Website address:
https://www.gesundheitsindustrie-bw.de/en/article/press-release/eu-regulation-approved-g-ba-collaborates-european-health-technology-assessment

EU regulation approved: G-BA collaborates on European health technology assessment

Today, the EU Parliament adopted the EU Regulation on Health Technology Assessment (HTA), which includes not only new medicines (including gene and cell therapies), but also medical devices.

Professor Josef Hecken, Impartial Chair of the German Federal Joint Committee (G-BA) and Chair of the Pharmaceuticals Subcommittee stated: 'The use of HTA for innovations at European level will especially improve the assessment of medicinal products in Member States that were previously unfamiliar with this systematic, comparative analysis of clinical data. However, the new EU regulation will also change certain aspects in Germany, particularly the benefit assessment of new medicinal products. In future, joint clinical assessments at European level must be included in early benefit assessments when the G-BA has to decide on the additional benefit to patients. However, HTA at European level is not expected to affect added value judgements or reimbursement decisions'.

G-BA develops standards for HTA with EU partners

As part of the EUnetHTA21 consortium, the G-BA is already working together with the Institute for Quality and Efficiency in Health Care (IQWiG) on the foundations for implementing the new regulation. The G-BA is responsible for working on process and structural requirements as well as methodological issues for clinical consultations. In future, clinical assessment at EU level is to be included in national decisions on the added benefit of new medicinal products. A joint assessment of cancer drugs and advanced therapy medicinal products (ATMPs) is scheduled to begin in 2025.

Hecken added: 'In the coming years, it will be a matter of defining binding standards for HTAs together with other EU partners. This means jointly agreeing on which methodological tools are suitable for HTAs, how to deal with different endpoints and how to include different evidence. We agree that comparative controlled studies are the best scientific basis for this. At the same time, however, it has become apparent in practice that new medicines often come onto the market with weak data. The issue of how to deal with the growing demand to use real-world evidence, that is, data from everyday health care, for HTAs will also be challenging. One of the key tasks for implementing the regulation will therefore be to develop methodological solutions for these kinds of difficult cases. This will become the best prerequisite for the national committees that will make the actual decisions on added value'.

Hecken concluded: 'The G-BA brings a great deal of experience from its national assessments over the last ten years to work done at European level. Although the German AMNOG procedure is quite strict, it is also a learning system that is flexible enough to react to changes. This is certainly one reason why it is accepted by both industry and health insurance funds'.

Background

The EU HTA Regulation, which the EU agreed on this year after years of negotiations, provides the basis for binding cooperation between the national HTA authorities of the EU Member States. Previously, there was voluntary exchange through the EUnetHTA network. With the help of HTA, the added value of new health technologies and procedures for patients is assessed in comparison to approaches that already exist. In the future, a clinical assessment of data will be carried out at European level as part of the HTA process. Member States are required to take this into account, provided that these data are suitable for the national issue and meet quality requirements. In Germany, the actual decision on the additional benefit of new medicinal products will continue to be made by the G-BA. Its decision remains the basis for price negotiations between the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) and the individual pharmaceutical companies.

13 EUnetHTA member organisations (HTA agencies from Spain, Austria, Belgium, France, Italy, Portugal, Ireland, Hungary, Norway, Sweden, the Netherlands, as well as the G-BA and IQWiG from Germany) are to prepare the implementation of the EU HTA Regulation which will be the basis for future binding joint work. Methods, procedures and

papers from previous EU HTA projects will be included. After the first joint assessments of cancer medicines and ATMPs, medicines for rare diseases (orphan drugs) will follow, and then all other procedures including new indications and medical devices.

Press release

14-Dec-2021
Source: Federal Joint Committee

Further information

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