European Commission

Medical Device Coordination Group

Agenda point 3 - Targeted evaluation MDR/IVDR

Stakeholders session, 14 October 2024

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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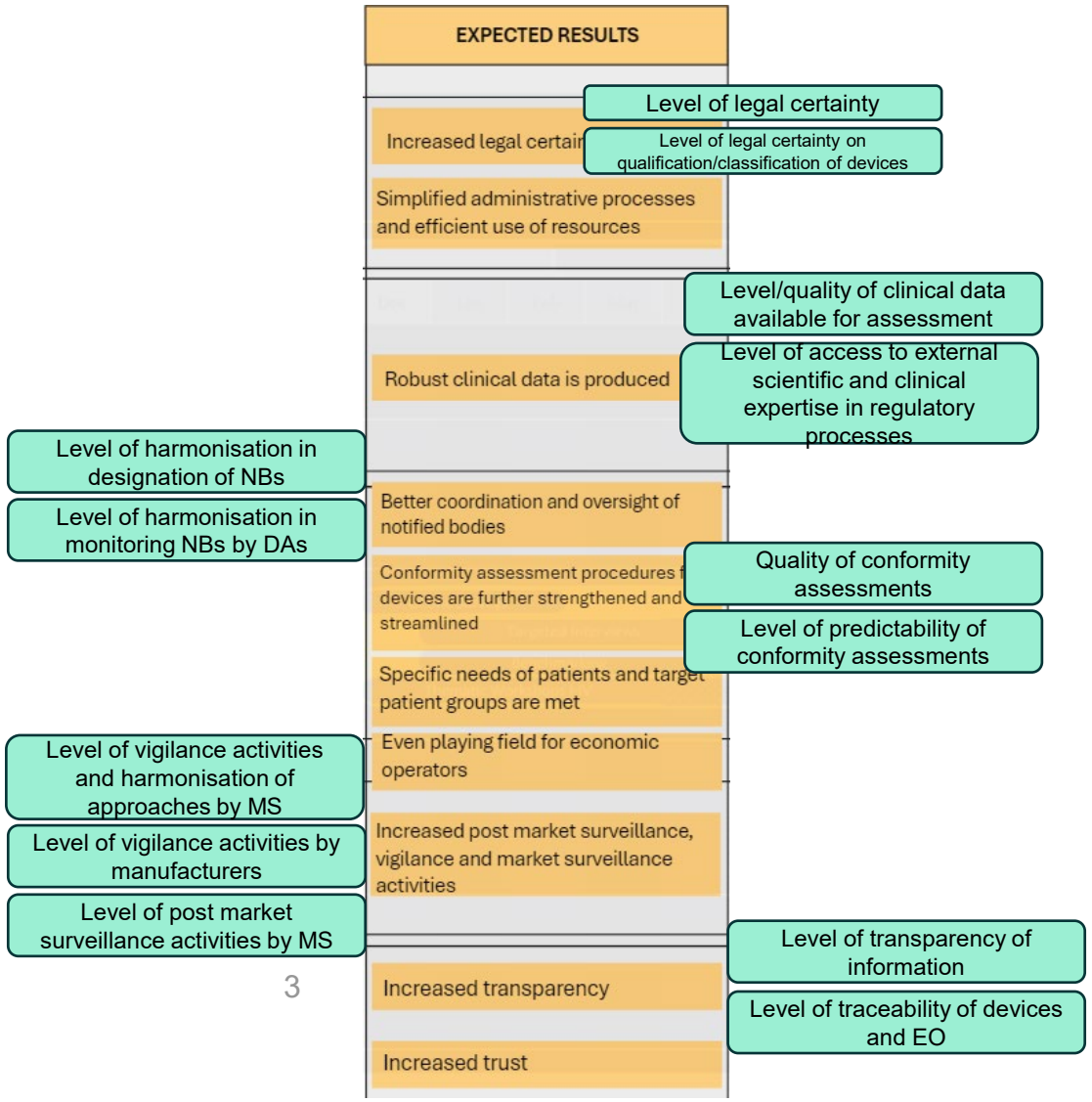
Measuring effectiveness and efficiency

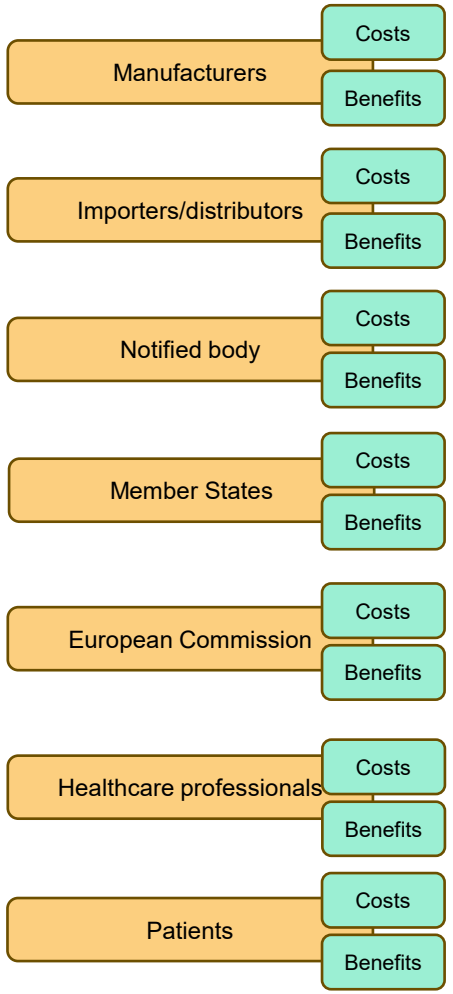
Examples

Data mapping and indicators

Effectiveness



Efficiency



Is the data already available?

Robustness/timeliness of available data to be considered

Triangulation needs to be considered

For the identified data gaps: who needs to be consulted?

Additional considerations

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Elements of consultation strategy

Tentative timeline!

For the identified data gaps, how can it be best collected?

		Start	End
1	Call for evidence and public consultation (see more info on next slide)	Q4 2024	Q1 2025
2	Study on monitoring the availability of medical devices/IVDs (including survey for notified bodies -large data set-, poss. CAs survey, poss. patient survey)	Q4 2024	Q2 2025
3	Additional targeted consultation activities (including specific survey to EO on efficiency, dedicated workshops on various topics etc.)	Q4 2024	Q1-Q2 2025
4	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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Breakdown of costs for stakeholders

For last certificate issued/breakdown QMS/product certificate

Phase	Activity	Type of cost	Risk class of device	Magnitude of cost
When is the cost being incurred? E.g. pre-market, certification process, post market?	Description of the activity generating the cost	Adjustment cost? Administrative cost? Enforcement cost? *Definitions on the different types of costs to be provided*	Differentiation between MDs/IVDs and risk classes	Number of working days spent by staff Average hourly cost of staff member Cost of outside experts (e.g. consultancies, lawyers, experts) Fees paid to notified bodies/authorities Investment costs

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 at same time

- on the *Have Your Say* portal
- in all EU languages
- open to the public and stakeholders
- at least 12 weeks duration

Thank you