ECKER ECKER

ACCESSUS HEALTH
A brand of ECKER ECKER

HPR72

J. Tasler, A. Meyer, T. Ecker , J. Leismann
Ecker + Ecker GmbH, Hamburg, Germany

EU HTA, Joint Clinical Assessment and the JCA Report – What Is the Possible Impact on Price Negotiations for Orphan Drugs in Germany?

Download Poster

Background

- Price negotiations for pharmaceuticals with new active substances in Germany follow a clearly defined framework, primarily considering the additional benefit (which is guaranteed for Orphan Drugs (OD) by law) as determined by the Federal Joint Committee (G-BA).
- Since the G-BA does not define an appropriate comparative therapy (ACT) for OD and comparable products are often lacking, other benchmarks are necessary to determine an appropriate price (***figure 1***).
- With the introduction of Joint Clinical Assessment (JCA), starting for OD in 2028, and already from January 2025 for OD in oncology indications, the JCA report (JCAR) can provide guidance on the monetisation of the additional benefit.
- Within the JCAR, treatment alternatives (TA) are defined at the European level, and their relative effectiveness (RE) compared to the drug to be assessed is provided.
- The TA, when valued with prices, can serve as a benchmark for price negotiations (***figure 2***).

Objectives

- To identify the potential impact of the JCAR on price negotiations for OD in Germany.
- To anticipate the possible differences in the information base for price negotiations of OD with or without prior JCA.
- To prepare for the possible impact of three potential timings for integrating the JCAR into the German benefit assessment (***figure 3***):

a Available at dossier submission
b Available post-submission, but before benefit assessment publication
c Available only after consultation has started

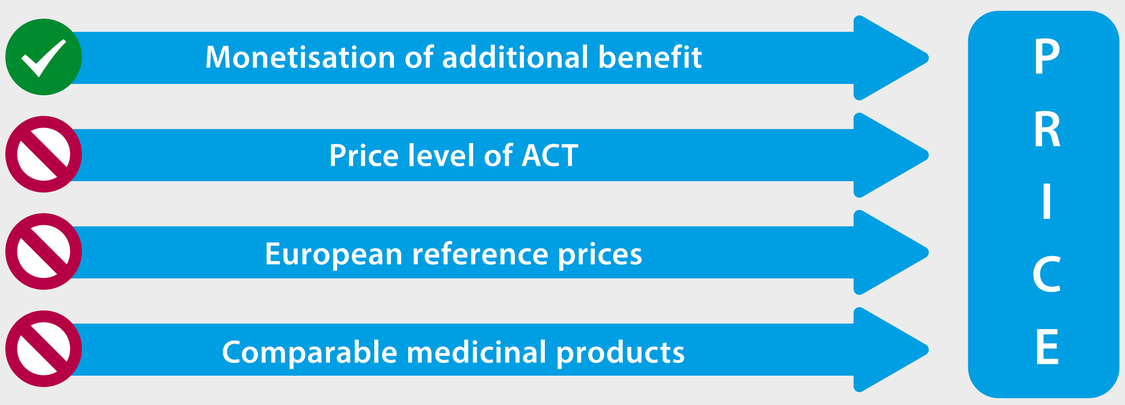
Methods

- Consideration of two possible scenarios (case 1 and 2)
- Review of arbitral awards for OD
- Extensive experience in price negotiations

Results: Case 1 (without prior JCA)

Figure 1

G-BA resolution and AMNOG dossier as basis for price negotiation



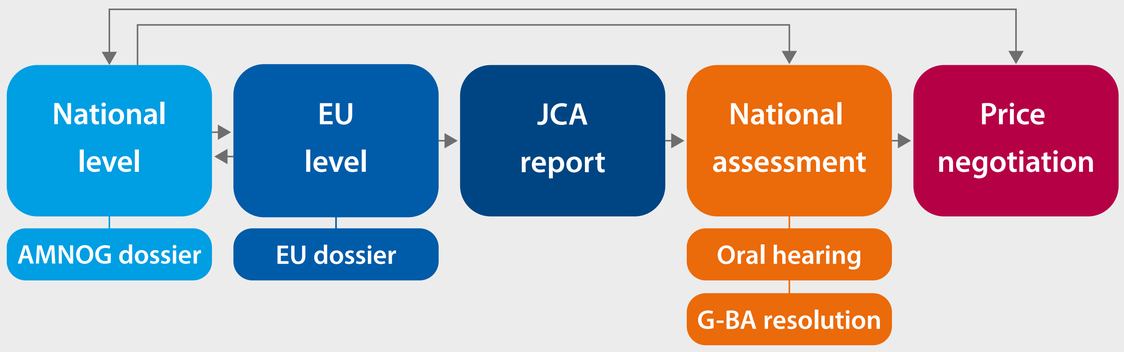
Monetisation of the additional benefit often is a "black box". Based on experience and analysis of arbitral awards, the following criteria guide price determination, though they are not intended to be exhaustive:

- Analogous cases
- The willingness to pay of the solidarity community
- Drug-specific value decisions, taking into account the therapeutic area and medical need

Results: Case 2 (with prior JCA)

Figure 2

G-BA resolution, AMNOG & EU dossier and the JCAR as basis for price negotiation



- Regulation (EU) 2021/2282, Article 13, states that Member States shall **give due consideration** to the JCAR and all other information available on the IT platform. However, the outcome of the JCA should not affect the discretion of Member States to make subsequent decisions on pricing and reimbursement of health technologies.
- When the assessment scope for the JCA is defined (i. e. the PICOs requested by the Member States), the G-BA will also specify a comparator for the JCA for products with Orphan Designation.
- The JCAR comprises comparators and (indirect) evidence on their RE compared to the drug to be assessed. TA can be monetarily valued for price negotiation in Germany, serving as a monetary benchmark (can be either advantageous or disadvantageous).

Figure 3

Potential timelines for case 2

Conclusions & Recommendations

- Case 2 may involve additional influencing factors compared to case 1, due to a broader information base (treatment alternatives and relative effectiveness).
- Depending on the timing of JCAR publication, its integration into the benefit assessment (and thus its perceived impact on price negotiations) may vary. An unofficial impact is conceivable even in scenario c).
- It is recommended to be prepared for each potential scenario, acknowledging that JCA presents both challenges and opportunities.
- The actual impact of the JCAR on price negotiations in Germany will depend on the specific case, the potential reaction of the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) remains uncertain.
- National responsibility for reimbursement and pricing decisions is not interfered with.

References

1. Social Code Book V (Sozialgesetzbuch Fünftes Buch – Gesetzliche Krankenversicherung, SGB V)
2. Framework Agreement acc. to Section 130b, para. 9 Social Code Book V
3. Regulation (EU) 2021/2282
4. Ordinance on the Benefit Assessment of Medicinal Products (AM-NutzenV)
5. Arbitral awards for OD
6. G-BA Countdown für EU HTA, https://www.g-ba.de/service/veranstaltungen/countdown-fuer-eu-hta/ [last access Sep. 26, 2025]

Ecker + Ecker GmbH · Warburgstr. 50 · 20354 Hamburg · Germany
+49 (40) 41 330 81-0 · info@ecker-ecker.de · www.ecker-ecker.de