European Commission

Targeted evaluation MDR/IVDR

Meeting MDCG with stakeholders, 17 December 2024
Agenda point 4

Our overall timeline

Scoping phase

Building the foundations of the Evaluation (intervention logic, Evaluation questions)

Data mapping & consultation strategy

Call for evidence & public consultation

Data collection and analysis

Scrutiny, Validation, Adoption

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Elements of consultation strategy

Tentative timeline!

		Start	End
1	Call for evidence and public consultation (see more info on next slide) Launched	Q4 2024	Q1 2025
2	Study on monitoring the availability of medical devices/IVDs (including 12th survey for notified b[illegible]s, 2nd survey for MF/AR[illegible]s, poss. CAs survey, poss. patient survey) Launched Launched	Q4 2024	Q2 2025
3	Dedicated workshops on various topics	Q1 2025	Q2 2025
4	Conference on medical devices (date TBC)	Q4 2025	
5	Ongoing work in the Medical Device Coordination Group (including specific data collection activities, e.g. to gather data from CAs)	Continuous	

+ Use of data from other EU funded projects (e.g. study on regulatory governance and innovation, CORE-MD), use of scientific literature, use of publicly available data including position papers and data shared by stakeholders etc.

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Upcoming consultation activities

CALL FOR EVIDENCE

- **Document** describing :
  - context of the evaluation
  - purpose and scope (criteria, time period, countries)
  - how it will be carried out (consultation strategy; data collection and methodology)
- **'feedback':** one open text field

PUBLIC CONSULTATION

- **Web-based questionnaire**
  - to collect general information, views and opinions;
  - will include:
    - questions tailored to specific stakeholders;
    - written answers on **closed and open questions;**

Possible to submit additional information.

Published

- on the *Have Your Say* portal
- in all EU languages
- open to the public and stakeholders
- Open until **21 March 2025**

Thank you