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Combination products

14th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines - 23 June 2025

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What’s happened?

❑ Recap of recent activities

- Q&A update in Jan 2025:
  - Aimed to clarify requirements for class I (excluding Is and Im) integral device i.e. when a DoC is not available, a MAH’s declaration of compliance with the GSPRs can be provided instead.

- Analysis of NB Opinions submitted within MAA / Line extension / type II applications through the centralised procedure (covering the period from May 2021 to Dec 2024) :
  - presented at various external forum in 2025

What's next?

- **Upcoming update of Q&A related to variations guidelines revision : Q4 2025**
  - to adapt to the newly revised variation guideline including new variations categories for device changes based on a risk-based approach as to the impact on Q,S,E to determine to the level of variation to submit (IA, IB or II).
- **Establishment of an operational group on combination products : Q4 2025**
  - Scope :
    - combination products (with integral, co-packaged and PI referenced device / supplied separately)
    - Consultation procedures (on ancillary medicinal substances, companion diagnostics, systemically absorbed substance based medical devices)
  - Composition: notified bodies, medicines and medical devices regulators
  - Goal: aims to serve as a dedicated forum to support cross-sector dialogue, improve understanding of the applicable frameworks, and address procedural and technical issues linked to combination products and related consultation processes.
  - Plan for ad-hoc interactions with Industry stakeholders

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Thank you

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