The Consumer Voice in Europe

# BEUC COMMENTS TO EUROPEAN COMMISSION'S PROPOSAL REGULATION HEALTH TECHNOLOGY ASSESSMENT

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EC register for interest representatives: identification number 9505781573-45

Co-funded by the European Union

Ref: BEUC-X-2018-027 - 6/04/2018

# Why it matters to consumers

The European Consumer Organisation (BEUC) welcomes the European Commission's proposal on Health Technology Assessment (HTA). Too many new drugs[1] or medical devices do not make a real difference compared to those already on the market but are nonetheless reimbursed by healthcare systems. In addition, an increasing number of medicines are authorised on the basis of very limited data but still come to the market at a very high price. HTA is a process that helps promote evidence-based healthcare. Therefore, if implemented properly, HTA has the potential to help governments save money, and rewards only health technology that brings benefits to consumers.

The EC proposal goes in the right direction as it proposes a stable mechanism to facilitate cooperation among HTA around Europe. This would be particularly beneficial for those countries that do not have a robust system in place, due to limited capacity and/or resources.

BEUC suggests the following points to further improve the proposal:

## Recital (31)

- The independence of HTA bodies is crucial to ensure that only medicines with real added value are reimbursed by authorities. A fee-paying mechanism, as proposed in Recital 31 bears a risk of regulatory capture, therefore safeguards need to be built in to prevent such capture.

## Section 1- Joint clinical assessments ("The assessments")

- The current proposal does not leave enough margin to Member States to adapt the assessments to their national context. A certain scope for such adaptation needs to be guaranteed in light of the different standards of care that exist among Member States. National HTA bodies should be able to review and revise the assessment carried out at European level if this does not fully meet their criteria.

- Further, when the coordination group reaches an agreement over a joint clinical assessment by majority, divergent views and reasons thereof must be reported and made public to ensure transparency and accountability.

- The current formulation does not include sufficient obligations for the manufacturer to provide all relevant evidence. This should include data coming from all the trials conducted, as well as all studies in which the technology has been used, both paramount to ensure high quality of the assessments.

[1] http://www.bmj.com/content/359/bmj.j4530

- The assessments at the end of the process should be published in their entirety and all the health technologies that undergo the joint clinical assessments have to be published in the List. This includes also those that do not arrive at the final stage because of substantive and/or procedural requirements.

- Explicit rules on conflict of interest for experts involved in the assessments have to be developed and enforced.

- Consumers should also be mentioned in the text and taken into account for the assessments of some health technologies that benefit the whole society and not specific group of patients.

## Section 2- Joint scientific consultations ("Early dialogue, ED")

- Once the assessment is concluded, the ED reports have to be published and available for public scrutiny. The report should include information about the company, the product and the main conclusions.

- In the case where the health technology developer decides not to follow the ED, its decision and the motivation need to be made public.

- Explicit rules on conflict of interest for experts involved in the assessments have to be developed and enforced. The experts involved in this procedure cannot be the same than those involved in the assessments as this would create a conflict of roles that can potentially undermine the robustness of the assessments.

## Section 4 - Rules for clinical assessments

- Procedural rules for ensuring the independence and transparency of HTA processes should be included in the Regulation and not be relegated to implementing acts.

*This publication is part of an activity which has received funding under an operating grant from the European Union's Consumer Programme (2014-2020).*