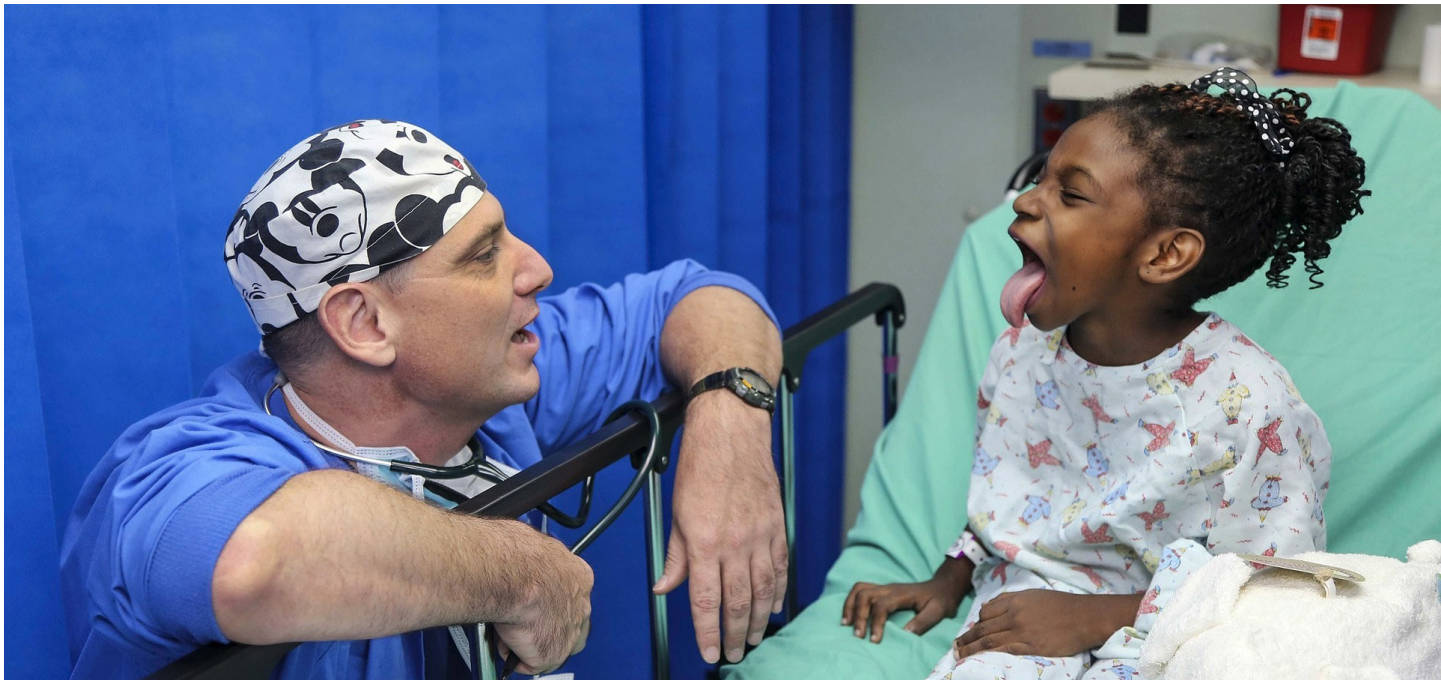
POLICY BRIEF

19 June, 2018

KEY RECOMMENDATIONS ON **HEALTH TECHNOLOGY ASSESSMENTS**



HEALTH TECHNOLOGY ASSESSMENTS IN THE EUROPEAN UNION

Health Action International (HAI) supports a framework of sustainable cooperation on health technology assessments (HTA) at the European Union (EU) level, driven by high standards of quality, transparency and independence. Commitment by all concerned parties to these principles is crucial.

Collaborative efforts have the potential to strengthen health systems across the EU. However, while harmonisation can be a means, it cannot be a goal in itself and flexibility should be shown on the grounds of national needs.

In the context of the current discussions about the European Commission's proposal for a regulation on HTA, HAI makes the following key recommendations:

1. HIGH EVIDENTIARY STANDARDS

- The added therapeutic value of health technologies, such as pharmaceuticals, must be demonstrated on patient-relevant outcomes (e.g., reduced mortality or morbidity, improved quality of life, reduction of adverse drug reactions).
- As a general principle, health technology developers must submit the results of at least one randomised, controlled trial comparing a health technology against the best proven intervention (standard treatment), or the most common one, where no standard treatment exists.
- Health technology developers must submit information on all studies carried out for the medicine/indication under assessment. HTA bodies should receive full clinical study reports and individual patient-level data.

2. FLEXIBILITY

- If the system of collaboration were to entail the expectation that all Member States participate in joint clinical assessments by default, it must be ensured that—at a minimum—it is always possible for Member States to complement these assessments with additional clinical evidence to address national requirements, and, on the grounds of national needs, Member States have the right to carry out their own clinical assessments.

3. TRANSPARENCY

- The outputs resulting from joint work must be publicly available and reflect dissenting views.
- All evidence submitted by health technology developers should be made publicly available, and public health must always override commercial interests.
- The input provided by stakeholders in consultation processes must be reported, and declarations on conflicts of interest made publicly available.

4. INDEPENDENCE

- The system of European collaboration on HTA must be publicly funded.
- Assessors, experts and other consulted parties in joint work must be free of conflicts of interest.
- Adequate safeguards should be in place to ensure that health technology assessments are research-based, without undue interference from political bodies. Likewise, collaboration of HTA bodies with the European Medicines Agency (EMA) should take place in a way that preserves their distinctive mandates.

5. ENGAGEMENT WITH PATIENTS, CONSUMERS AND HEALTHCARE PROFESSIONALS

- The Stakeholder Network should be comprised of not-for-profit organisations representing non-commercial entities.
- There must be adequate processes for consultation with patients, consumers and healthcare professionals in the joint work (e.g., topic prioritisation, clinical assessments, development of scientific guidelines/scientific advice).
- Eligible organisations representing patients and consumers, non-governmental organisations working in the field of public health, and healthcare professional groups should be offered the opportunity to interact on a regular basis with HTA bodies and exchange views on issues of common interest through established working parties.

CONCLUSION

Cooperation on HTA is a work in progress and remaining challenges must be overcome. The priority should now be to ensure that the proposed system of collaboration is effective in delivering outputs that are useful to everyone. Taking this and the uncertainties surrounding the methodological standards that will apply into consideration, the Regulation should not seek to harmonise HTA processes conducted at the national level. In addition, the technology prioritisation process should be extended beyond the transition period. HTA bodies should decide, in consultation with relevant stakeholders, which health technologies would benefit most from joint work. For joint work to garner enough support and legitimacy, decisions should be adopted by consensus or, where consensus cannot be reached, by a two-thirds majority.

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