EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on the Expert Panels' activities

Industry Standing Group (ISG) meeting, 22 November 2022

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Content of the presentation

1. Update on the Expert Panels' activities
   - Clinical Evaluation Consultation Procedure
   - Performance Evaluation Consultation Procedure
   - Additional activities
2. Expert panels scientific advice to medical device manufacturers
   - Implementation of the scientific advice procedure
   - Timetable and communication

Tasks of the Expert Panels

Legal mandate of Regulation (EU) 2017/745 - MDR and Regulation (EU) 2017/746 - IVDR:

- Opinions on the Clinical Evaluation Assessment Reports (CEAR) of the notified bodies (NB) for **class III implantable medical devices and class IIb active medical devices** destined to administer and/or remove a medicinal substance (ARMP) => Clinical Evaluation Consultation Procedure (CECP);
- Views on the Performance Evaluation Reports (PER) of the manufacturers **for class D IVDs** => Performance Evaluation Consultation Procedure (PECP).

State of play regarding CECPs and PECPs

CECP

- **38 applications** received from notified bodies (NB)
  - **10** decisions of the screening experts that an **opinion** is needed
- Most of the applications were in the **Circulatory system (18)**, followed by **Orthopedics, traumatology, rehabilitation, rheumatology (6).**

PECP

- **16 applications** received from manufacturers (via NBs)
  - **16 views** delivered by the IVD panel
- Most of the applications were for devices for **SARS-CoV-2 detection**

- All decisions/opinions/views delivered within the set deadlines for PECP and CECP **– Predictability**

Expert Panels - Additional activities

- The Expert Panels – IVD Panel - has provided advice to the Medical Device Coordination Group (MDCG) on a certain influenza virus and the adequate classification for the IVDs to detect the virus strain
- Coordination Committee meeting on the 14th November 2022
  - Chairs, Vice-Chairs and Representatives of the screening panel
  - Ensure effective exchange of information between panels
  - Topics covered:
    - Experience with the CECP and PECP and potential process improvements
    - Patient input to the expert panels
    - Communication of expert panels' activities
    - Additional activities for the expert panels

Additional activities for Expert Panels: MDR Art. 106(10)

• **Manufacturers**	✓ Advice on their intended clinical development strategy and proposals for clinical investigation for all class III and ARMP devices (Art. 61(2))
• **Commission and the Medical Device Coordination Group (MDCG)**	✓ Scientific, technical and clinical assistance in relation to the MDR implementation ✓ Contributing to the development and maintenance of appropriate guidance and Common Specifications, in particular for clinical investigations, clinical evaluation and Post-Market Clinical Follow-up (PMCF), performance studies, performance evaluation and post-market performance follow-up (PMPF) ✓ Contributing to identification of concerns and emerging issues on the safety and performance of medical devices

Expert Panels – Advice to MD manufacturers on clinical development

Article 61(2) of Regulation (EU) 2017/745:

*"For **all class III devices and for the class IIb devices referred to in point (b) of Article 54(1)**, the manufacturer may, prior to its clinical evaluation and/or investigation, consult an expert panel as referred to in Article 106, with the aim of reviewing the manufacturer's intended **clinical development strategy and proposals for clinical investigation**. The manufacturer shall give due consideration to the views expressed by the expert panel. Such consideration shall be documented in the clinical evaluation report referred to in paragraph 12 of this Article.*

The manufacturer may not invoke any rights to the views expressed by the expert panel with regard to any future conformity assessment procedure."

Expert Panels – Pilot Scientific Advice to MD manufacturers

- Following feedback from the last ISG stakeholders' meeting and the expected capacity of the expert panels in 2023, the proposal is to **open an early pilot for scientific advice** for manufacturers in Q1 2023.
- The pilot will help shape the future scientific advice procedure after 2024.
- This activity will foster **innovation development** in Europe and promote **faster access** to patients of safer and better performing devices.

Expert Panels – Pilot Scientific Advice to MD manufacturers

- EMA has **more than 20 years experience** providing scientific advice to medicine developers by the SAWP/CHMP
- EMA secretariat is preparing the pilot for scientific advice to medical device manufacturers:
  - Plan for 2 phases to ensure no core business disruption:
    1. Applicants can submit a **high-level overview** of their **products** and their **clinical development strategy in Q1 2023**
    2. Following selection of application, applicants are invited to submit the clinical development plan for advice
  - **Only** the selected applications will need to develop a **full briefing document** for the advice phase
  - **Similar process to SAWP/CHMP advice to medicine developers,** with a pre-submission meeting with applicant and a **Q&A form** for the advice

Expert Panels – Pilot Scientific Advice to MD manufacturers

- Limited number of submissions: up to 10 requests for 2023
- Prioritisation of certain clinical areas depending on the number of requests
  - Ensure a broad distribution of products and clinical areas to ensure the relevance of the pilot for the development of the future process
- During the pilot phase, it is important to take different types of requests:
  - Different clinical areas (e.g., cardiology, neurology)
  - Different potential of data acquisition (e.g., "orphan" device or a breakthrough device for a high prevalence condition)
  - Different stages of development (early, middle or late development)

Expert Panels – Pilot Scientific Advice to MD manufacturers

Class III or class IIb ARMP devices

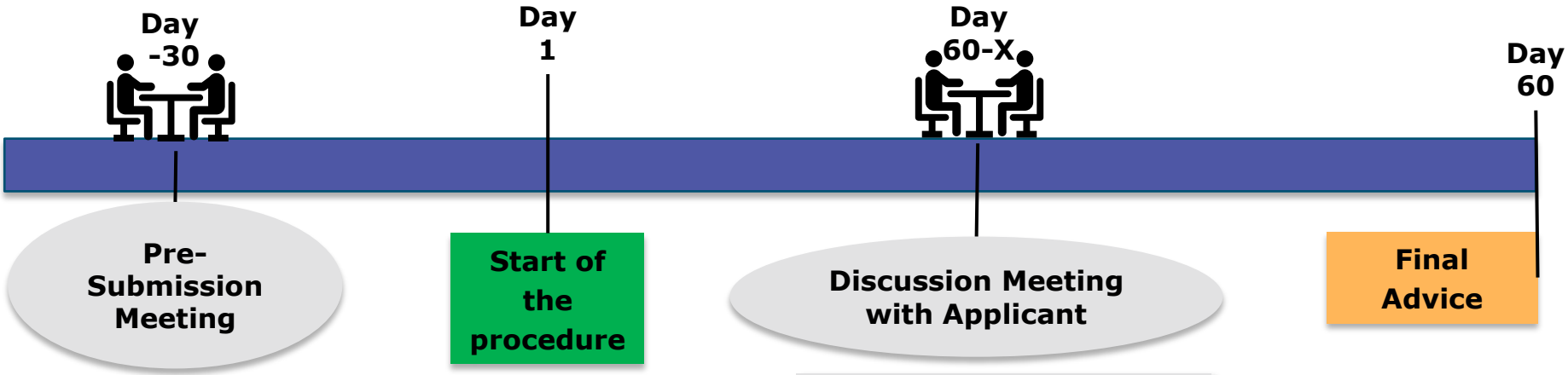
Possible areas of interest for advice:

- 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 MD manufacturers

- Interaction between the expert panels and the applicant:
  - Pre-Submission meeting with the applicant takes place to help with the preparation of the submission
  - Every advice procedure will include a discussion meeting with the applicant before the final advice is provided
- During the Pilot Phase, the advice will take approximately 90 days (30 days pre-submission + 60 days advice procedure)

Expert Panels – Pilot Scientific Advice to manufacturers
Procedural timeline



30 days prior to the start of every procedure:
- Pre-Submission meeting (PSM)
- Applicant submits a draft application and briefing document

Day 60-X: Discussion Meeting with Applicant

Expert Panels – Pilot Scientific Advice to manufacturers Timetable

Date	Action
Nov_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 projects procedures
Q3/2023	• Selection of submissions based on expert panel capacity (2nd phase)
Q4/2023	• Preliminary review of the pilot in view of 2024 full implementation
Q2/2024	• Closure of the Pilot phase

Any questions?

Further information

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