

IS IT LIGHTS OUT FOR THE HTA LEGISLATIVE PROPOSAL?

HTA LEGISLATIVE PROPOSAL

In 2016, the European Commission launched the formal process to strengthen EU cooperation on Health Technology Assessment in response to calls from EU countries, the European Parliament, and interested parties to ensure its sustainability beyond 2020. In its 2017 Work Programme, the European Commission announced that a key objective would be to reduce the duplication of work for national HTA bodies.

How was EUnetHTA involved?

EUnetHTA was consulted during the drafting process and the work of the EUnetHTA Consortium will be used as the basis of cooperation beyond 2020.

An unprecedented heat wave gripped much of Europe this summer, putting demands on the European electrical grid system. The system, however, managed to handle the unexpected demand and is intact. Like that large international and cooperative electrical system, the HTA Legislative Proposal has weathered difficulties but is also still intact. While some Member States have legitimate and justifiable concerns, the HTA Proposal has also been broadly supported by a coalition of Member States, industry, health professionals and patients who see real benefits in European HTA non-duplication.

Commissioner Andriukaitis, passionately speaking at the July 9th event "The Way Forward for HTA Cooperation – the Views of Stakeholders" in Brussels, where over 300 policy makers, healthcare providers and patient representatives discussed future cooperation on Health Technology Assessment, said, "We understand the need to fully respect the competences and the diversity of Member States. We believe that adequate and balanced solutions could be explored and we are open to engage in and facilitate this discussion with the co-legislators."^[1]

Participants at "The Way Forward for HTA Cooperation" gave important recommendations on the way forward:

Engaging with patients and clinicians on HTA. *Transparent and systematic engagement with stakeholders is needed, both on product-specific reports and on a broader strategic level. The involvement of patients and health professionals in the joint clinical assessment guarantees that the reports consider patient-relevant endpoints. Appropriate resources such as training are needed to enable their contributions.*

Generating evidence that meets the needs of patients and health system decision makers. *A higher involvement of stakeholders will generate the relevant evidence that meets the needs of the health system decision-makers (including regulators, HTA and payer bodies) and that is also relevant for patients. The issue of transparency is key for the success and acceptance of the exercise.*

Managing uncertainty in the post-launch phase. *Post-launch evidence is a key component of the re-assessment of health technologies. Registries and real world data form an important part of the body of evidence on the effectiveness and efficacy of medical devices. The EU's Digital Single Market offers numerous opportunities for interoperable ICT solutions, common standards, data security and digital competences.^[2]*

EUnetHTA, as always, remains neutral, but our work through three Joint Actions and the contributions of our 81 partner organisations and institutions is the basis of future cooperation. While the future of the HTA Proposal is uncertain, there is a very stark reality that will most likely happen if consensus cannot be formulated: there will be no Commission funding for European HTA cooperation post 2020.

It remains to be seen what will become of the work of our partners, or the substantial efforts of the EUnetHTA Secretariat to build a lasting framework for cooperation. However, no agreement seems a waste of genuine, well-intentioned and dedicated European cooperation. HTA cooperation produces and will produce very tangible benefits not only for patients, but also improve the quality and sustainability of health systems when Europe needs them most.

What are these tangible benefits?

Regardless of the outlying altruistic nature of the HTA Proposal, non-duplication saves hard cash while serving the interests of stakeholders, especially patients, who are or should be at the heart of everything we do. Indeed, all stakeholders benefit from non-duplication. Member of European Parliament Soledad Cabezon might have said it best by remarking, "The right to health is a fundamental right and a key factor for social cohesion and productivity. European HTA is about giving patients the best possible healthcare alternatives."^[3]

When looked at in an overarching visual way (back page), passage of the HTA Proposal might come down to the bottom line: the Proposal will save time, money and effort, if given the chance.

While the future is uncertain for the HTA Proposal, EUnetHTA will continue to serve the needs of all its stakeholders and do its utmost to continue to provide its deliverables under our mandate until 2020. European HTA cooperation is a long end-game that, left unresolved, will have repercussions on European health long past 2020. Commissioner Andriukaitis also said on July 9th, "Europe cares for patients." The HTA Proposal is "...an opportunity to establish a mechanism that ensures that HTA is used to its maximum potential."^[4]

When extra power is needed, Europe has built a system to send power where it is needed most. It is also not lights out for the HTA Proposal. Europe reaches consensus and builds systems through frank dialogue and the viewpoints of participants. The HTA Legislative Proposal is no exception.

¹ https://twitter.com/EU_Health

² <https://goo.gl/TttGh5>

³ https://twitter.com/EU_Health

⁴ <https://goo.gl/TttGh5>