EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medical device expert panels – ongoing pilot projects

Industry Standing Group (ISG) meeting
26th September 2024

Presented by Miguel Antunes
Expert Panels and Groups Office, EMA

Pilot on Advice to Manufacturers

Period: Submission done in 3 phases: last one ended in June 2024

Remit: Class III devices or IIb active devices to administer/remove medicines (MDR Art 61(2))

Area of advice: Clinical only (development of the clinical strategy and/or proposal for clinical investigations)

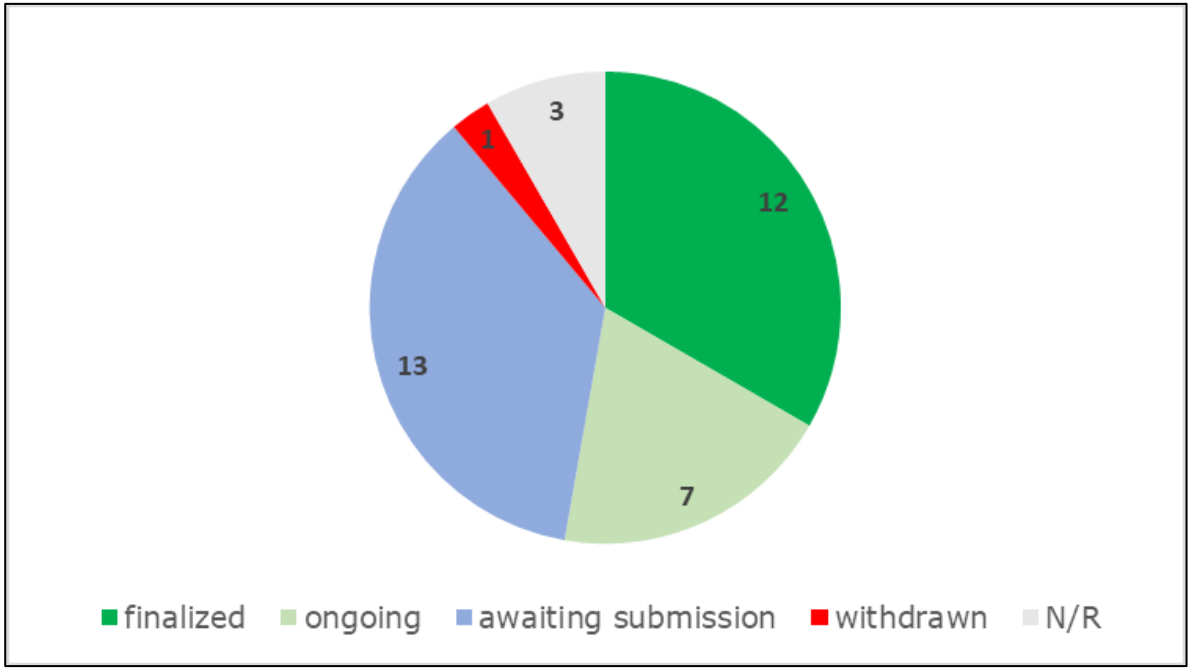
Applicants: manufacturers/authorised representatives established in the EEA (SMEs encouraged to submit)

Publication: Advice delivered in this pilot phase will not be published; however, the advice given needs to be addressed in the **Clinical Evaluation Report** (CER) of the manufacturer

HTA: HTA bodies might be invited to observe advice procedures during the 3rd phase

Pilot on advice to medical device manufacturers

36 letters of interest (1st + 2nd phase): State of play



Pilot on advice on orphan devices

Period: started 2nd Aug 2024; ending 31st Oct 2024

N.er requests: 4 in total (OD status + sufficiency of data/further clinical development)

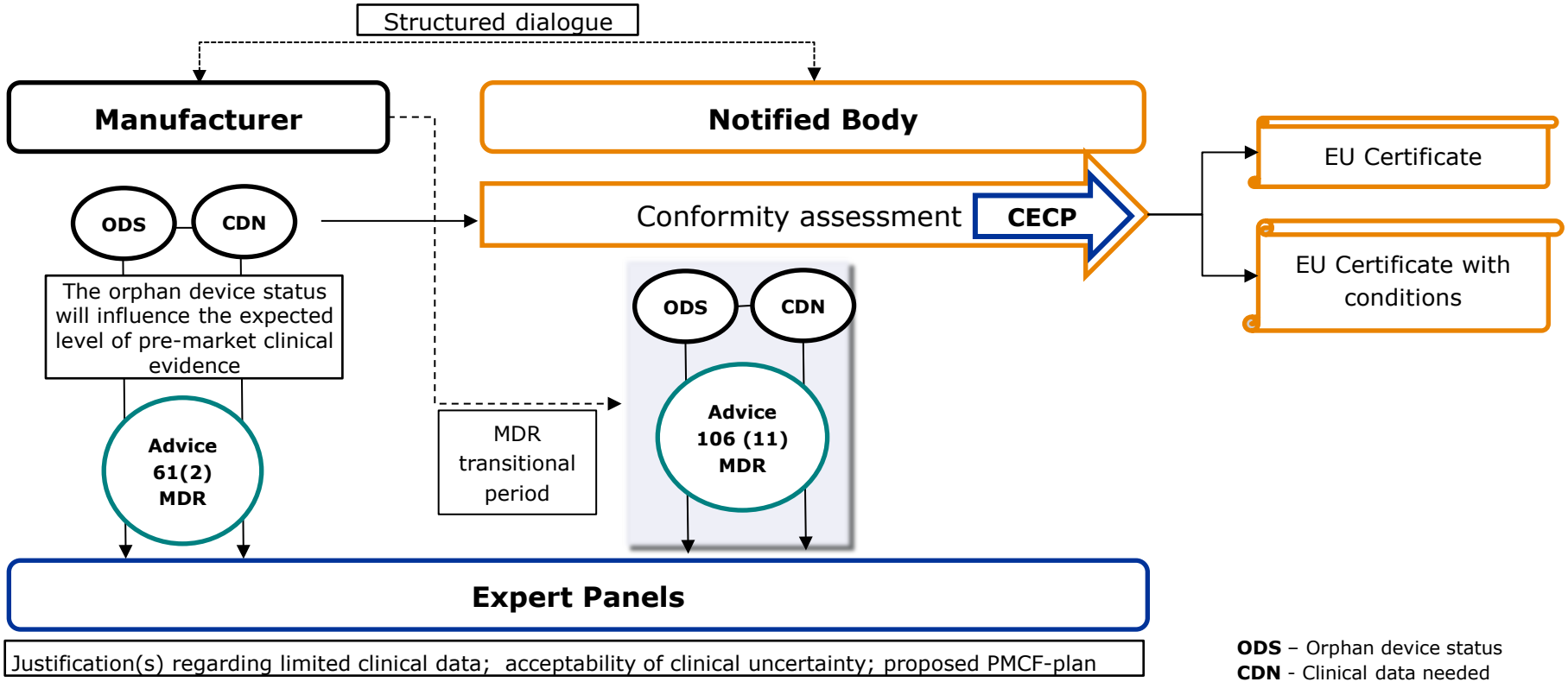
Remit: Class III devices or IIb active devices to administer/remove medicines (MDR Art 61(2) or Art 106(11))

Area of advice: Orphan device status + sufficiency of clinical data/clinical strategy

Applicants: Manufacturers / NBs

Publication: Advice mentioned in the CER/CEAR

Role of the Expert Panels supporting orphan devices (optional/voluntary)



ODS – Orphan device status
CDN - Clinical data needed

Application structure

1. **Letter of interest**
2. **Application/ briefing document**

- **1st part** on the OD status criteria
- **2nd part** with 'question and answer' format on clinical development strategy/ proposals for clinical investigations

Output of the procedure

- **Advice letter on the OD status criteria**

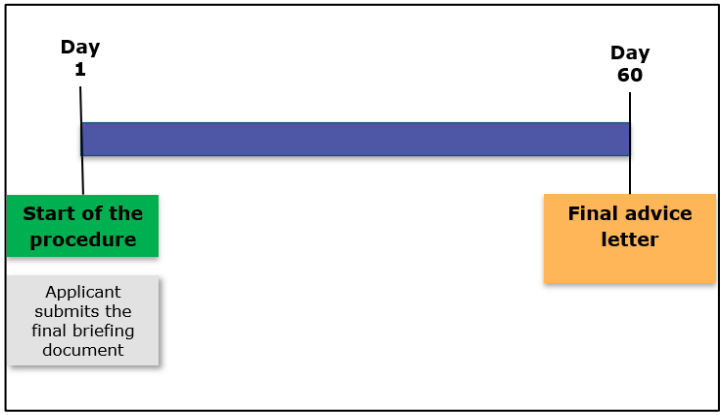
OR

- **Advice letter on the OD status criteria +** the applicant's **clinical development strategy**/ proposals for clinical investigations

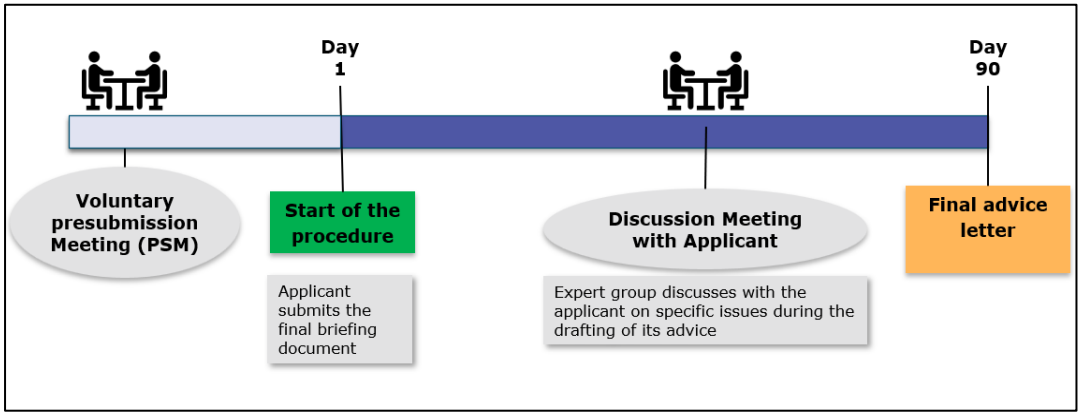
Early advice or advice if clinical evaluation is in advanced stage or completed

Procedural timeline in the pilot (tentative)*

OD status



OD status + clinical development



*** Assuming it is a simple advice**

Webinar on orphan medical devices

- Held on 23 September 2024
- Speakers from the European Commission, National Competent Authorities, Manufacturers, Healthcare Professionals, Notified Bodies and Expert Panels
- Presentation of the **MDCG guidance 2024-10** on clinical evaluation of orphan devices and of the implementation processes to address the unique challenges facing these devices
- The Expert Panels pilot on orphan devices will be a **unique opportunity to test the guidance** under real conditions, namely the application of the orphan device definition and the consultation process for the expert panels' advice, in particular in cases of late/closed clinical development

Any questions?

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