Leem & vfa joint position on European cooperation on HTA

Creating benefit across Europe

In a changing global world with transforming powers Europe is requested and well-advised to have a strong and united voice. Thereby, Europe must demonstrate its competitiveness but also show that it wants to expand its excellence further. 'A Union that strives for more'[1] has to lead in shaping new megatrends which are going to bring profound changes to the economy and society by setting new standards aiming for a global competitive advantage.

In that way, the European Union must build on its key values, make use of its strengths and has to demonstrate the added value it provides vis-à-vis its citizens. The common understanding that an EU intervention in certain areas can achieve more than every Member State individually on a small scale will help to prove that Europe is able to work for a better future. The cooperation of national authorities would fill this principle with life. A joint understanding and assessment of evidence seems a logical consequence as it will help to structure efficient processes, pool respective skills, resources and experiences for the best standards with an outcome benefitting all. Accepting their responsibility, France and Germany should lead the way.

Therefore, "Les Entreprises du médicament en France" (Leem) and "Verband der forschenden Pharma-Unternehmen in Deutschland" (vfa) support the proposal by the European Commission for a joint assessment with an exclusive focus on the assessment of the clinical evidence as well as joint scientific consultations with national HTA bodies and the European Medicines Agency (EMA).

A unique opportunity to promote medical progress and quality standards in HTA

For a global industry such as pharma, Europe plays a central role: Companies have R&D and manufacturing facilities in Europe as well as headquarters. In light of increasing therapeutic options it will be crucial for Europe to sustain its competitiveness.

A European approach on joint clinical assessments – as proposed by the European Commission in January 2018[2] – would not only combine national strengths but also consider companies' asks for a predictable and harmonised assessment process at EU level. Further, Member States with already well-established HTA systems are providing a firm ground to build upon and to continue the collaborative development of common European standards for high-quality HTA. The success of the EMA shows how beneficial such cooperation can be.

Harmonisation of the technical assessment of clinical evidence facilitates national health care decisions

As representatives of the pharmaceutical industry in France and Germany , we support an efficient European cooperation of joint clinical assessments which results have to be recognized by Member States. Therefore, it is essential that Member States and their HTA bodies e.g. the Federal Joint Committee (G-BA) and the French National Authority for Health(HAS) commit themselves to engage actively in a European cooperation and finally, use the results of a European report for their value-based health care decisions without duplicating work.

[1] Guideline of the European Commission 2019-2024
[2] COM (2018/0018) COD

Clear responsibilities: EU-wide joint clinical assessments do not affect national decisions on appraisal and pricing

We support a strengthened European HTA cooperation, particularly to achieve the following objectives:

- Joint scientific consultation as an instrument to ensure one high-quality evidence base for Europe;
- Harmonisation through joint clinical assessment of new drugs;
- Creating synergies and avoiding duplication of work on national scales

We are not concerned about subsidiarity since the proposal fits with national processes and respects national competences:

- The joint clinical assessment is in line with national pricing and reimbursement systems and ensures timeliness for Member States' subsequent, autonomous appraisal processes.
- Pricing and reimbursement decisions remain in each Member States' national responsibility.

Strengthened scientific cooperation leads to strong study results

We explicitly welcome the opportunity for the manufacturer to clarify any evidence requirements for the marketing authorisation process, the joint clinical assessment as well as evidence necessary for national reimbursement processes already at an early stage during the drug development process.

Further, the results of the joint scientific consultation should receive the same level of relevance for the joint clinical assessments as the scientific advice provided by EMA for the marketing authorisation process.

Taking the time to build trust across Europe

As representatives of the pharmaceutical industry in France and Germany, we are convinced that one EU-wide joint clinical assessment is a key element to help create more informed healthcare systems based on robust evidence across Europe. As always, collaboration requires trust past borders. We believe our countries should lead the way in building that trust until all Member States will contribute confidently to a new system of clinical assessments.

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