EU HTA procedure

Structural and methodological limitations of the EU HTA procedure for oncology drugs in Germany

Germany is one of the most important pharmaceutical markets in Europe and is characterized by the immediate reimbursability of newly authorized drugs at the time of market launch. Since the Pharmaceutical Market Restructuring Act (AMNOG) came into force in 2011, new drugs have been subject to a benefit assessment by the Federal Joint Committee (G-BA), which forms the basis for subsequent price negotiations. The aim of this system is to allow price premiums only for drugs with a proven added benefit over an appropriate comparator therapy (zVT) determined by the G-BA, while ensuring transparency and methodological consistency [1]. With the EU HTA Regulation (HTAR), a mandatory joint procedure for the clinical assessment of newly authorized drugs at European level has been introduced in stages since January 2025.

>> Oncology drugs and advanced therapy medicinal products (ATMPs) are the first product groups for which such a Joint Clinical Assessment (JCA) is envisaged. The EU HTA procedure runs in parallel with the marketing authorization procedure. The defined assessment scope is intended to be inclusive and to reflect the needs of the member states as comprehensively as possible. The European Commission expects this coordination to avoid duplicate assessments at national level, accelerate market access and make more efficient use of resources [2].

In Germany, the procedural link to the EU HTA procedure was implemented through an amendment to the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) and the Rules of Procedure of the G-BA (VerfO). In view of the learning processes expected during the introductory phase at EU level and in the interlinking with national procedures, only minor adjustments to the legal basis were made initially [3]. The EU HTA report itself is not at the center of the procedure; instead, under Section 4(2a) AM-NutzenV, the pharmaceutical company (pU) is given the option of referring to the EU manufacturer dossier in the German AMNOG dossier [4]. The prerequisite, however, is that congruent data sets are available that have been analyzed in line with the methodological requirements applicable in Germany. Since the Institute for Quality and Efficiency in Health Care (IQWiG) usually assesses the AMNOG dossier on behalf of the G-BA, these requirements follow the institute's current methods paper.

Using benefit assessments of oncology drugs initiated in 2024 as examples, this article analyzes the extent to which the objectives of the HTAR are compatible with the German AMNOG procedure in its current form. Owing to immediate reimbursability, the market availability of newly authorized drugs in Germany is already ensured early and comprehensively [5]. The focus is therefore on differences in timing, data currency and methodological requirements that affect the practical usability of results from the EU HTA procedure in the German context and thus bear on both the avoidance of duplicate assessments and the efficient use of assessment resources.

Materials and methods

A retrospective analysis was conducted of the benefit assessments for oncology drugs and ATMPs initiated by the G-BA in Germany in 2024. Data sources were publicly available G-BA decision documents, IQWiG assessment reports and the European Public Assessment Reports (EPARs) of the European Medicines Agency (EMA) [6, 7]. In addition, information on the marketing authorization procedure and the pivotal studies was taken from the EMA's Medicines Data Table and from ClinicalTrials.gov.

Only initial assessments after first marketing authorization and procedures for indication extensions were included. Reassessments after a time-limited prior procedure and reassessments of orphan drugs after the loss of national assessment privileges were excluded. New drugs authorized as an active substance combination on the basis of a joint EPAR were counted as one procedure (no double counting).

For drugs with study results presented in the G-BA decision, data recorded included the clinical data cut-off current at the time of the marketing authorization application, the duration of the marketing authorization procedure and whether data updates were taken into account during either procedure. Where several studies or data cut-offs were considered, the date of the later data cut-off was used. Based on the available information, a timeline was modeled for a hypothetical EU HTA procedure running in parallel. It was then examined whether the clinical data updated during the marketing authorization process could also have been submitted and used in an EU HTA procedure, and to what extent results from a hypothetical EU manufacturer dossier or EU HTA report would have been eligible for consideration in the German benefit assessment.

Direct usability was defined as the possibility of using clinical data from the EU manufacturer dossier or the EU HTA report in the AMNOG procedure without the need to analyze additional data cut-offs or make methodological adjustments. The direct usability of clinical data is a basic prerequisite for the compatibility of the EU HTA procedure.

Results

Temporal decoupling and data currency: EU HTA versus AMNOG

In 2024, the G-BA initiated 39 benefit assessments of oncology drugs. These included one CAR T-cell therapy as an ATMP, and 10 active substances had orphan drug status.

Of the 39 procedures, 12 assessments concerned initial marketing authorizations and 27 concerned indication extensions. A total of 26 AMNOG decisions presented data from pivotal studies and used them for the benefit assessment. No decision was time-limited.

The duration of the marketing authorization procedure (submission to the EMA to Commission decision) was a median of 432 days for an initial authorization (min. 337 days, max. 501 days) and a median of 317 days for an indication extension (min. 193 days, max. 554 days). No accelerated assessment was reported in the EPAR for the procedures examined. For the 12 procedures with an initial authorization, a median of 65 days (min. 21 days, max. 333 days) elapsed between the Commission decision and market availability in Germany.

For a standard EMA procedure (initial authorization without accelerated assessment), Appendix A of the Procedural Guidance for the EU HTA procedure allows 406 days until endorsement of the draft reports by the HTA Coordination Group [8]. Endorsement must take place no later than 30 days after the Commission decision on marketing authorization [2]. A duration of 376 days including clock stops was therefore assumed for the marketing authorization procedure. In 11 of 12 AMNOG procedures after initial authorization, the marketing authorization procedure took longer, and the EU HTA report could have been endorsed on time. Subsequent publication by the European Commission follows promptly after a procedural review [2].

For an indication extension, the Implementing Regulation sets shortened EU HTA deadlines for defining the assessment scope, preparing the dossier, submitting missing information and the manufacturer's factual accuracy check [9]. As these coincide with the deadlines for an accelerated assessment, the shorter timelines for further procedural steps described in Appendix B of the Procedural Guidance were also adopted as the best approximation of the EU HTA procedure for an indication extension [8].

For an EMA accelerated assessment, a processing time of only 277 days is envisaged for the EU HTA procedure [8]. A duration of 247 days was therefore assumed for the marketing authorization procedure. In 8 of the 27 AMNOG procedures examined for indication extensions, authorization was granted within a shorter period.

In 16 of 26 AMNOG procedures with study data accepted by the G-BA, a more recent data cut-off became available during the marketing authorization procedure and was additionally considered in the EPAR. Of these, IQWiG rejected 2 data cut-offs because they had not been prespecified in the study protocol or requested by a regulatory authority (e.g., EMA, FDA, Swissmedic). The EU HTA procedure likewise gives priority to prespecified data cut-offs [10]. In 2 AMNOG procedures, no results were submitted for single-arm open-label extension phases building on a randomized controlled trial (RCT) that the EPAR considered on the basis of a new data cut-off.

In 8 of 12 cases, the more recent data cut-off was also used in the subsequent AMNOG procedure. In 3 of 4 cases with an unsuitable data cut-off, the benefit assessment reverted to the initial data cut-off considered in the EPAR. In only 6 procedures did both the EPAR and the benefit assessment reflect solely the data cut-off initially submitted for marketing authorization. In a total of 9 procedures, more recent data cut-offs going beyond the EPAR were considered in the benefit assessment. These exclusive data cut-offs were already submitted with the AMNOG dossier in 7 cases and were provided subsequently during the national commenting procedure in 2 cases [Figure 1].

The clinical study reports of the individual procedures were not accessible. Starting from the date of the data cut-off, however, about 90 days can be assumed for the preparation of a study report [11, 12]. For the drugs examined with study results presented in the G-BA decision, a median of 214 days (min. 121 days, max. 481 days) elapsed from the initial data cut-off reflected in the EPAR to the marketing authorization application. Although this period includes data preparation for the marketing authorization dossier, it is likely to overestimate its duration, since other strategic and regulatory factors may also come into play. Based on the AMNOG procedure and the time needed to prepare a marketing authorization dossier, about 180 days can be estimated for the complete preparation of a new data cut-off, including all PICOs, endpoints and subgroup analyses, for an EU manufacturer dossier [12, 13].

Under these assumptions, for an initial authorization, first results from a data update during the marketing authorization procedure – measured from the date of application and operationalized as the date of the data cut-off + 90 days – would have become available in 2 of 3 cases with a prespecified new RCT data cut-off only after the calculated deadline for submitting an EU manufacturer dossier in a standard procedure (88 days initiation/scoping + 100 days for dossier preparation = 188 days). For an indication extension, first results from a data update during the marketing authorization procedure would have become available in 7 of 9 cases only after the calculated deadline for submitting an EU manufacturer dossier in an accelerated assessment (51 days scoping + 60 days for dossier preparation = 111 days) [Fig. 2].

In 4 cases, the start of the benefit assessment in Germany was delayed in order to gain efficiency by bundling procedures for an active substance with closely consecutive authorizations in several therapeutic indications. In these cases, the delay had no impact on the availability of exclusive data cut-offs.

Methodological differences between EU HTA and AMNOG

In addition to timing aspects, there are also methodological differences that make it more difficult to transfer results from an EU HTA procedure to the German benefit assessment.

In 7 of the 39 benefit assessments examined, the pivotal evidence was based on single-arm clinical studies. While such study designs may be accepted in the regulatory context, outside clearly defined orphan drug constellations they rarely meet the methodological requirements of the German benefit assessment procedure [14]. Accordingly, no study results were considered in the AMNOG decision in these 7 procedures.

To answer the PICO questions defined in the assessment scope, the EU HTA procedure also provides for indirect comparisons, which are to be presented in a structured manner in the EU manufacturer dossier [9, 15]. However, matching-adjusted indirect comparisons (MAIC) based on aggregated study data are not accepted by the G-BA and IQWiG for methodological reasons [16, 17]. Adequate adjustment by propensity score matching (PSM) requires all relevant confounders to be available, which is a high hurdle for practical implementation, particularly in historical

comparisons. To offset the baseline risk of bias inherent in PSM-adjusted indirect comparisons, IQWiG additionally requires a minimum effect size for conclusions on benefit or harm [18]. Under the methodological standards applicable in the German AMNOG procedure, indirect comparisons based on single-arm studies submitted for an EU HTA procedure would generally not constitute evidence relevant to the procedure.

In a further 6 benefit assessments, RCTs were available, but their comparators were not recognized by the G-BA as the appropriate comparator therapy (zVT). In these cases, too, the available clinical data were not considered in the decision. This shows that the compatibility of the EU HTA procedure depends not only on the quality of the study design but also on nationally specific requirements for the comparator therapy. If a study comparator does not correspond to the zVT, however, the G-BA may accept an indirect comparison according to Bucher via a bridge comparator, provided that IQWiG does not reject the similarity assumption for the two RCTs required [16, 19]. In the 6 procedures concerned, no indirect comparisons according to Bucher were submitted for assessment [Fig. 1].

For responder analyses of patient-reported outcomes (PROs), the AMNOG procedure generally applies a response criterion of at least 15% of the scale range to identify a noticeable change [16, 19]. Responder analyses for morbidity and quality-of-life endpoints within the EU HTA procedure would therefore only be directly usable if the pU proactively submits analyses using the threshold accepted in Germany.

Overall assessment of compatibility

Across all 39 procedures considered, only 9 benefit assessments showed a data constellation in which direct usability of the results from a hypothetical EU manufacturer dossier or EU HTA report in the subsequent AMNOG procedure can be assumed. These comprise 6 marketing authorization procedures based solely on initial data cut-offs and 3 marketing authorization procedures with unsuitable new data cut-offs for which no new results were submitted in the AMNOG procedure either. Methodological differences between the EU HTA procedure and the German benefit assessment system may further restrict the direct usability of results from the Joint Clinical Assessment, irrespective of timing aspects.

Discussion

This analysis shows that there are structural tensions between the early, Europe-wide harmonized approach of the EU HTA procedure and the requirements of the German benefit assessment system, which are of practical relevance particularly for oncology drugs. Pivotal studies in oncology are often event-driven, so that data maturity and certainty of results increase with longer follow-up and additional data cut-offs. While the EU HTA procedure formally begins with the submission of the marketing authorization application to the EMA, the benefit assessment in Germany is tied to the date of market launch or authorization of a new therapeutic indication. Typically, 12 to 18 months lie between these two dates, during which additional evidence relevant to the assessment can be generated, in particular from new data cut-offs on overall survival, disease-free survival or safety-related endpoints.

The results of this study make clear that the EU HTA procedure is necessarily based on an early evidence status from the regulatory authorization process. By contrast, the German benefit assessment procedure is designed to assess the most complete and methodologically consistently prepared data set available at the time of market entry. In the marketing authorization procedure, the EMA can integrate new data cut-offs into the assessment flexibly and with a focus on selected endpoints. In the EU HTA procedure, by contrast, the preparation of new data cut-offs in line with the guidance requirements is limited by tight procedural deadlines and the complexity of the defined assessment scope [20, 21].

The Implementing Regulation provides that new study data submitted to the EMA during a Joint Clinical Assessment are to be provided by the pU at the assessors' request. However, the deadline of 7 to 30 days envisaged for this is unrealistic for the complete preparation of a new data cut-off. At most, the envisaged option of a limited extension of the deadline for submitting the EU manufacturer dossier may in individual cases help to take into account data cut-offs that become available while the assessment scope is being defined or the dossier is being prepared [9].

Against this background, there is an increased risk that many EU HTA reports will already have been superseded, at the time of national decisions in Germany, by data cut-offs that became available during the assessment procedure or afterwards, and can therefore contribute only to a limited extent to decision-making.

EU HTA reports published late, which are to be expected particularly in the case of indication extensions, can still be included in the

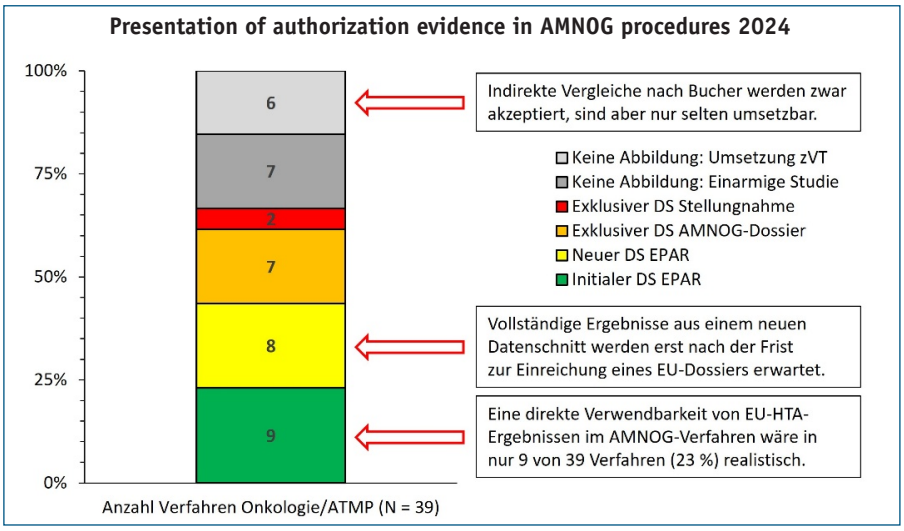


Fig. 1: Proportion of benefit assessments with potential direct usability of clinical data from a hypothetical EU HTA procedure. 39 oncology drugs with AMNOG procedures in 2024 were examined with regard to the presentation of study results in the G-BA decision and the data cut-offs (DS) considered in the marketing authorization and AMNOG procedures. Source: own illustration.

benefit assessment up to 3 months after the start of the procedure as part of the national commenting procedure [3].

In addition to timing aspects, there are methodological divergences between the EU HTA approach and the German benefit assessment system. The compatibility of Joint Clinical Assessments appears limited in particular where indirect comparison methods are applied. While the EU HTA procedure provides for a descriptive presentation of the available evidence, the German benefit assessment requires a normative condensation of the results using nationally defined methodological thresholds and relevance criteria.

The national implementation of the HTAR in Germany takes account of the methodological differences and structural tensions described by not providing for automatic adoption of EU HTA reports, but merely allowing reference to the EU manufacturer dossier under strict conditions. Responsibility for the methodological preparation and assessment of the evidence thus remains within the national procedure. In practice, the EU HTA procedure will therefore not replace any essential elements of the German benefit assessment system, but will add an additional and complex level of assessment to it. In particular, problems arising from differing evidence levels cannot be resolved even through learning processes in the introductory phase of the EU HTA procedure.

Overall, the results suggest that the efficiency gains sought through the EU HTA procedure can be realized only to a limited extent in the German context – at least for oncology drugs. Although EU HTA reports are formally taken into account in the AMNOG procedure if published on time, a substantial reduction in the national assessment workload or an acceleration of decision-making processes cannot be expected under the current procedural and methodological framework.

Limitations of the study

This article is subject to several limitations. First, it is a retrospective analysis of a limited observation period, and the number of data cut-offs available in the marketing authorization or AMNOG procedure may be higher or lower in subsequent years. Second, the study focused on oncology drugs, so the results can be transferred to other therapeutic areas only to a limited extent.

Furthermore, the assessment of compa-

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tibility is based on assumptions about the practical implementation of Joint Clinical Assessments, as no EU HTA procedures had been completed at the time of the analysis. The results should therefore be understood as indicative of structural challenges and not as a conclusive evaluation of the effectiveness of the EU HTA system as a whole.

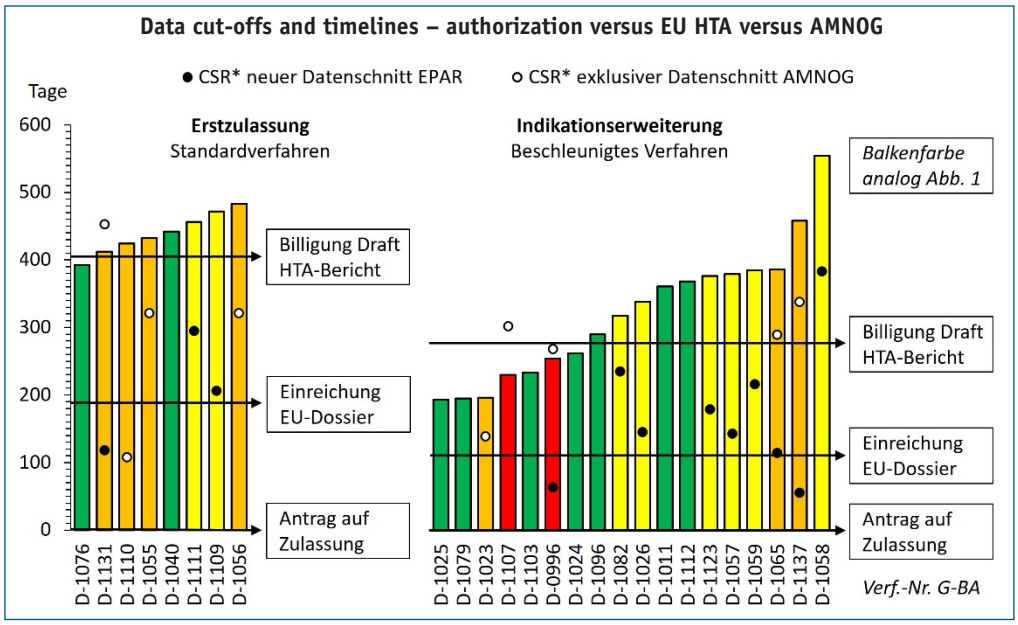


Fig. 2: Sequence of key procedural steps in the EU HTA procedure for initial authorizations and accelerated procedures according to Procedural Guidance Appendix A/B, shown in relation to the availability of new data cut-offs in the marketing authorization and AMNOG procedures. Included are 26 oncology drugs with AMNOG procedures in 2024 for which study results were reported in the G-BA decision. The expected availability of a clinical study report (CSR*) was operationalized as the date of the data cut-off + 90 days. Source: own illustration.

Conclusions

In its current form, the EU HTA procedure is only of limited suitability for substantially simplifying or accelerating the benefit assessment of oncology drugs. In particular, the early timing of the Joint Clinical Assessment, the high dynamics of evidence generation in oncology and methodological differences between EU HTA guidance documents and national assessment requirements restrict practical compatibility. There is a risk that parallel assessment structures will persist and that EU HTA procedures will act primarily as an additional reference level without making the intended contribution to reducing duplication of work and increasing efficiency in the HTA system.

A targeted further development of the EU HTA framework could increase the relevance of Joint Clinical Assessments for national benefit assessments. A key starting point would be to postpone submission of the EU manufacturer dossier to the time of the EMA's recommendation for marketing authorization. At that point, authorization can be expected, the final therapeutic indication is fixed, and consistent reference to the evidence status documented in the EPAR would be possible. However, such a postponement would mean that EU HTA reports would only become available after the current deadlines for submitting an AMNOG dossier. If EU HTA reports are to serve as a central data source in the early benefit assessment in the future, national timelines will need to be adjusted accordingly.

It could also be specified in the EU HTA reports themselves, specifically with reference to prespecified final data cut-offs, that an update is required. It would then be possible to dispense with the subsequent consideration of new data cut-offs in the AMNOG procedure. Instead, the relevant decisions should be time-limited until the update at EU level.

Further methodological consolidation between EU HTA guidance documents and the requirements of the German benefit assessment procedure is not sufficient on its own to establish EU HTA reports as a central data source in the AMNOG procedure, but can additionally support this approach. <<

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Florian Jantschak is employed by the National Association of Statutory Health Insurance Physicians (KBV). This publication reflects the views and conclusions of the author. The preparation, analysis and interpretation of the data and the drafting of the manuscript were carried out by the author without the involvement or financial support of third parties. The author declares that there is no conflict of interest.

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Abstract

Introduction: The aim of the EU HTA Regulation is to reduce duplicate assessments, accelerate market access and realise efficiency gains. This paper examines whether the expectations associated with the Regulation are realistically achievable in the German AMNOG context.
Methods: An analysis was conducted of the benefit assessments for oncological medicinal products initiated in Germany in 2024. The focus was on differences in data maturity, data acceptance and the alignment of timing between marketing authorisation and benefit assessment, as well as the potential implications arising from these for forthcoming EU HTA procedures.
Results: In a relevant proportion of the procedures examined, more recent clinical data cuts were available at the time of the German benefit decision than those included in the EPAR. Data updated during the marketing authorisation procedure would, on the basis of a modelled EU HTA timeline, often only have become available after the envisaged deadline for submission of an EU manufacturer dossier. In other cases, single-arm study designs or non-congruent comparator therapies would have limited the usability of the results. Overall, only 9 of the 39 benefit assessments examined showed a realistic prospect of compatibility with an EU HTA assessment.
Discussion: Under the current framework conditions, it cannot be assumed that the EU HTA procedure will generate substantial added value for the benefit assessment of oncological medicinal products in Germany. Without targeted adjustments, there is a risk that parallel assessment structures will persist and the intended efficiency gains will fail to materialise.
Keywords: EU HTA, AMNOG, oncology, benefit assessment, market access