German Early Benefit Assessments and the impact of medical societies – an analysis

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Objectives

Professional scientific societies are involved in the early benefit assessment (EBA) of pharmaceuticals in Germany, where they are given the opportunity to critically assess evaluations and to provide insights into relevant aspects of care [1]. Which impact do these societies and their opinions have on the outcomes of EBAs? We aimed to investigate how scientific medical societies, and the Medicines Commission of the German Medical Association (AkDÄ) participate in and potentially influence EBAs of oncology drugs under Germany's Pharmaceuticals Market Reorganisation Act (AMNOG) [2]. We examined to what extent their positions align with or diverge from the Institute for Quality and Efficiency in Health Care (IQWiG) and how far the Federal Joint Committee (G-BA) reflects these clinical perspectives in its final resolutions. The work focuses on oncology because of its high volume of assessments and rapidly evolving evidence, and it seeks to clarify whether practice-based arguments from societies measurably shape reimbursement outcomes.

Methods

We conducted a retrospective quantitative and qualitative content analysis. The study analyzed 83 completed oncology EBAs conducted between 2021 and 2023, identified via the G-BA database using predefined inclusion criteria (oncology; 2021–2023; completed procedures; orphan drugs excluded; complete documentation available) [3]. For each procedure, conclusions on probability and extent of additional benefit were extracted from IQWiG reports, G-BA resolutions and justifications, the G-BA summary documentation of written/oral statements, and – where available – AkDÄ statements [4]. The unit of analysis was the intervention–indication pair; when assessments differentiated patient subgroups, these were recorded as separate entries. Comparative columns were created to code each society's or AkDÄ's position relative to IQWiG as "higher," "lower," or "agreement." A subgroup of all non-agreement cases was then examined qualitatively by summarizing the parties' reasoning and mapping each argument to standardized keywords (e.g., "data statistically significant," "weight of adverse events," "clinically irrelevant subgroups"). Frequencies of conclusions and keywords were computed with a short Python script (pandas) [5] operating on CSV exports from Excel [6]. Simpler comparative tallies (e.g., higher/lower/agreement counts) were computed in Excel.

Conclusions

Across oncology EBAs from 2021 to 2023, IQWiG's position is predominantly conservative and tightly evidence-driven, whereas medical societies tend to emphasize clinically contextualized and patient-centered considerations such as real-world tolerability, clinically meaningful endpoints beyond overall survival, and therapeutic need. The aggregate data indicate a moderate but not dominant influence of societies on G-BA's final resolutions. Around one quarter of cases show G-BA alignment with societies when there is no unanimous agreement, and G-BA's written justifications frequently incorporate societies' arguments in deviating cases. Overall, the findings suggest that multidisciplinary input enhances the EBA process by complementing evidence synthesis with practice insights, while preserving the central role of rigorous methodology in pricing and reimbursement. Notably, comparison with earlier literature implies a shift toward greater agreement between societies and IQWiG than previously reported [7]. However, limitations include sparse AkDÄ participation and the need to interpret non-standardized society statements into the formal AMNOG categories.

Abbreviation	Meaning
AMNOG	Arzneimittelmarktneuordnungsgesetz (Germany's Pharmaceuticals Market Reorganisation Act)
AkDÄ	Arzneimittelkomission der deutschen Ärzteschaft (Medicines Commission of the German Medical Association)
EBA	Early Benefit Assessment
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)

Results

Conclusions and comparison of additional benefit

Across 83 oncology EBAs, "no additional benefit" is the common baseline – IQWiG issued this in 61 of 96 conclusions (64%), and the G-BA in 66 of 100 resolutions (66%), reflecting cautious interpretations when evidence is limited. Societies share that baseline but are comparatively more willing to recognize higher categories (e.g., "indication of considerable additional benefit" in 17% of conclusions, compared to only 10% of IQWiG's conclusions). As a result, societies showed agreement with IQWiG's conclusions in 65% of cases, had concluded a higher additional benefit in 34% of cases and a lower additional benefit in just a single case (see Fig. 1)

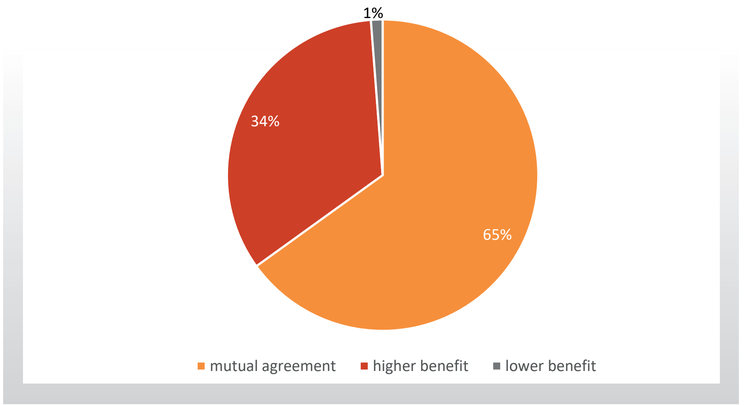

Figure 1: Societies' position compared to IQWiG

Opinions of societies and potential impact on G-BA final resolution

Table 1 shows the count of keywords of the reasons the societies presented during the written and oral statements, to justify the deviating benefit assessment. In total, 29 deviating benefit assessments were found, which resulted in a total of 49 reasons given by the societies. We observed that generally, their reasons cluster around practice-facing claims: statistically significant gains in patient-relevant endpoints (18% of reasons) such as overall survival, progression-free survival or quality of life, re-weighted tolerability and adverse events (16%), objections to clinically irrelevant subgrouping (14%), and arguments about filling therapeutic gaps (10%). In comparison, Table 2 shows the count of keywords of the published justifications for the final resolutions on the benefit assessment by G-BA. Here, the G-BA most often emphasizes statistical significance (40%) and, notably, explicitly reflect societies' views in about a third of cases (34%), indicating that clinical perspective is received and sometimes integrated. Using a cautious definition of "influence," about a quarter of procedures (24%) show the G-BA moving toward societies' positions, while half of all cases end in tri-partite agreement (52%) (see Fig.2).

keywords societies reasons	count	%
data statistically significant	9	18
weight of adverse events	8	16
created subgroups clinically irrelevant	7	14
fills therapeutic gap	5	10
clinically relevant endpoints	3	6
inclusion of data	3	6
calculation of additional benefit	3	6
additional benefit in population subgroups	2	4
new standard of care	2	4
missing data	1	2
comparator does not reflect current practice	1	2
adverse events vs. resurgence	1	2
well tolerated	1	2
strong patient preference	1	2
rate of adverse events too high	1	2
flawed evaluation conduct	1	2

Table 1: Keywords of societies' reasons

keywords G-BA justifications	count	%
data statistically significant	20	40
societies' opinions included	17	34
no suitable data	6	12
adverse events too severe	4	8
uncertainty due to study data	1	2
data deemed insufficient to demonstrate benefit	1	2
no advantages or disadvantages	1	2

Table 2: Keywords of G-BA's justifications

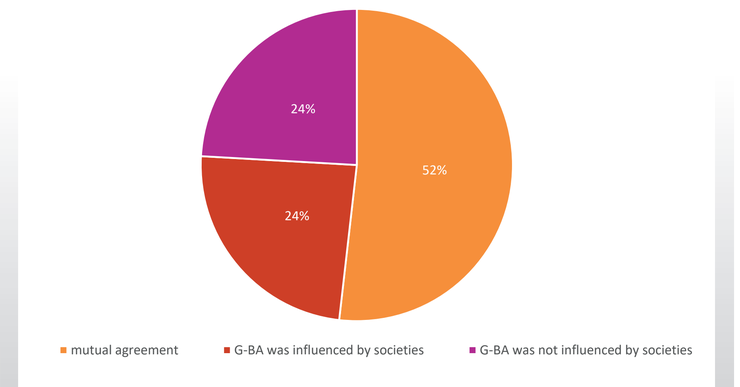

Figure 2: Possible influence on G-BA's final decisions

G-BA position in comparison to IQWiG and societies

Figure 3 shows the G-BA's position compared to the other parties involved. Viewed across all assessments, the system tends toward consensus (52% mutual agreement), but in non-unanimous cases the G-BA balances between methodological and clinical pulls: it aligns with societies in 24% of cases, with IQWiG in 14%, and reaches its own conclusion in 10%. This distribution supports our core argument and understanding of the system: rather than a dominance of any single actor, governance emerges from calibrated synthesis, wherein IQWiG sets the evidentiary floor, societies inject relevant clinical context, and the G-BA translates both into defensible, implementable policy.

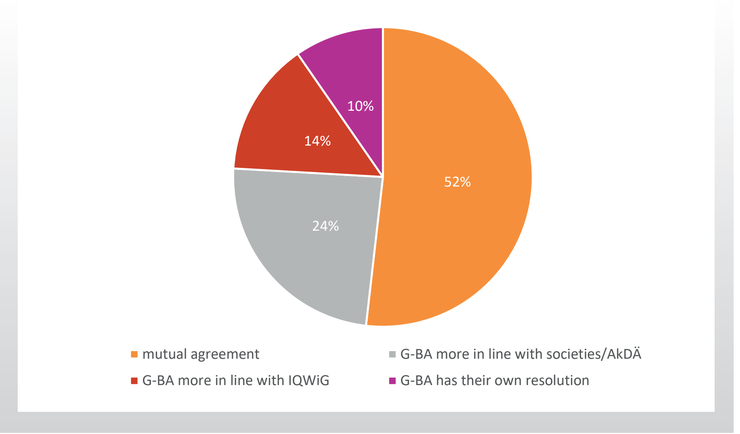

Figure 3: G-BA position compared to other parties

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