EMA
EUROPEAN MEDICINES AGENCY

3. Medical device Expert Panels

12th ISG meeting

28/03/2025

Presented by Silvy da Rocha Dias – Expert Panels and Groups Head of Office

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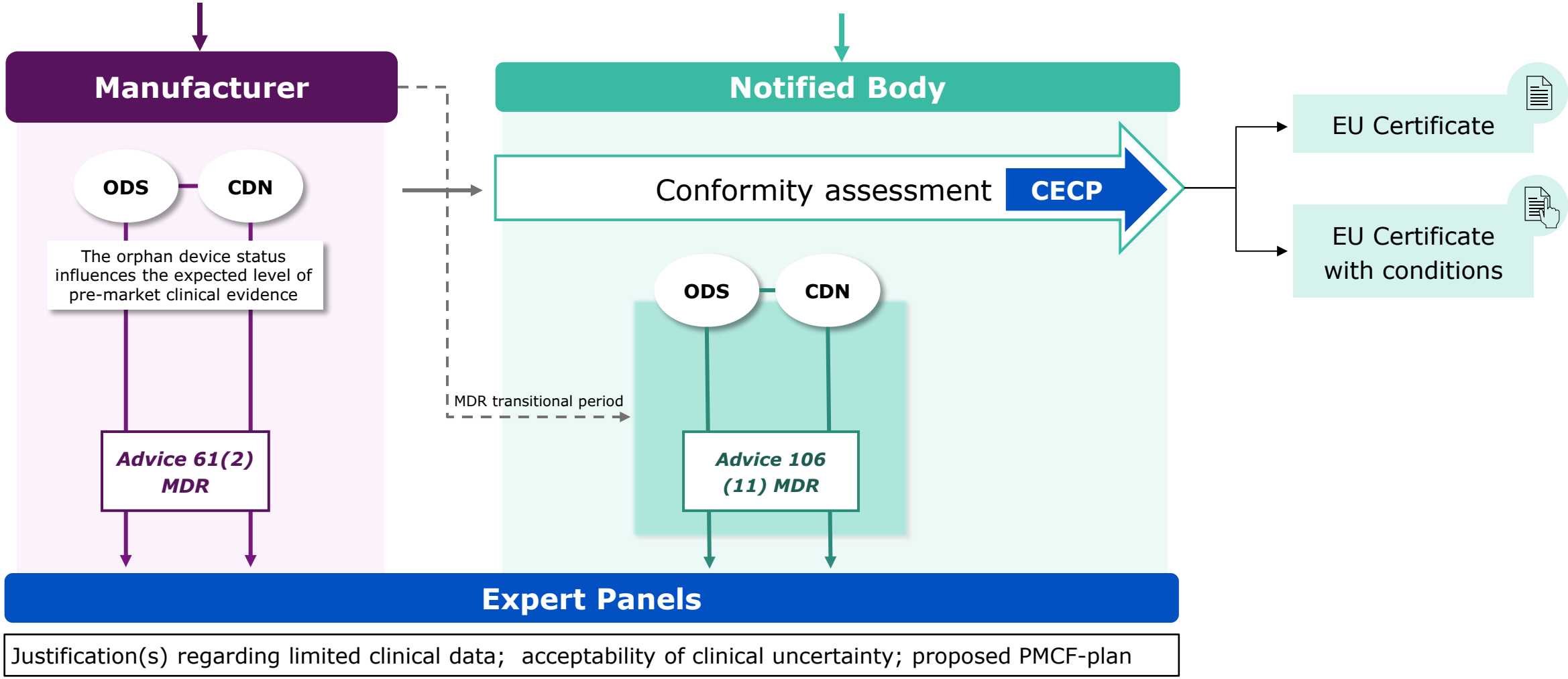
3.1. Orphan device pilot

ODS – Orphan device status
CDN - Clinical data needed



3.1. Orphan device pilot programme

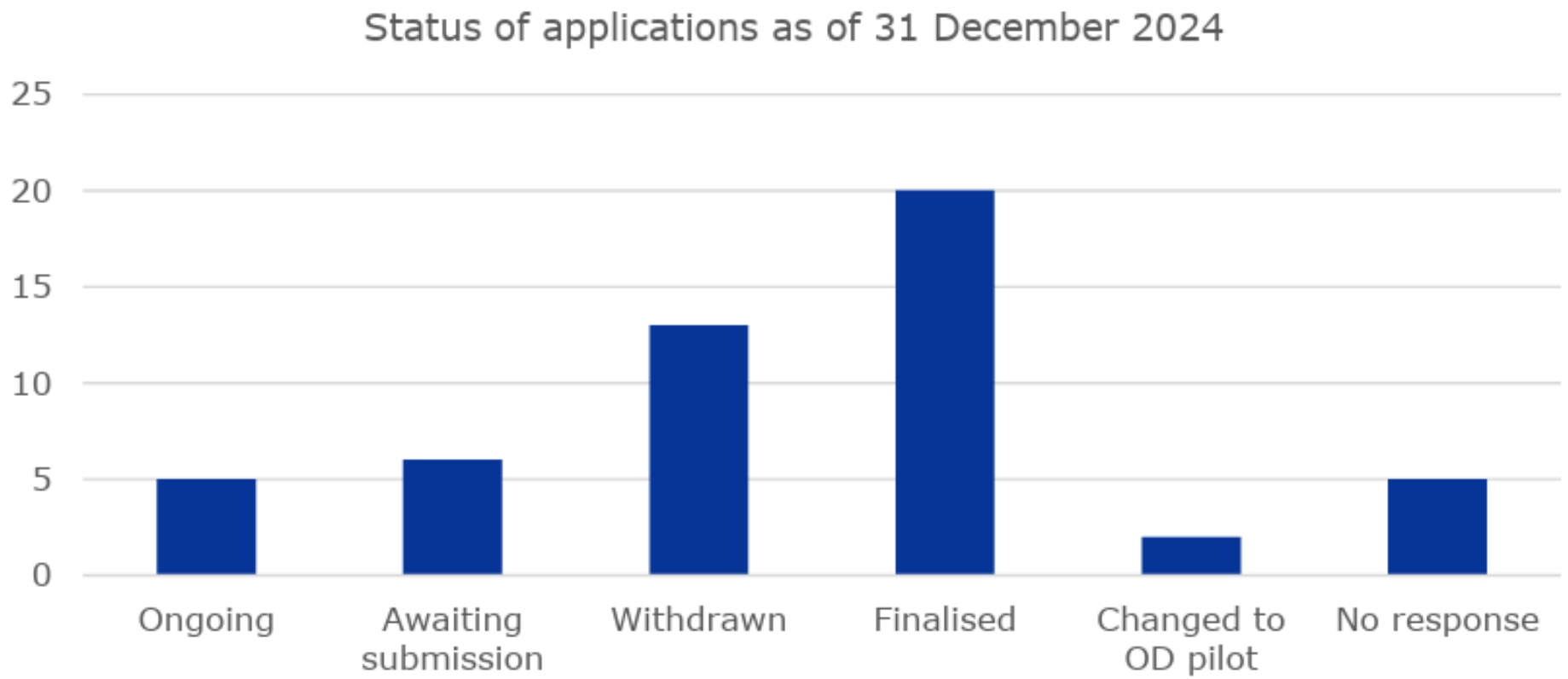
- Submission of case studies opened on 2 Aug 2024; ends in December 2025
- Free advice to **Manufacturers** and **Notified Bodies**:
  - orphan device status and
  - sufficiency of clinical data/clinical strategy for conformity assessment
- 4 test cases ongoing but open for other additional cases – submission portal open

3.2. Update on advice to manufacturers

- The expert panels advise on intended clinical development strategies and clinical investigation proposals, in line with Article 61(2) of the MDR for:
  - class III medical devices;
  - class IIb active medical devices intended to administer or remove medicines from the body.
- Pilot launched in February 2023, closed in December 2024. **Interim report*** recently published
- Regular service opened since **Feb 2025**

*https://www.ema.europa.eu/en/documents/report/pilot-advice-expert-panels-manufacturers-high-risk-medical-devices-interim-report-experience-pilot-february-2023-december-2024_en.pdf

3.2. Update on advice to manufacturers



Note: Main reason for request withdrawal are delays/changes in the development program

3.2. Update on advice to manufacturers

Distribution of submissions per clinical area across all 3 submission phases

Thematic panel	# applications	%
Circulatory system	16	31
Orthopaedics, traumatology, rehabilitation, rheumatology	14	27
Neurology	7	14
General and plastic surgery and dentistry	6	12
Nephrology and urology	3	6
Gastroenterology and hepatology	2	4
Respiratory and anaesthetic devices, intensive care	1	2
Ophthalmology	1	2
Other	1	2
Total	51	100

3.2. Update on advice to manufacturers

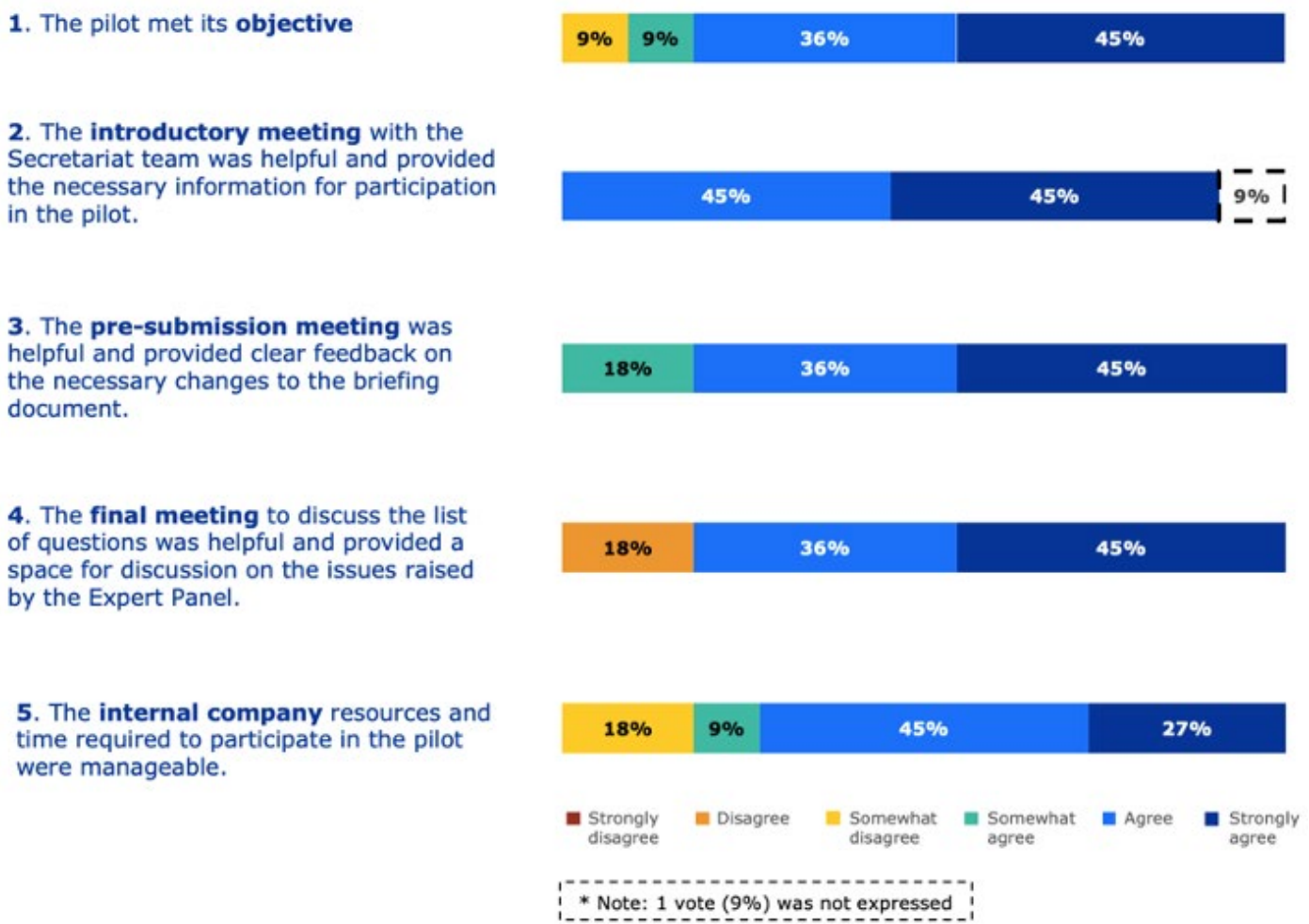
SME status and "prioritisation criteria" across all 3 submission phases

SME	# applications	%
Yes	38	75
No	13	25
Total	51	100

Prioritisation criteria	# applications
Novel device with a possible major clinical or health impact	44
Device for unmet medical needs	28
Device intended to benefit a relatively small group of patients	18

3.2. Update on advice to manufacturers

Overview of feedback received from applicants (manufacturers)



3.2. Update on advice to manufacturers

Recommendations for process improvement and new measures for the efficient implementation of the standard procedure for advice to manufacturers

	Learnings	Recommendations
Improvement of the process with streamlining of communication	• Streamlining the process (more focused timelines, replacement of meetings by written exchanges where appropriate)	• Meetings during the procedure are now all optional, to leave the flexibility to have exclusively written exchanges, where appropriate.
Regulatory context and timelines	• Clarity on expected time commitment, timelines and expectations for both experts and applicants • Clearer scope for the advice • Clearer requirements of the documentation to be submitted	• A guide to experts and a guide to applicants including respective expectations and instructions have been developed and published. • A template for the briefing document with detailed instructions for applicants has been developed and published.
Increase predictability and transparency	• Fixed advice timeline and timetable	• A fixed timing for the advice (60 days from submission of final briefing document) has been implemented, along with a published timetable with defined submission slots for applicants.
Increase collaboration and communication	• More communication from the Secretariat about the status of the procedure	• Standard communications are sent to the applicants and experts at each step of the process.

3.2 Update on advice to manufacturers

Main benefits perceived by the participants

- **Flexibility** of the process and possibility of engagement with other stakeholders (e.g., pilot on orphan devices and the future Parallel HTA/EMA joint scientific consultation - JSC)
- It provides a link between early development and the opinion issued by the experts panels at the end of the conformity assessment => **predictability**
- It is the only mechanism of advice formally recognised in the MDR
- Developers access a group of experienced clinicians working in the relevant clinical field across the EU

3.3. HTA observership of advice to manufacturers' procedures

- HTA bodies are following procedures of advice to manufacturers
- Experience gained will inform on the future **parallel Joint Scientific Consultation (JSC)** between HTA bodies and Expert Panels
- Currently 3 procedures:
  - 2 in the Cardiovascular system
  - 1 in Hepatology
- Parallel JSC for medical devices is foreseen to **open in 2025**

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Thank you

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