW OF GERMAN AMNOG DOSSIERS WITH PRICE ANALYSIS BEFORE AND AFTER EARLY BENEFIT ASSESSMENT

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Background

The outcome of the early benefit assessment process (according to § 35a SGB V) is crucial for the successful launch and commercialization of pharmaceuticals in Germany. We aimed to give an overview of evaluated dossiers by the Federal Joint Committee (G-BA) since the Pharmaceutical Market Restructuring Act (AMNOG) in 2011. Additionally, we analyzed the change in reimbursed price after the early benefit assessment.

Methods

In a first step, the data from all AMNOG dossiers evaluated by the Federal Joint Committee (G-BA) from January 2011 until December 2017 were extracted from HTA Database by IQVIA Commercial GmbH & Co. OHG and were then analyzed by indication, orphan drug status and benefit assessment outcome.

In a second step, the product prices between 01.01.2014 and 01.10.2018 were taken from the official German database for drug prices (LAUER-Taxe, not for drugs treating orphan diseases).

In a third step, launch price vs. reimbursement price after one year were investigated and the price development (in %) was then calculated and categorized into groups.

Finally, relations between G-BA assessment status and price development before and after early benefit assessment were analyzed.

Products with an Opt-Out were not included in the analysis.

Results

In total, n=327 dossiers evaluated by the G-BA were included in our analysis. Among those were 78% (n=256) non-orphan and 22% (n=71) orphan dossiers. In these groups, the G-BA evaluated 21% (n=54) of the non-orphan and 12% (n=9) of the orphan dossiers with a considerable benefit.

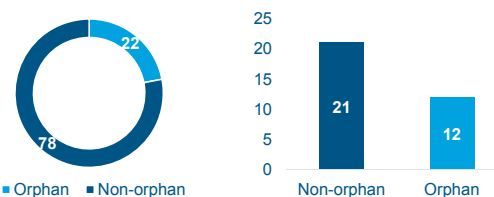
When evaluating cases for which price change is available to date, the most common price change was in the categories between -0 to -20% price decrease followed by the >-20% to -40% price decrease category.

Remarkably, 23% of the pharmaceuticals assessed with "no added benefit" by the G-BA, experienced a price increase after one year. In contrast, pharmaceuticals evaluated with considerable benefit did not reach a positive or zero price change one year after market entry. Price decreases of more than 60% were only observed for the "no added benefit" and "minor added benefit" categories.

Conclusion

As in previous publications, our analysis found no clear relation between G-BA benefit assessment and price development after one year.

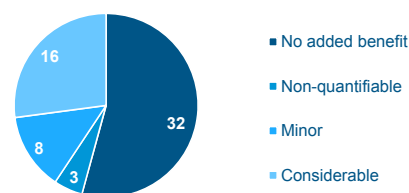
1 Share (in %) of orphan and non-orphan dossiers (Total: n=327) and share (in %) of dossiers with additional benefit



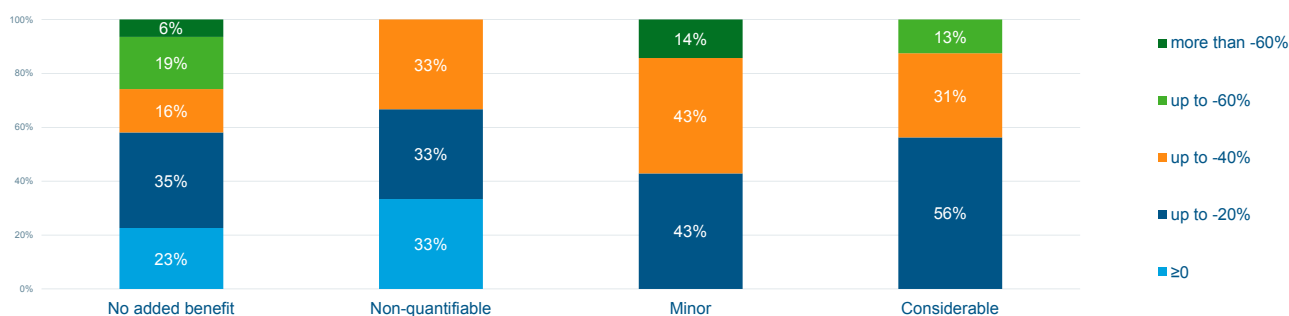
2 Overview of price development according to the G-BA assessment

	No added benefit	Non-quantifiable benefit	Minor benefit	Considerable benefit
≥ 0	7	1	0	0
Up to -20%	11	1	3	9
Up to -40%	5	1	3	5
Up to -60%	6	0	0	2
More -60%	2	0	1	0
No price change yet	1	0	1	0

3 Overview of dossiers before and after price change in Germany



4 Distribution of price development according to the price change groups and G-BA assessment outcome



Key findings

As in previous analyses, our analysis found no clear relation between G-BA benefit assessment and price development after one year.

Remarkably, the groups with no added and non-quantifiable benefit were the only ones who reached no price decrease one year after market entry.

Sources:

- Lauer Taxe (2018). Information system: Prices. Accessed under: <https://www.lauer-fischer.de/LF/Seiten/Verwaltung/Kundencenter/1.aspx>. Last access date: 23.10.2018. (Data status: 01.10.2018)
- HTA Database by IQVIA Commercial GmbH & Co. OHG.

Disclosures

All authors are employees of IQVIA (IQVIA Commercial GmbH & Co. OHG).