



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Feedback from the latest discussions of the Focus group- agreed actions and next steps

11th Industry stakeholder platform on research and development support

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An agency of the European Union





Agreed follow-up activities and next steps

- 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 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.



Thank you for your attention

Further information

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