EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medical Device Expert Panels' Activities

9th Industry stakeholder platform on research and development support, 5 December 2022

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Content of the presentation

1. Brief presentation on the Expert Panels and their activities

2. Expert panels scientific advice to medical device manufacturers (Pilot Phase)

   - Remit and objectives of the scientific advice pilot phase
   - Timetable and communication

Who are the Medical Device Expert panels?

- Experts in their field appointed by the **European Commission** on the basis of their scientific, clinical and technical expertise following a call for expression of interests.
- Foreseen in Articles 106 and 48(6) of the Medical Device Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 on *In Vitro* Medical Devices (IVDR) to support the scientific assessment and advice.
- Selected by the European Commission and appointed in consultation with the **Medical Device Coordination Group (MDCG)**.
- On 1 March 2022, the coordination Secretariat has been handed over to the **European Medicines Agency (EMA)**.

12 Expert panels:

1. Screening panel - determines whether there is a need for a scientific opinion
2. Orthopaedics, traumatology, rehabilitation, rheumatology
3. Circulatory system
4. Neurology
5. Respiratory system, anaesthesiology, intensive care
6. Endocrinology and diabetes
7. General and plastic surgery and dentistry
8. Obstetrics and gynaecology, including reproductive medicine
9. Gastroenterology and hepatology
10. Nephrology and urology
11. Ophthalmology
12. *In vitro* diagnostic medical devices

Tasks of the Expert Panels

Mandatory Activities:

- **Opinion** on the Clinical Evaluation Assessment Report (CEAR) on **class III implantable** or **class IIb active devices** to administer or remove medicines (ARMP) => Clinical Evaluation Consultation Procedure (CECP);
- **View** on the Performance Evaluation Report (PER) of **class D IVDs** => Performance Evaluation Consultation Procedure (PECP).

Additional (voluntary) Activities:

- Scientific, technical and clinical assistance to the Commission and the MDCG in relation to the MDR implementation or the identification of concerns on the safety and performance of medical devices.
- Contributing to the development and maintenance of appropriate guidance and Common Specifications.
- Providing advice to manufacturers on their intended clinical development strategy and proposals for clinical investigation for all class III and ARMP devices.

Expert Panels – Pilot Scientific Advice to MD manufacturers

- **Any Class III** or **class IIb ARMP device** (Art. 61(2) of the MDR).
- During the pilot phase, it is important to ensure a **broad distribution** of products and clinical areas to guarantee representativeness for the development of the future process.
- **Areas of interest** for advice:
  - Novel devices that have a potential for major health or clinical impact
  - Devices to diagnose or treat diseases with few diagnostic/treatment options
    - Orphan devices
    - Specific paediatric devices
  - Medical devices in drug-device combinations (where the principal intended action is not achieved by the medicine).

Expert Panels – Pilot Scientific Advice to manufacturers Timetable

Date	Action
Dec/2022	• Stakeholders' announcement • Preparation Q&A on the SA process and submission documents
Q1/2023 Mar/2023	• Public announcement • Webinar to potential applicants • Submission portal to receive applications • Selection of submissions **(1st phase)**
Q2/2023	• **Start of the pilot SA procedures**
Q3/2023	• Selection of submissions based on expert panel capacity **(2nd phase)**
Q4/2023	• Preliminary review of the pilot in view of future full implementation
Q2/2024	• Closure of the Pilot phase

Any questions?

Further information

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