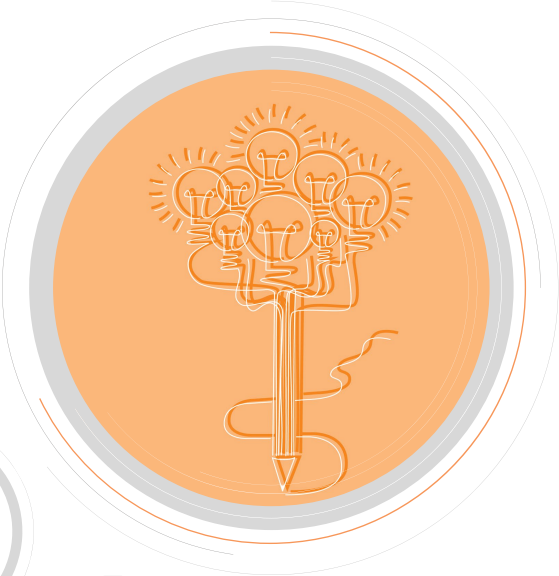
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products



Underlying actions

EMA's Regulatory Science Strategy to 2025 – Human Stakeholder Workshop

Chaired by Anja Schiel, SAWP and Koenraad Norga, PDCO on 18 November 2019
Presented by Armin Ritzhaupt, Regulatory Affairs, EMA

Disclaimer

Comments to the underlying actions represent the views of stakeholders and not the European Medicines Agency.

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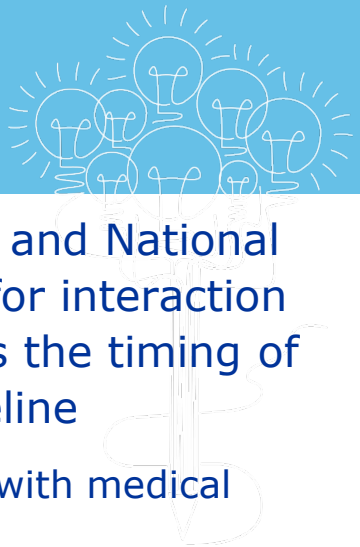
Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products

- Define how risk-benefit of such products is assessed and communicated
- Enrich expertise at the interface between medicines, medical devices and borderline products
- Facilitate the regulatory pathway between notified bodies and medicines' regulators
- Gain insight in innovation on drug-device combination products via horizon scanning

Regulatory requirements and guidance development

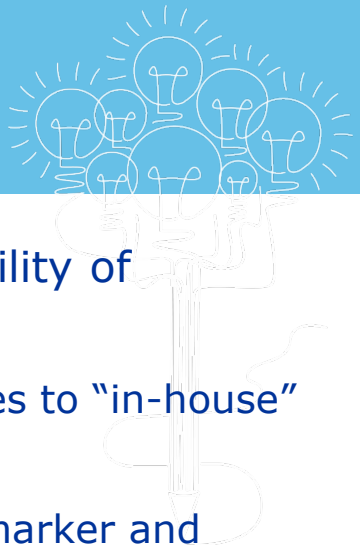


- A clear outline of the roles and responsibilities of Notified Bodies and National Competent Authorities/EMA is essential. Therefore, the process for interaction between EMA/National Competent Authorities and NBs as well as the timing of the various assessments should be defined in a procedural guideline
  - Mechanism for integrated MAA/NB review process of a drug combined with medical device, or an in vitro diagnostic
  - Clarification of how information and assessment of a CDx will be shared with EMA/NCAs during the drug approval process
  - Considerations regarding information from the device, or in vitro diagnostic to be included in the Risk Management Plan

Regulatory requirements and guidance development

- Definition of a mechanism for resolution of conflict in case of misalignments between NBs and EMA/NCA.
- Possibility of approval of a therapeutic product without an approved (CE marked) CDx.
- Considerations for conditional/accelerated approval scenarios, timing of CDx marketing application.
- Guidance is missing on the use of companion diagnostics in an investigational setting.

Regulatory requirements and guidance development



- Support is needed to ensure transparent performance comparability of different assays
  - Requirements for concordance/sensitivity testing and bridging studies to "in-house" tests and 2nd generation CDx for CE Marking
  - Transparency is needed in CDx labelling; it should be clear how biomarker and assay performance information is to be provided in the SmPC and CDx label
- Guidance addressing roles and responsibilities, process, bridging studies and follow-on test panels will be key

Regulatory requirements and guidance development

- Alignment and harmonisation with other jurisdictions (e.g. FDA) is essential as development of medicinal products and NGS based products is a global enterprise.
- The definition by the EMA Inspection group, of an inspection guidance for drug - device combination product / device constituent and support for a mutual recognition of inspection with FDA.
- The new database for devices (EUDAMED) should be linked with pharmaceutical databases. Possible consequences for both diagnostic and medicine manufacturers need to be addressed.

Building network of expertise to provide support throughout the continuum of product development and lifecycle

- In the context of digital health, a strong collaboration with medical device community and Notified Bodies is important to ensure aspects such as qualification of new digital methodologies for drug development are carried out with the best available expertise and in a holistic manner.
- More workshops bringing together industry, regulators and notified bodies could be extremely helpful, as would on-going training of assessors via case-studies through the EMA network. The continued work of the HMA/CAMD Strategic and Operational groups on this topic would also be appreciated.
- FDA's Office of Combination Products set-up in 2002, coordinating review across different divisions and still learning; consider setting up assessment teams for combination products and medicinal product/CDx.

Mechanism for early interaction with EMA and NBs to obtain joint advice during development

- Essential for developers to have possibility to gain acceptance of their development plan before implementation. It should therefore be possible to ask for development advice from the stakeholders involved in the assessment of these products. By design, such platform should allow for timely joint advice, involving notified bodies, NCAs and/or EMA, depending on the type of questions.
- A mechanism for timely involvement of Health Technology Assessment bodies in the co-development between medicinal product/in-vitro diagnostics.
- Explore and identify best practices and correlate standards in the areas of product quality and design, clinical validation, patient utilization, and regulatory approval oversight of novel therapeutics.

Any questions?

Further information

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