

EFA Position on the European Commission proposal for a regulation of the European Parliament and the Council on Health Technology Assessment (HTA)

Background

EFA welcomes the proposal of the European Commission on HTA cooperation in Europe for four main reasons.

1. In the first place, different national processes and methodologies on HTA can result in diverse data and, therefore, conclusions. Consequently, different decisions will be taken on the same medicines and medical devices across Europe, which will justify Member States reimbursement decisions and can contribute to an **increase of EU inequalities** on needed or innovative health technologies available for patients.
2. Secondly, joint assessments will bring together EU expertise on HTA and will save money in the long-term by **preventing unnecessary duplication of work**. Moreover, standardised methods on HTA will improve the level of transparency in the methodology carried out.
3. Thirdly, promoting EU collaboration in HTA can **help in advancing and mainstreaming patient and patient organisation involvement** in HTA at all levels.
4. Finally, joint HTA, especially on core issues, **does not threaten national healthcare systems** because reimbursement decisions will always be done at national level and covered by national budgets.

Joint clinical assessments

EFA supports joint clinical assessments. In the first place, mandatory joint clinical assessments will avoid repetition of the same analysis, therefore, more informed decisions on medicinal products and medical devices will be taken resulting in improved patients' quality of life. Apart from that, joint clinical assessments will be based on scientific and medical evidence, which will positively contribute to transparency of decision-making across the EU, including reimbursement decisions.

In the second place, EFA also supports the mandatory inclusion of joint clinical assessments at national level because the added value of joint assessments can only be realised if they are fully implemented by the Member States. Finally, it is important that HTA processes starts as early as possible. It is therefore very positive that joint assessments of medicinal products will be aligned with the marketing authorisation procedure under the European Medicines Agency (EMA) responsibility.

However, it is being identified in the proposal that joint assessments would be limited to new technology. In this context, **EFA welcomes HTA bodies to assess existing and old technologies** to identify ineffective devices and medicinal products and to withdraw them from the market or improve their efficiency.

Moreover, **EFA highlights the need to increase patient involvement** within the joint clinical assessments sub-groups. In the current Commission proposal, they would be given the opportunity, together with other stakeholders selected, to provide comments during the preparation of the draft

joint clinical assessment report. There should be no assessment conducted without the involvement of patients, who know better than anyone else what it means to live with the disease.

Joint scientific consultation – Early dialogue

EFA supports early dialogue between the industry and HTA bodies at national and EU levels. This first step will enable **patients to provide their input** on their priorities and needs, which will result in better research and development.

Nevertheless, effective patients' involvement in joint scientific consultations together with joint clinical assessments will be possible only thanks to **training for patients** to facilitate and optimise their participation as well as a financial compensation. In this context, **EFA believes** that the [European Medicines Agency training](#) and [procedures for involvement for patients and consumers](#) is a best practice that **should be replicated in the HTA cycle**.

HTA cooperation structure

EFA believes that patients should be involved at every step of the HTA process to capture their needs and opinions during the entire cycle as well as they would help to identify repeated errors during the assessments. Patients' involvement in HTA cooperation at EU level is recognised but it is not clear how exactly patients will be involved since there is no agreement on the best methods for involving patients.

The Coordination Group should ensure appropriate involvement of patients from all disease areas, including allergy, asthma and COPD, to give input in an easy and accessible way by inviting them to join the Member States Coordination Group on HTA as members.

To do so, **guidelines should be developed to ensure meaningful and systematic patient involvement in HTA.** In addition, the selection criteria to be involved in the Stakeholder Network should be aligned with other existing criteria, for example, the EMA eligibility criteria for patient and consumer organisations.

Conclusions

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) supports the Commission's legislative proposal. EFA calls upon the Members of the European Parliament to support the enclosed amendments, to ensure the adoption of a Regulation that will bring real progress towards a more transparency decision-making processes and will allow more equitable access on needed and innovative health technologies across the EU.