EUCOPE

European Confederation of Pharmaceutical Entrepreneurs AISBL

POLICY BRIEF

The EU HTA Procedure

REFERENCES

[1] European Commission, Directorate-General for Health and Food Safety, Chamova, J., Mapping of HTA national organisations, programmes and processes in EU and Norway, Publications Office, 2018, https://data.europa.eu/doi/10.2875/5065

[2] Regulation (EU) 2021/2282 on health technology assessment Article 16 (1)

[3] Regulation (EU) 2021/2282 on health technology assessment Article 8 (6)

[4] Regulation (EU) 2021/2282 on health technology assessment Article 11 (5)

[5] Regulation (EU) 2021/2282 on health technology assessment Recital 7, 47 and Article 4 (4)

ABOUT EUCOPE

The European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) is the voice of small to mid-sized health technology companies in Europe. Representing 2600+ innovative biopharmaceutical companies directly or through national associations, EUCOPE advocates for sound public policy that supports innovation, while fostering a community built on a shared purpose: improving and saving the lives of European patients through innovative therapies and medical technology.

The Role of the Health Technology Developer

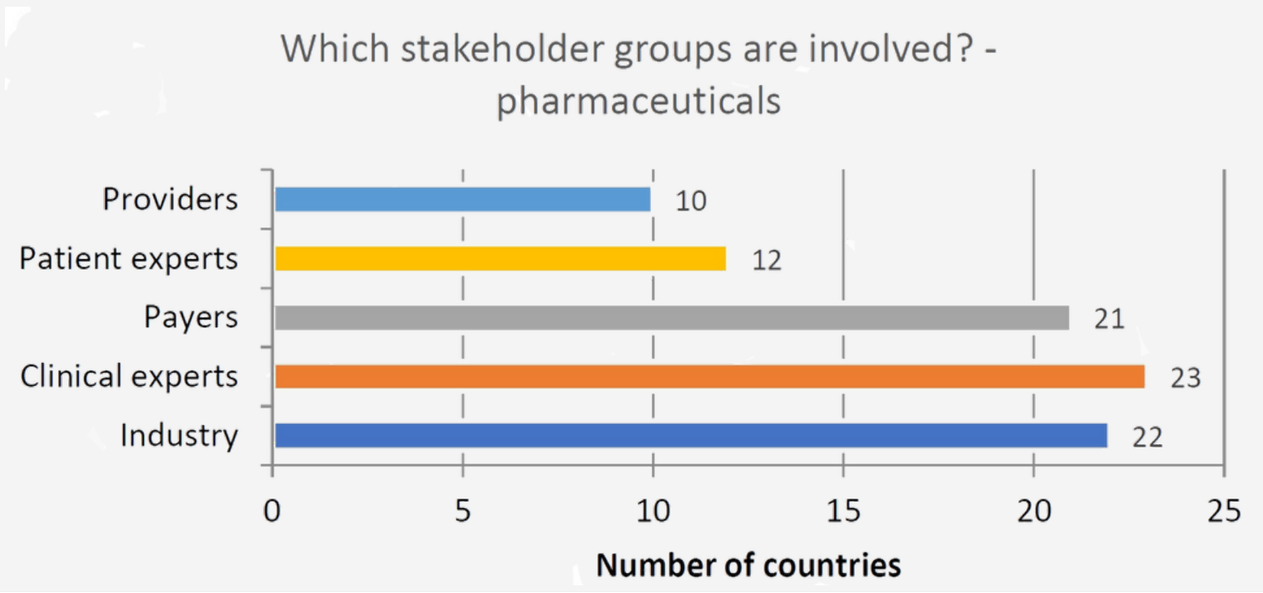
With the Regulation (EU) 2021/2282 on health technology assessment (HTA) coming into application 12 January 2025, Joint Clinical Assessments will be performed at the EU level and be made available for use for the 27 Member States of the European Union. By introducing a Union level mechanism, the Regulation aims to reduce the significant administrative burden, the high costs and the lack of business predictability for health technology developers, and in particular smaller companies with limited resources, that arise from submitting data, analyses and other evidence to different Member States, at various points in time.

In order for this new joint procedure to be a success, it must *inter alia* ensure a broad involvement of relevant stakeholders:

- **The health technology developer should be included in the scoping meetings** to inform the selection of the appropriate evidence and comparators, and
- Developers must be given the opportunity to respond to technical clarifications as needed, **to prevent poor outcomes due to technical mistakes.**

The health technology developer is a key stakeholder in HTA, and frequently involved in the process alongside clinical experts and payers, as illustrated in European Commission mapping of HTA national organisations, programmes and processes in EU and Norway (Figure 1). [1]

FIGURE 1. STAKEHOLDER GROUPS INVOLVEMENT IN HTA OF PHARMACEUTICALS IN THE EU COUNTRIES & NORWAY



The role of the developer in HTA goes beyond preparing and submitting the required evidence and data for the assessment, and the new legal framework reflects the importance of involving the health technology developer throughout the process, in Joint Scientific Consultations,[2] at the scoping stage[3], and at the draft stage of the report.[4]

Building on Experiences to Date

During the period 2022-2025, the detailed procedural rules and methodologies for EU HTA will need to be developed, with consideration of the main outcomes (in particular methodological and guidance documents) from the voluntary HTA cooperation, carried out under the previous EUnetHTA Joint Actions.[5]

At the end of EUnetHTA Joint Action 3, a White Paper was produced to take stock of the work to date and to provide recommendations for the future model of cooperation. Here, the role of the health technology developer was described at various stages of the procedure, including: participating in the scoping meeting, responding to clarifications and providing a fact check of the output (draft report).

This policy brief aims to support the development of a successful EU HTA procedure, by examining current practices in selected Member States, focused on the modes of interaction with the health technology developer as a key stakeholder. We are convinced that these important interactions must be maintained when the new EU procedure eventually supplants equivalent national procedures.

The Modes of Interactions with Industry in National HTA Processes in the EU

FIGURE 2. CURRENT POINTS OF INTERACTION

	Scientific Advice	Scoping Decision	Issuance of HTA Report
Germany	✓		✓
France	✓		✓
Belgium	✓	✓	✓
Finland		✓	✓
Czechia		✓	✓

The benefits of interactions between the Health Technology Developers and Assessors

- **Opportunities for dialogue between the developers and HTA bodies reduce the risk of misunderstandings** regarding what evidence can be expected to be brought forward, which methods to apply and which comparators should be used for an assessment. If misunderstandings are not resolved at the earliest possible stage, there is a higher risk of assessments becoming delayed or discontinued.
- **Assessments of Orphan Medicinal Products (OMPs) and Advanced Therapy Medicinal Products (ATMPs) especially stand to benefit from repeated points of interaction** between developers and the assessors, so that the complexities of the disease and the technology can be appropriately captured. These technologies typically rely on less conventional methodological approaches in order to improve interpretability, due to practical and ethical limitations of evidence generation.
- There are currently large variations in standards of care between Member States and allowing for a discussion of the proposed scope, i.e. PICO(s), during a scoping meeting helps ensure that appropriate comparators are selected for the assessment and **it allows developers to share their insights and specific considerations and to identify any possible issues with compiling the dossier.**

Scientific Advice

Developers may request a meeting with G-BA and submit questions regarding suitability of study designs, or definition of endpoints, to ensure relevancy for patients and choice of appropriate comparators. It can also involve input of professional societies (e.g. AWMF, AKdÄ). Developers are invited to a meeting with G-BA within 10 weeks, and G-BA provides meeting minutes to the developer after the meeting.

Developers can request: (1) an in-person meeting with the HAS or (2) written questions/answers to get their opinion on Phase III trial design, prior to its implementation.

Early advice is offered together with national regulatory scientific advice, through written questions.

Scoping Decision

Stakeholders are involved in the scoping process for the assessment.

Developers may propose a topic for the assessment and also submit to Fimea non-requested material relevant for the assessment.

The developer, payer and SUKUL are involved in deciding the scope of an assessment, with the latter making a final decision.

Issuance of HTA Report

Stakeholders and experts provide written statements on the IQWiG assessment once it is published and the developer may provide a written reply within 3 weeks to the G-BA sub-committee. An oral hearing is organised to allow developers and experts to further respond to the IQWiG benefit assessment. Stakeholder input will be considered to inform the final G-BA decision on the early benefit assessment.

Prior to the publication of the final opinion, developers may submit written comments or request a hearing but no new elements can be raised.

For the hearing with industry, this can lead to substantive modifications of the assessment, subject to a vote of the final opinion by CT or CEESP.

Developers can react to preliminary advice of the SECM committee, and a separate meeting is arranged, if needed. Industry representatives also participate as observers alongside other stakeholders in the CRM commission, which makes recommendations for reimbursement based on the HTA report.

Developers have the ability to perform a general review of the draft report, and to review it for confidentiality issues.

Developers and other stakeholders may provide comments throughout the procedure, and developers have involvement in the scoping, production and review of the assessment.