BPI Bundesverband der Pharmazeutischen Industrie e.V.

vfa. Die forschenden Pharma-Unternehmen

Implementation of the EU HTA Regulation needs directional correction

Drive alignment of standards, implement methods for special therapies and improve participation

The European HTA[1] Regulation entered into force on 11 January 2022. The regulation aims to improve access to innovative therapies in Europe, reduce the administrative burden for companies and HTA authorities, and strengthen the quality of the clinical assessment. The EUnetHTA21 consortium, consisting of HTA institutions from 12 EU Member States, is currently developing methods and processes that are important milestones.

The German Pharmaceutical Industry Association (BPI) and the German Association of Research-Based Pharmaceutical Companies (vfa) are concerned about the direction of implementation. Current developments give rise to fears that the objectives of the regulation cannot be achieved. The European HTA process should be implemented considering the following points to ensure that the objectives of the Regulation are achieved.

Aim for common European assessment methods

EUnetHTA21 designs the European HTA assessment as a mere amalgamation of national practices. The current fragmentation of the different requirements and methods of the member states is thus merely exported to the European level. It does not reduce the administrative burden for companies and HTA authorities. The joint HTA assessment should seek an alignment on common European methods and information requirements as well as harmonised HTA criteria to reduce the administrative burden.

Implement specific methods for orphan and advanced therapy medicinal products

EUnetHTA21 does not respect the requirements of the Regulation, which provides for adapted methods for the assessment of orphan medicinal products (OMP) or advanced therapy medicinal products (ATMPs). This might lead to the fact that special features of the evidence generation recognised in the marketing authorisation cannot be considered in the HTA procedure. These often-vital therapies might therefore fail in the European HTA assessment with potential negative consequences for patient access. The methodological guidelines need to be adapted to consider the specificities of therapeutic situations.

Strengthen health technology developer participation in the EU HTA process

Current developments show that opportunities for health technology developers to participate in individual EU HTA process steps are limited and meaningful interactions with the assessors are prevented. This weakens the quality of the joint clinical assessments and consultations. Developers should have the opportunity to effectively express their views on the accuracy and relevance of the facts and circumstances that are the subject of the procedures. Developers should be able to contribute their unique know-how especially in the so-called scoping process. For this purpose, a scoping meeting with the health technology developer should be established.

[1] HTA: Health Technology Assessment

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Better integrate the expertise of all stakeholders during implementation

Despite extensive stakeholder commentary on the EUnetHTA21 proposals, there have been few changes so far. However, input from patient organisations, medical societies, HTA experts and industry can improve the quality of methods and processes and should therefore be taken more into account. Stakeholder involvement is a crucial step under the principles of better regulation and represents the best quality assurance for the implementation phase of the HTA Regulation. It strengthens the applicability and acceptance of the future European work.

Seize opportunities to reduce divergences in Europe

The implementation of the HTA Regulation requires rethinking. HTA authorities, as well as industry, need to adapt their workflows to ensure that the new framework can be used as an opportunity for improved clinical assessment, reducing divergence across Europe, reducing the administrative burden for companies and HTA authorities, and improving access to new medicines.

The German Federal Government and HTA institutions are called upon to engage in a constructive dialogue with the European Commission and the HTA Coordination Group of the Member States for an alignment of standards, the implementation of methods for special therapies and the improvement of participation.

Background

The EU HTA Regulation entered into force on 11 January 2022. It regulates a joint clinical assessment of new medicinal products at European level, which is to start from January 2025 for the first products, including advanced therapy medicinal products (ATMPs) and oncology medicinal products (incl. orphan drugs). The framework is to be concretised. Currently, the EUnetHTA21 consortium is preparing proposals for process and method guidelines on behalf of the EU Commission, which have been put out for public consultation. The final documents, which should be available by September 2023, are considered the basis for the implementing legal acts of the EU Commission and the adoption of European methods by the HTA coordination group of the Member States, which are expected in 2024.

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