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.

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:

2. HTA Database by IQVIA Commercial GmbH & Co. OHG.

Disclosures

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