Statement on ENVI Committee Report on Health Technology Assessments

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AMSTERDAM—Following the European Parliament's ENVI Committee adoption of a legislative report on Health Technology Assessments, Health Action International's Senior Policy Advisor, Ancel.la Santos Quintano, made this statement:

"Health Action International (HAI) welcomes today's vote by the ENVI Committee on the Health Technology Assessments (HTA) Report, which is a considerable improvement on the Commission's proposal from earlier this year, and addresses many of our key concerns.

The ENVI Committee has given a clear and positive signal that joint work by Members States on HTA should guarantee the highest standards of quality, and not be a race to the bottom. Requiring that, as a general rule, health technology developers submit data from at least one comparative trial against standard treatment (or the most common intervention) is a huge step forward. Such data is crucial for a better understanding of the added therapeutic value of a given medicine.

HAI also welcomes the emphasis throughout the report placed on principles of transparency and independence. The obligation to publish comprehensive joint clinical assessments, which includes the clinical data compared, dissenting views from assessors and input from consultations, is crucial to ensure accountability and public trust. However, it is important to ensure that redactions performed on the basis of 'commercial confidentiality' are kept to an absolute minimum, and that they never work against the interest of public health. We note that the ENVI Committee has gone a step further than current practice by requiring that scientific consultation reports on health technologies that have undergone joint clinical assessments are made public. This will help illuminate processes that are currently very opaque. We also welcome a clear reference to the fact that the joint framework of collaboration should be publicly funded.

As HAI has previously stated, there must be flexibility in the scope of joint clinical assessments. We are therefore pleased that the Members of the European Parliament have addressed this concern and inserted specific language on the possibility for Member States to complement joint reports with additional clinical evidence and analyses. This is an essential element to ensure HTAs are fit for purpose. Likewise, we welcome the proposal to encourage, but not oblige, Member States to adopt common rules and methodologies outside the HTA framework of collaboration. We believe in a step-wise approach towards further collaboration and harmonization.

The Report includes several references to the specificities of orphan drugs. It is important to emphasise that some of the most expensive medicines are orphan drugs, and that the

pharmaceutical industry is consolidating a lucrative business model around them. Both healthcare professionals and patients with rare diseases need high quality scientific evidence about the added therapeutic value of these medicines—the specific needs of national and regional health systems should also be taken into account. This information is also important in reimbursement decisions. We are therefore concerned by claims that it might not always be necessary for orphan drugs to undergo further clinical analysis beyond the European Medicines Agency's assessment.

HAI will continue to be part of this legislative process and deliver a much needed civil society voice to ensure this collaborative framework works in the best interest of European citizens".

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