

The Consumer Voice in Europe

EU REGULATION ON HEALTH TECHNOLOGY ASSESSMENT

BEUC recommendations for the trilogue negotiations



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Why it matters to consumers

To make people healthier, new medicines should work better than the treatments already available. But this is not always the case. The same happens with medical devices. Health Technology Assessment (HTA) identifies to which extent new health technologies are of added value, and helps governments decide which should be reimbursed and at what price. Therefore, HTA can help ensure better value for money for public health systems and consumers.

Introduction

The European Consumer Organisation, BEUC, welcomes the long-awaited trilogue negotiations on the European Commission's proposal for a Regulation on Health Technology Assessment (HTA). The adoption of a solid HTA cooperation framework among EU Member States is necessary to help ensure wiser public spending on healthcare and quicker consumer access to new medicines and medical devices of added value.

To make the most of the proposed framework, the European Parliament, Council and European Commission must agree to the following key points.

Recommendations

1. Member States must make use of the joint clinical reports

To avoid duplication of work and reduce inefficiencies, Member States should not replicate the work carried out at EU level. At the same time, the system should include some flexibilities to safeguard the specificities of national healthcare systems. To get there:

- Member States must use the joint clinical assessments in their national HTA procedures.
- They should have the possibility to complement joint clinical assessments with additional evidence that is relevant in the national context.
- Member States should remain responsible for drawing their own conclusions on the added value of the health technology concerned.

2. Consumers must have their say

Consumers are the end users of health technologies. Therefore, the new HTA framework should ensure that their views and needs are considered. More specifically:

- Patient and consumer organisations should have the opportunity to provide input during the drafting of the annual work programme and during the joint clinical assessments.

3. Joint clinical assessments should be adopted by consensus or simple majority

Considering the *scientific* nature of joint clinical assessments, and the fact that the Coordination Group (CG) will not decide on the overall added value of the concerned health technology, national experts sitting at the CG should vote on the final report on an equal footing. As such:

- The Coordination Group should strive to adopt the joint clinical assessments by consensus.
- When consensus is not possible, decisions should be taken by simple majority (instead of using a qualified majority system based on the country's population size).

4. A progressive and ambitious timeline for the assessment of pharmaceutical products

Member States will need some time to adjust to the new cooperation framework, and some national HTA bodies will have to develop additional expertise. The best way to enhance capacity-building is by getting all Member States engaged in the system from the beginning. For this reason:

- We support the Council's proposal to get all Member States involved in the system from the beginning.
- However, the Council's stepwise approach lacks ambition. The Coordination Group should include more types of medicines in their work programme, and thus do more joint clinical assessments, from the beginning.
- The overall timeframe for the inclusion in the framework of all the pharmaceutical products under the scope of the Regulation should be shorter than the 11 years proposed by the Council (i.e., seven years as proposed by the European Parliament).

5. New medicines must be compared with standard of care, not placebos

Today, many clinical trials are conducted against placebos. Such comparisons provide an insufficient basis for assessment on the added value of the new medicine over standard treatment. To reverse this:

- The Regulation must oblige the manufacturer to conduct, where possible, comparative trials against the best available treatment.

6. Orphan medicines should be assessed with the same rigour

Patients and consumers should receive the best available treatments. Accordingly, all medicines should be assessed with the same rigour. That includes orphan medicines, for which there is usually less available evidence on their safety and efficacy when they are first placed on the market. On top of that, some of these medicines are very expensive:

- The Regulation should ensure that all drugs will be assessed by the Coordination Group with the same rigour, including orphan medicines.

BEUC's full position on the proposed Regulation is outlined here ['Making sure consumers access treatments that work at a fair price. BEUC's demands for an EU Regulation on Health Technology Assessment'](#), 2019.

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