EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medical device expert panels - State of Play

Industry Standing Group (ISG) meeting
28th June 2024

Presented by Miguel Antunes
Expert Panels and Groups Office, EMA

Medical device Expert Panels

Mandatory and additional/voluntary advisory activities

- **On the clinical assessment done by the Notified Bodies on class III implantable/class IIb AARMP or on the performance evaluation done by manufacturers of class D IVDs**
- Class III and class IIb AARMP **medical device manufacturers** on their clinical development strategy/proposals for clinical investigations (possibility of doing it in parallel with HTA authorities)
- **Commission or the MDCG** on any specific topic related to the implantation of the medical device Regulations
- Identification of **concerns and emerging issues** on the safety and performance of any device
- Development and maintenance of appropriate **guidance** and **Common Specifications**

CECP and PECP and other advice

Period: 21st Apr 2021 – 27th June 2024

CECP

- **121 files submitted:**
  - **93%** class III implantable devices and **7%** class IIb active ARMP devices
  - **13 opinions** delivered; **1** being finalized

Expert panels' thematic areas	N.er of files submitted
Circulatory system	37
Orthopaedics, traumatology, rehabilitation , rheumatology	30
General and plastic surgery and dentistry	22
Neurology	19
Respiratory system, anaesthesiology, intensive care	8 (all AARMP)
Endocrinology and diabetes	1
Nephrology and urology	3
Gastroenterology and hepatology	1
Obstetrics and gynaecology, including reproductive medicine	0
Ophthalmology	0
Total	**121**

Number of CECP/Opinions/PECP					
Year	2021	2022	2023	2024	Total
CECP	12	37	39	33	121
Opinions	*3*	*7*	*1*	*2 + 1**	*14*
PECP	15	1	2	2	20

PECP

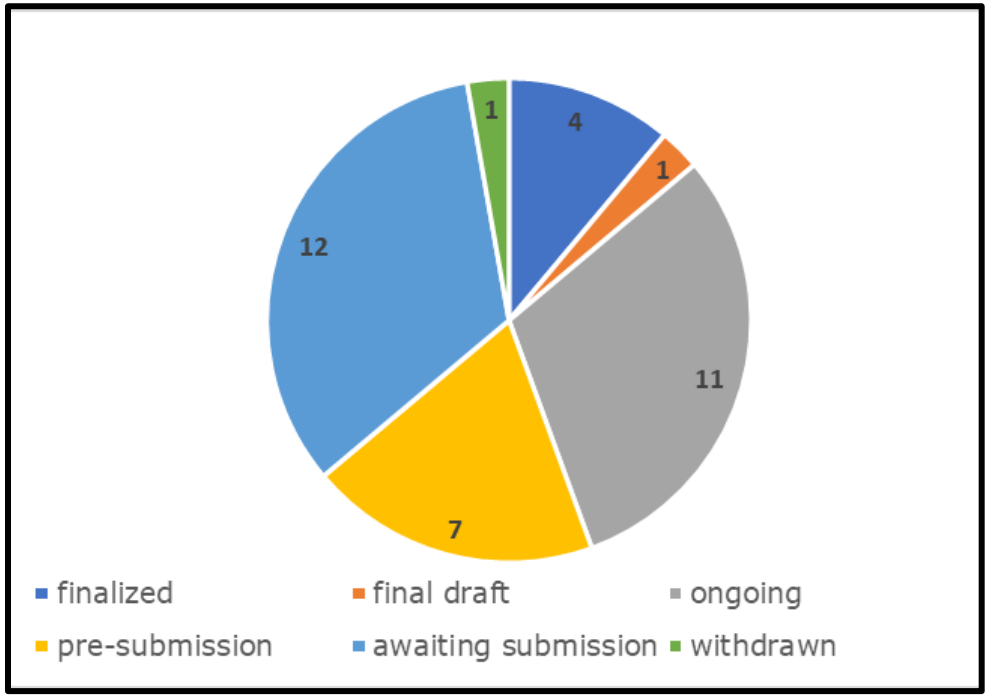
- **20 files submitted**
  - **20 views** delivered

MDCG Advice

- Influenza virus A(H1N1)pdm09 clinical epidemiology (transmissibility and disease severity)
- SARS-CoV-2 neutralizing antibodies
- Monkeypox virus clinical epidemiology (transmissibility and disease severity) – FU question
- Indirect antiglobulin tests

Pilot on advice to medical device manufacturers

Feb 2023 – Dec 2024



- **36 projects**
- 3rd phase open for submissions until **30th June 2024**
- Pilot foreseen to end in **2024**
- Possibility of **HTA bodies** observing
- Orphan devices special pilot

MDCG 2024-10

Clinical evaluation of orphan medical devices

June 2024

25/06/2024

Today, the European Commission has published guidance on the clinical evaluation of orphan medical devices.

Orphan devices are medical devices or their accessories, which are intended to be used for diseases or conditions affecting only a small number of individuals each year. Often, they are used to treat a rare disease or medical condition for which very few diagnostic or therapeutic options exist. Orphan devices can be crucial to fulfil an otherwise unmet medical need.

Today's guidance provides criteria for determining when a medical device or an accessory for a medical device should be regarded as 'orphan device' under the Medical Devices Regulation 2017/745 (MDR). It aims to guide manufacturers and notified bodies when applying the MDR's clinical evidence requirements and help overcome some of the challenges that lead to delays in patient access to orphan devices. The guidance includes the possibility for manufacturers and notified bodies to seek advice from European Medicines Agency expert panels on the orphan device status and the clinical data needed for their clinical evaluation.

This guidance was developed by the Medical Devices Coordination Group (MDCG), which is made up of representatives of the Member States and chaired by the Commission. It was done in collaboration with stakeholder representatives including healthcare professionals, academic societies, notified bodies and industry.

The guidance on orphan devices is one of the important actions endorsed by MDCG in August 2022 to enhance notified body capacity and to support manufacturers in the transition to the Medical Devices Regulations, see Daily News 29 / 08 / 2022 (europa.eu).

- Guidance MDCG 2024-10

Link to Guidance MDCG 2024-10

MDCG 2024-10

Clinical evaluation of orphan medical devices

June 2024

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Clinical evaluation of orphan medical devices

June 2024

- **MDR increased clinical evidence requirements**
- Challenging for devices specifically intended for use in **rare diseases/conditions**, or in specific indications for **rare cohorts** of patients with an otherwise non-rare disease/condition
- In many cases, there are very few diagnostic or therapeutic options: **unmet medical need**
- **Objective:** to help these devices meet the pre-market clinical evidence requirements without unduly delaying patient access

MDCG 2024-10

Clinical evaluation of orphan medical devices

June 2024

Orphan Device

the device is specifically intended to benefit patients in the treatment, diagnosis, or prevention of a disease or condition that presents in **not more than 12,000 individuals in the European Union per year[1];**

- and at least one of the following criteria are met:
  - there is **insufficiency of available alternative options** for the treatment, diagnosis, or prevention of this disease/condition, or
  - the device will offer an option that will provide an **expected clinical benefit compared to available alternatives** or state of the art for the treatment, diagnosis, or prevention of this disease/condition, taking into account both device and patient population-specific factors.

1. Extrapolated from population estimate criteria for HUD designation established by the U.S. FDA

MDCG 2024-10

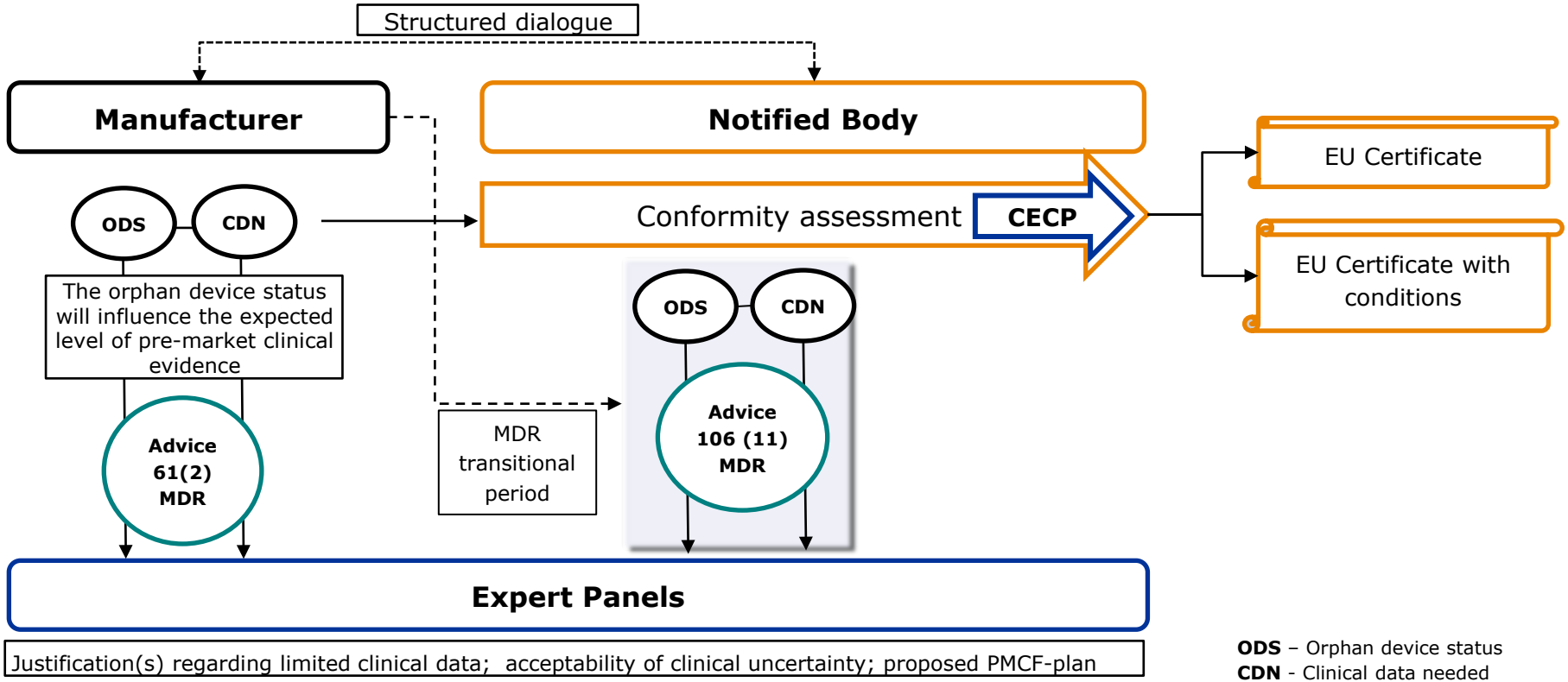
Clinical evaluation of orphan medical devices

June 2024

Justification of orphan device status

- provide documentation on the epidemiological based criterion by way of **population incidence estimates**.
- include additional supporting data for incidence estimates, for example from **national level data**, **health service level data** or from **independent clinical experts** or **medical society consensus** statements.
- Where data available are limited, the OD status may be justified by providing an EU population incidence based on **extrapolation**.
- For **orphan subpopulations**, factors to consider include device-specific factors such as **mechanism of action**, and **patient-specific factors** that make it medically plausible that the device is for use only for that specific subpopulation of patients

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



ODS – Orphan device status
CDN - Clinical data needed

Workshop with Notified Bodies

- Held on 22 April 2024
- The first of a group of planned interactions destined to align processes
- Specific discussions on the current consultation and advice procedures: process improvement
- The upcoming (now published) MDCG guidance 2024-10 on orphan devices was presented high-level. It was identified as an additional possibility for cooperation between expert panels and notified bodies

Take home messages

- The number of CECP procedures is lower than forecasted; however, the numbers for S1 2024 ≈ total for 2023 or 2022
- Advice to manufacturers has been welcomed by both applicants and the experts. While it provides an opportunity to encourage innovation in the EU, it also promotes a framework to improve the collection of data for the conformity assessment and PMCF-plan
- Interactions with the HTA Regulation will start in 2025; preparatory work is ongoing
- Expert panels will play a key role in verify the possible orphan status of a device and in providing support for its development/ assessment. IVD orphan devices will be covered as an upcoming work item
- Improvements to the current consultation processes are being discussed, namely with NBs

Any questions?

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