

1 February, 2018

For immediate release

**HEALTH ACTION INTERNATIONAL STATEMENT ON
EUROPEAN COMMISSION PROPOSAL ON
HEALTH TECHNOLOGY ASSESSMENTS**

BRUSSELS—Following the release of the [European Commission's Proposal for a Regulation on Health Technology Assessment](#) on 31 January, 2018, Ancel·la Santos Quintano, Senior Policy Advisor with Health Action International made the following statement:

Health Action International (HAI) values the role of health technology assessments (HTA). Most new medicines do not demonstrate meaningful benefit to patients compared to medicines already on the market.^{1, 2} At the same time, high prices for new medicines threaten affordability of care. HTA better informs patients, consumers and healthcare professionals about the added therapeutic value of the medicines they use or prescribe. It also assists payers in their reimbursement decisions.

While we welcome the European Commission's acknowledgement of the increasingly important role of HTA in the European Union (EU), we have a number of concerns about the proposed Regulation:

First, making joint clinical assessments mandatory among EU Member States is a counterproductive step if high evaluation standards are not upheld. There is need for further reassurances in this regard.

Second, we are deeply concerned that the new HTA framework would soon end up being funded through industry fees. HTA fulfills a public interest role; therefore it should be publicly financed and protected against undue influence, or situations that could be perceived as such.

In addition, while we encourage collaboration between the European Medicines Agency (EMA) and HTA bodies, this collaboration should occur in a way that protects their distinctive mandates. Given current regulatory trends to accelerate medicines approval and accept less robust data—for example, the EMA's initiative on Adaptive Pathways—the independence of HTA bodies in assessing medicines is more important than ever.

Given these concerns, HAI recommends:

- Continued synergy-building between Member States through a voluntary approach to HTA collaboration—one that takes place within a strengthened and more sustainable structure.

1. Prescrire International (2017). New products and new indications in 2016: a system that favours imitation over the pursuit of real progress. *Prescrire International* Volume 26 N° 182
2. Davis C, Naci H, Gulpinar E, Poplavska E & Pinto A, Aggarwal A (2017). Availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency: retrospective cohort study of drug approvals 2009-13. *BMJ*, 359:j4530



- The introduction of a mandatory uptake of joint clinical assessment reports by participating bodies only where there are clear 'exit clauses' they could invoke. There may be situations in which it is justified to re-do an assessment at national level.
- The identification of health technologies that would most greatly benefit from joint work on HTA in consultation with patients, consumers, healthcare professionals and payers.
- Assurances that HTA processes and outcomes are transparent and prioritise the public interest over considerations of commercial confidentiality. This also applies to scientific advice procedures.
- The adoption of robust policies on conflicts of interest that regulate the involvement of individuals and organisations in HTA.

It should also be noted that robust health technology assessments are highly dependent on the quality of the evidence submitted by health technology developers. We hope that the continuing discussions on HTA provide the opportunity to delve deeper into the need for more clinical trials that compare experimental medicines against the best available treatment.

The Commission's proposal clearly acknowledges that, currently, the use at national level of joint clinical assessments produced through EU cooperation is low. While we acknowledge that this leads to duplication of work, it also sends a signal that the benefits of joint assessments may not yet apply equally to all the parties. We call for the continued building of synergies through various means, and a more incremental increase in collaboration, including on joint clinical assessments, up to the point that is feasible and beneficial for all.

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For interview requests and further information, please contact:

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Health Action International is a non-profit organisation that conducts research and advocacy to advance policies that enable access to medicines and rational medicine use for all people around the world. We pursue advocacy from the patient level up to the highest levels of government through our 'official relations' status with the World Health Organization and respected relationship with the European Medicines Agency. To safeguard our objectivity and integrity, we are resolutely independent of the pharmaceutical industry and protect ourselves from all other conflicts of interest.