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from diagnosis to cure

PRESS RELEASE

European Parliament further clarifies Commission proposal on HTA for medical technologies, paving the way for negotiations with the Council

Brussels, 3 October 2018 – Today, the European Parliament voted on a new regulation on Health Technology Assessment (HTA), setting the stage for negotiations to take place in the Council. MedTech Europe recognises the positive elements introduced by the Parliament with regards to assessing medical technologies. This builds the foundation for further negotiations with the Council.

MedTech Europe shares the goal to make innovative technologies accessible for the benefit of patients and health systems in a timely manner. MedTech Europe appreciates all the relevant considerations that happened in the European Parliament to make the proposal more relevant and appropriate for medical technologies.

In the end, any new EU HTA regulation on medical technologies needs to prove that it would positively impact decisions on access to innovative technologies of value for patients and health systems. Any new regulation should not create an extra layer of assessments nor duplicate any elements already answered by the new Medical Device and In Vitro Diagnostic Regulations that are currently being implemented. This is because the role of CE marking is to demonstrate safety, performance, & a clinical benefit whereas HTA's role is to assess the relative effectiveness of a technology compared to the current standard of care.

Three key areas must be well addressed to make EU HTA collaboration on medical technologies relevant for access to patients and healthcare systems: the focus on the collaboration between groups of Member States which share the same assessment needs, the clear distinction between the role of CE marking and HTA, and the need for an appropriate phase-in of medical technology into the new HTA regulatory framework.

Three key areas

Regarding HTA cooperation, the association welcomes the European Parliament's decision on a further defined scope of medical technologies that will undergo assessments by also focusing on the expected impact of these innovative technologies to patients and healthcare systems. For Council discussions, we encourage to organise medical technology assessments by voluntary cooperation within groups of Member States with the same needs and questions by decision makers, without the need to force a 28-fits all approach. This would enhance the uptake of assessments in national decision making around access.

Regarding the distinction between CE marking and HTA, the European Parliament has rightly introduced the relevance of the appropriate point in time for the assessment of medical technologies that will recognise, the learning curve of healthcare professionals, the structural and organizational changes in practices and the ability to use real-life data, in order to demonstrate the technologies' effectiveness. During the Council

negotiations, MedTech Europe strongly recommends that this distinction is fully taken in all areas of the draft regulation to avoid confusion, duplication of work and delay in access to technologies.

Thirdly, MedTech Europe appreciates the European Parliament's introduction of an impact assessment of the real access for patient and relevance for health system sustainability at the end of the transition period for Member States. This is particularly meaningful as it aims to measure the real impact of the joint clinical assessments on patient access to new technologies and sustainability of health systems.

For Council discussions, we suggest considering a more refined use of the transition period. HTA assessments for medical technologies should phase-in after the new regulatory systems for medical devices and in vitro diagnostics are fully implemented and operational. This will allow for the availability of real-life effectiveness data for innovative products that are evaluated for HTA.

MedTech Europe is committed to work with all stakeholders in achieving the shared goal of making innovative technologies accessible for the benefit of patients and to support health systems sustainability. In a value-based healthcare model, tools other than HTA should be developed and considered to assess the full value of medical technologies.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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