Challenges at the interface between EU-HTA (JCA) and national HTA in Germany (AMNOG): Expected limitations to synergy effects and implications for AMNOG dossier preparation

HTA69

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OBJECTIVES

After EU-HTA (JCA), submission of AMNOG dossiers remains mandatory for HTA in Germany. The requirements for AMNOG dossiers have been revised to integrate JCA into AMNOG benefit assessment and to avoid content duplication [1]. As of now, the updated AMNOG RoP have not yet come into effect. We aimed to identify prevailing and emerging challenges HTDs are likely to face when preparing AMNOG dossiers post-JCA.

METHODS

We qualitatively compared G-BA's current RoP and AMNOG dossier requirements [2] with anticipated and approved EU-HTA related dossier changes by reviewing the updated, preliminary RoP [1], information on the alignment of AMNOG and JCA provided on the G-BA website and in informational meetings [3-5]. Additionally, we analyzed the published, preliminary dossier templates [1] for potential synergy effects by comparing them with the requirements for JCA. We defined categories on the potential of using synergy effects and assigned them to the corresponding dossier sections. Based on that, we derived key challenges for HTDs preparing AMNOG dossiers post-JCA and mapped these to the relevant dossier content.

RESULTS

The results of the analysis on the potential of using synergy effects when preparing AMNOG dossiers post-JCA as well as potential challenges are presented in Table 1.

AMNOG dossier requirements have been adjusted to JCA to enable referencing for selected dossier sections. However, at least 4 challenges are likely to limit synergy effects between JCA and AMNOG dossiers, potentially preventing reductions in workload for HTDs. Referencing is particularly limited when updates of the dossier's underlying assumptions arise between JCA dossier and AMNOG dossier submission. These updates may result from new data cuts, completion of further relevant studies, regulatory updates, and new/updated treatment guidelines. Additional data analyses and adaptations due to revised strategy for the AMNOG dossier may also become necessary if G-BA-defined ACT changes after JCA PICO scoping. Moreover, alterations to the indication pose a challenge to synergy effects, as the AMNOG dossier requires presenting information, that was not included in the JCA dossier. Certain sections of the AMNOG dossier require JCA information to not be older than 3 months (e.g., SLR/SRR). As a result, an outdated JCA dossier results in necessary content updates for the AMNOG dossier. While updating analyses and new data cuts cannot be avoided, synergies can still be used in programming and calculation efforts. Despite these potential synergies, a considerable number of AMNOG dossier sections do not allow referencing at all. For some sections, selected JCA information can be reused, creating moderate synergy. However, most of these sections must be fully redeveloped to meet AMNOG specifications.

DISCUSSION & CONCLUSION

G-BA shows clear intent to align AMNOG with JCA, creating the possibility to leverage synergy effects. At the same time, challenges at the dossier interface remain. Although G-BA introduced the possibility of referencing, it is limited to selected dossier sections and only useful if the content of the JCA and AMNOG dossiers are unanimous. If AMNOG methodology was applied in JCA, referencing allows substantial reduction in workload for some sections. However, the main risks to using synergy effects for HTDs result from the uncertainty of potential changes during JCA that lead to extensive adjustments for the AMNOG dossier.

Early alignment between HTD's JCA and AMNOG teams as well as gap analyses are critical to identify deviations and prepare necessary adaptations and additional post-hoc analyses. To mitigate the risk of an ACT change, HTDs should seek early G-BA advice to clarify the current ACT for the planned indication and ensure correct data preparation. Additionally, continuous KOL engagement enables timely anticipation of guideline updates and close communication between the HTD's market access and regulatory team can create early awareness of possible changes to the indication and its implications on AMNOG dossier strategy.

Final clarity will become apparent once updated RoP come into effect at the end of 2025, with further adjustments expected after initial JCA experience.

Table 1 – Overview of synergy effects and potential challenges between JCA and AMNOG dossiers

Potential to use synergy effects	Dossier content area/topic	Challenges potentially limiting synergy effects			
		ACT change	AMNOG dossier assumptions update*	Indication change	JCA dossier out of date**
	Characteristics of included studies	☐	☑	☐	☐
	Endpoint operationalization	☐	☑	☐	☐
	Study design & methodology description	☐	☑	☐	☐
	Description of data analysis and synthesis methods	☐	☑	☐	☐
	Description of disease & target population	☑	☑	☑	☐
	Mechanism of action of new drug	☐	☐	☐	☐
	Requirements for quality-assured application	☐	☑	☐	☐
	Results from information retrieval (SLR/SRR)	☑	☑	☑	☑
	Search strategy for information retrieval (SLR/SRR)	☑	☑	☑	☑
	Study result presentation	☑	☑	☑	☑
	Subgroup analyses	☑	☑	☑	☑
	Description of information retrieval (medical data & target population)	☐	☐	☐	☑
	Documentation of information retrieval (SLR/SRR)	☑	☑	☑	☑
	Information on treatment administration	☑	☑	☐	☐
	Prevalence & incidence in Germany	☐	☐	☑	☐
	RoB assessment	☐	☑	☐	☐
	Studies performed or sponsored by HTD	☐	☑	☐	☑
	Unmet therapeutic need	☑	☑	☑	☐
	Administrative information regarding the drug	The absence of synergy effects poses an inherent challenge.			
	Appropriate comparative therapy				
	Approved areas of application				
	Calculation of annual therapy costs				
	Calculation of German target population				
	Clinical trial participants in Germany				
	Conclusion of study result presentation				
	Description & presentation of AMNOG-specific data analyses				
	Description of endpoint patient-relevance				
	Deviation of added benefit				
	Information retrieval from G-BA website				
	Necessity of adjusting EBM				
	Requirements for quality-assured application, information from German SmPC				
	Summary of the dossier				
	Underlying documentation & references				

Dossier topics were ranked based on an assessment of the extent of possible synergies in alphabetical order.

* Updates may comprise new relevant studies, more recent data cuts, regulatory decisions or new/updated relevant treatment guidelines.

** Dossier is ≥ 3 months old.

- High synergy, JCA content can be referenced completely, no addition of information needed.
- High synergy, if JCA dossier content is unanimous with AMNOG requirements and dossier strategy.
- Moderate synergy, JCA dossier content requires additions or changes to be used in the AMNOG dossier.
- No synergy, referencing is not possible. AMNOG dossier section needs to be recreated completely.

References: [1] G-BA (2025): Rules of Procedure: Amendment to Chapter 5 – Amendments resulting from Regulation (EU) 2021/2282 EU-HTA and the First Regulation amending the Drug Benefit Assessment Regulation, available at: https://www.g-ba.de/beschluesse/7315/; [2] G-BA (2025): Rules of procedure, available at: https://www.g-ba.de/richtlinien/42/; [3] G-BA (2025): Countdown to EU HTA: What changes will there be to the AMNOG procedure?, available at: https://www.g-ba.de/service/veranstaltungen/countdown-fuer-eu-hta/ ; [4] G-BA (2025): FAQ, available at: https://www.g-ba.de/service/faq/ ; [5] G-BA (2025): The benefit assessment of medicinal products in accordance with the German Social Code, Book Five (SGB V), section 35a, available at: https://www.g-ba.de/english/benefitassessment/

Abbreviations: ACT: Appropriate Comparative Therapy; AMNOG: German Medicines Market Reorganisation Act [Arzneimittelmarktneuordnungsgesetz]; EBM: German Uniform Evaluation Standard [Einheitlicher Bewertungsmaßstab]; EU: European Union; G-BA: Federal Joint Committee [Gemeinsamer Bundesausschuss]; HTA: Health Technology Assessment; HTD: Health Technology Developer; JCA: Joint Clinical Assessment; KOL: Key opinion leader; PICO: Population, Intervention, Comparator, Outcome; RoB: Risk of Bias; RoP: Rules of Procedure; SLR: Systematic literature research; SmPC: Summary of Product Characteristics; SRR: Systematic registry research

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