EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on the scientific publication

7A Evidence planning for combination developments comprising of medicinal products with medical devices and/or companion diagnostics

12th Industry stakeholder platform on research and development support

Presented by Stiina Aarum on 4 July 2024

Agreed follow-up activities and next steps in Dec 2023

- Scientific publication- to publish the discussions and conclusions of the FG discussions on scientific questions and expertise needs for scientific dialogue -EMA lead, start with a document structure, timeline Q2 2024.
- Building on the experience from the existing pilot for advice by expert panels on high-risk MDs, exploring complementarity between SAWP (MP focus) and expert panel (MD focus)
- Possibilities of involving NCAs with device competence in EMA scientific advice on development proposals.
- Continue collaboration with the EC as Chair of the Medical Device Coordination Group (MDCG).

Agreed follow-up activities and next steps Dec 2023 cont.

- Options and specific actions within ACT EU and COMBINE –EMA issues collected in a COMBINE WS on 10 Nov.
- 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.
- In the long-term, contribute to the discussion of future policy options or legislative developments, based on further experience gathered until then.

Manuscript status

- Authors: Sub-group of the Focus Group, with representatives from the different stakeholder groups (SAWP, NCA, NBs, Industry, EMA)
- Four meetings since 14 Feb-17 June 2024
- Collaborative effort – THANK YOU!
- Publication under final revisions, intended submission to a scientific journal in Aug/Sep 2024

Manuscript content and overall messages

- Nine study cases illustrate what kind of questions would benefit from scientific dialogue with multiple stakeholders, and expertise needs- Gap analysis
- Cases include both drug-device combinations and drug-IVD/CDx combinations and different life cycles of the MP and MD.
- Questions on the clinical trial and performance study authorisation and conduct, as well as device classification and procedural and regulatory questions were not in scope for this exercise.
- Results highlight the need for increased scientific dialogue between the stakeholders throughout the life cycles of the medicine and medical device as well as potential for increased collaboration within the evolving regulatory framework.

Any questions?

Further information

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

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