EMA
EUROPEAN MEDICINES AGENCY

4. Medical device Expert Panels: support to innovation

ISG meeting– 30/09/2025

Silvy da Rocha Dias and Miguel Antunes –

Expert Panels and Groups Office

Expert panels update

Advise manufacturers of high-risk medical devices (MDR 61.2)

Orphan device status and clinical development (MDCG 2024-10)

Breakthrough device status and development

Advice to medical device manufacturers

- Pilot launched in February 2023, closed in December 2024. Interim report* published.
- Regular advice opened February 2025, but few applications received. Potential causes:
  - Uncertainty about potential future changes to the MDR
  - Confusion about structural dialogue from NBs
- In line with EMA's confidentiality obligations, the advice letters contain proprietary and commercially sensitive information, and therefore cannot be currently published
- Possibility of parallel advice with HTA Joint Scientific Consultation in the 3rd phase:
  - 3 procedures were observed by **8 HTA bodies**
  - Preparation for the parallel JSC in 2026

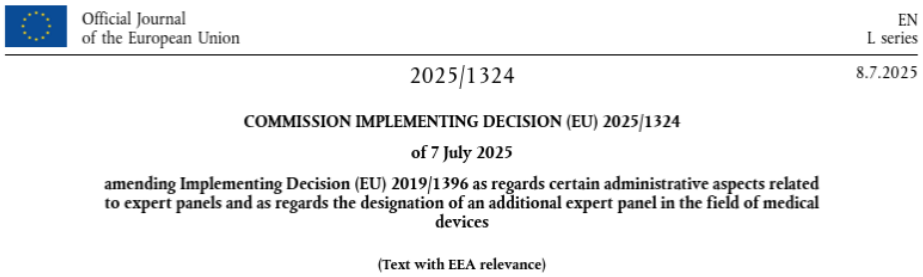
*https://www.ema.europa.eu/en/documents/report/pilot-advice-expert-panels-manufacturers-high-risk-medical-devices-interim-report-experience-pilot-february-2023-december-2024_en.pdf

Orphan device pilot

- 5 test cases

Expert Panel	General intended purpose	Procedure status
Circulatory System	Ventricular assistive device	**Completed**
Orthopaedic	Paediatric scoliosis device	**Completed**
Neurology	Glioblastoma (drug delivery)	**Completed**
Circulatory System	Pulmonary Arterial Hypertension (PAH) (drug delivery)	**Completed**
Circulatory System	Patent ductus arteriosus (PDA)	**Completed**

- Commission Implementing Decision (EU) 2025/1324 created the Paediatrics and rare diseases panel
- During pilot, orphan status report is not published – to be reconsidered when regular procedure is put in place



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2025/1324

8.7.2025

COMMISSION IMPLEMENTING DECISION (EU) 2025/1324

of 7 July 2025

amending Implementing Decision (EU) 2019/1396 as regards certain administrative aspects related to expert panels and as regards the designation of an additional expert panel in the field of medical devices

(Text with EEA relevance)

Outputs of the pilot

CARTHERA
Advanced Brain Therapy

Carthera receives EMA expert panel endorsement for Orphan Medical Device status of SonoCloud system

Following positive opinion, Carthera is one of the first companies to benefit from brand-new status - intended to support early access pathways for innovative devices targeting rare diseases

Paris, France, July 1, 2025 – Carthera, a spin-off from Sorbonne University founded by Pr. Alexandre Carpentier, and developer of SonoCloud®, an innovative ultrasound-based medical device to treat a wide range of brain disorders, today announces it has received EMA expert panel endorsement for Orphan Medical Device status of its SonoCloud system.

Carthera will be one of the first companies to benefit from EMA expert panel advice, supporting its clinical development strategy and clarifying the final steps before CE marking application. This advice, intended for medical device manufacturers and notified bodies, is part of the EU pilot program to support early access pathways for innovative devices targeting rare diseases. As part of the program, the EMA has prioritized certain types of orphan medical devices, such as those treating a medical condition that is life-threatening or that could cause permanent impairment of a body function, devices intended for children and novel devices with potential major clinical benefits.

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**
- **Expert Panels to be involved in status designation and advice on clinical investigations / performance studies**

Breakthrough devices pathway – under development

- **BtX designation opinion to agreed at the expert panels level**
    - Other levels of formalization under consideration
- **Designation might be possible for all risk classes** (voluntary process)
- **Secretariat of the expert panels** to facilitate the need for additional support
- **Expert panels can support NBs during conformity assessment, if requested**
- **Pilot to be started soon** (possibly by the end of this year)

Key messages

- Expert panels contribute to the development of innovative devices in the EU:
  - Advice to high-risk device manufacturers
  - Orphan devices
- A specific dedicated pathway is also being prepared for breakthrough devices in which expert panels will play a pivotal role
  - A pilot to test the breakthrough devices guidance might start still this year

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Thank you

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