EMA
EUROPEAN MEDICINES AGENCY

4. Medical device Expert Panels: support to innovation

ISG meeting– 30/06/2025

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Expert panels support to innovation

Advise manufacturers of high-risk medical devices on their clinical development strategy/clinical investigations (MDR 61.2)

Advise on **orphan device status** and further assist manufacturer with the clinical development or the NB with the clinical assessment (MDCG 2024-10)

Advise on **breakthrough device status** and further assistance to manufacturers/NB

Advice to medical device 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**
- Possibility of **parallel advice** with an **HTA Joint Scientific Consultation**

*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

Advice to medical device manufacturers

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

Advice to medical device manufacturers

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

Novel device with a possible major clinical or health impact	44 **(86%)**
Device for **unmet medical needs**	28 **(55%)**
Device intended to benefit a relatively **small group of patients**	18 **(35%)**

Orphan device pilot

- Submission of case studies opened on 02/08/2024; **ends on 31/12/2025**
- Advice to Manufacturers and Notified Bodies:

  1. orphan device status:
     - specifically intended for not more than **12,000 individuals/year** EU;
     - there is **insufficiency of available alternatives**, OR
     - **expected clinical benefit** compared to available alternatives or state of the art for the treatment, diagnosis, or prevention of this disease/condition.
  2. Clinical strategy/sufficiency of clinical data for conformity assessment

➢ Commission is considering a **new expert panel** “orphan and paediatric devices”

Orphan device pilot state of play

Expert Panel	General intended purpose	Procedure status
Circulatory System	Ventricular assistive mechanical support to patients with advanced heart failure	**1. OD status agreed** 2. Ongoing request for advice under 61(2)
Orthopaedic	Paediatric scoliosis	**1. OD status agreed**
Neurology	Glioblastoma (drug delivery)	**1. OD status agreed** 2. Ongoing request for advice under 61(2)
Circulatory System	Pulmonary Arterial Hypertension (PAH) (drug delivery)	**1. OD status agreed**
Circulatory System	Patent ductus arteriosus (PDA)	1. OD status ongoing

11 requests: 5 completed/active, 6 awaiting final briefing document submission

Breakthrough devices – medical devices and IVD

Technological

- **Degree of novelty** with respect to the device technology or the related clinical procedure

Clinical

- Significant clinical impact on patient or public health, for a **life-threatening or irreversibly debilitating disease or condition**:
  - **Significant positive clinical or health impact**
  - **Unmet medical need**

- **Guidance under discussion (MDCG – stakeholders)**
- **Expert Panels to be involved in status designation and advice on clinical investigations / performance studies**

Key messages

- Expert panels already contribute to the development of innovative devices in the EU:
  - High-risk devices (class III/IIb AARMP)
  - Orphan devices
- A specific dedicated pathway is also being prepared for breakthrough devices in which expert panels will play a pivotal role

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Thank you

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