Synergies between HTA and Regulatory - Considerations

Reflections of the medical device and *in vitro* diagnostic industries

As of April 2017

Background

- Following the decision taken under Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, the European Health Technology Assessment Network (HTAN) was formed.
- The HTAN is a voluntary network of national authorities nominated by Member States.
- The Strategy for EU Cooperation on HTA was adopted by HTAN in October 2014.
- The Strategy identified as one of its deliverables a reflection paper on HTA-Regulatory Synergies, with regulatory understood as covering also the conformity assessment procedures with notified bodies necessary for placing medical devices on market.

Concerns of industry

- A key deliverable of the Strategy is an HTA-Regulatory Synergies reflection paper for medical devices and IVDs, which proposes stronger synergies to facilitate patients' safe, sustainable and timely access, assisting medical devices conformity assessment, including development of relevant guidance for clinical evaluation. Ie. resulting in HTA type outcomes requirements with regulatory, CE-mark data requirements.
- Linking CE-marking and HTA may limit SME's presence, jeopardise innovation for the benefit of patients, and limit access to medical devices and IVDs due to sheer cost, especially as both industries are composed of more than 95% SMEs and are leading industries in terms of innovation in Europe.
- The Council positions on the IVD Regulation do not include requirements for HTA data and demonstration of clinical utility.
- All medical devices and IVDs must fulfil safety and performance requirements for CE-marking, however, HTA is only relevant for a very limited number of products so as to inform decision-making on their use and financing.
- The planned governance of HTA cooperation lacks clarity on the potential role of the European Medicines Agency (EMA), and lacks the needed expertise on medical devices and IVDs.
- Linking the CE-mark and HTA requirements undermines the European Commission's call for better regulation, resulting in delayed access for patients to new medical technologies and undermining the enhancement of healthcare for European citizens.
- All assessment methodologies (whether regulatory or HTA) should be suitable to the specificities of medical devices and IVDs, allowing for the demonstration of their value for patients and society.

Providing solutions

With regard to synergies between HTA and regulatory issues, **we call on Member State representatives and the HTA Network to:**

- Acknowledge the effectiveness of the current and especially the new EU regulatory framework in demonstrating safety, performance and clinical benefits of medical devices and IVDs as defined in the legislations;
- Ensure that any additional de facto requirements do not jeopardise innovation nor delay access to technologies;
- Ensure an informed dialogue in the planned 'HTAN Working Group on Synergies' for medical devices and IVDs that engages all relevant stakeholders, including payers, ministries of health with HTA and regulatory expertise, patients, healthcare professionals, and industry;
- Reconsider the timing appropriateness of the HTA-Regulatory Synergies Reflection, particularly as an intensive implementation of the new regulatory framework is foreseen by all actors which will take several years. Also, avoid any duplications and overlapping and have HTA as part of the European cooperation done at an appropriate time when real world data is available different from the time of CE marking, market entry.

For further information
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