EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Proposals moving forward to facilitate the scientific dialogue on drug-device and drug-companion diagnostic combinations within the current regulatory framework and potentially in the future

10th Industry Stakeholder Platform on Research and Development support
11 July 2023

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Objectives- where are we now?

- Analysis of questions to be addressed in scientific advice for medicinal product developments comprising of drug-device combinations (DDC) and drug-companion diagnostic (CDx) combinations, including concrete examples ✓
- Identification of relevant stakeholders and experts required for multi-disciplinary discussions ✓
- Draft workflow for scientific advice pilot → range of follow-up activities

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Short-term follow-up activities (start under 2023)

- Building on the existing pilot for advice by expert panels on high-risk MDs, explore the possibility to include high-risk MDs used in combination with a MP and build an operational bridge between expert panel (MD focus) and SAWP (MP focus).
- Look into the possibilities of involving NCAs with device competence in development proposals in EMA scientific advice through contact with HMA core group for devices to investigate different possibilities for collaboration.
- Capture the achievements of the FG in terms of scientific questions for scientific dialogue and expertise needs and disseminate to a wider audience by producing a scientific publication.
- Continue collaboration with the EC as Chair of the Medical Device Coordination Group (MDCG).

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Medium-term follow-up activities (2024)

- Review of experience in collaboration with the expert panel following completion of the current pilot and discuss future engagement options.
- Look into the options and specific actions related to developments in combination with medical devices including companion diagnostics within ACT EU, to collaborate with the In vitro diagnostic medical devices (IVD) subgroup e.g., on the CT advice.
- Review the results of the Notified Bodies Coordination Group for medical devices (NBCG-Med) position paper and consider eventual further actions and options for collaboration with NBCG-Med and the Notified Body Oversight (NBO) subgroup.

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Long-term potential outcome in terms of follow-up activities

- Contribute to the discussion of future policy options or legislative developments, based on further experience gathered until then.

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Thank you for your attention

Further information

[Insert relevant information sources or contact details as applicable.]

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