EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medical device expert panels' activities: update on CECP/PECP and additional activities

Industry Standing Group (ISG) meeting, 21 March 2023

Presented by Silvy da Rocha Dias – Expert Panels and Groups Head of Office *ad interim*

Content of the presentation

1. Update on the Expert Panels' activities
    - Clinical Evaluation Consultation Procedure/Performance Evaluation Consultation Procedure
2. Expert panels advice to medical device manufacturers
    - Pilot overview and updates

State of play regarding CECPs and PECPs

CECP

- **49 applications** received (**+ 11** since 22.11.2022)
  - ✓ **10 opinions** delivered
  - ✓ Most of the applications were in the **Circulatory system (21)**, followed by **Orthopedics, traumatology, rehabilitation, rheumatology (10)**

PECP

- **16 applications** received
  - ✓ **16 views** delivered
  - ✓ Most of the applications were for devices for **SARS-CoV-2 detection (5)**

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

Topics for discussion on the CECP/PECP

Estimations of CECPs and workload for expert panels

- Extension of transition period

Estimations of PECPs and workload for expert panels

- Common Specifications published: In vitro diagnostic medical devices - common specifications (europa.eu)

Focus on areas for improvement

- Tools available for the CECP/PECP processes (short term)
- Proposals to help streamline the process (long term)

Advice to manufacturers on medical devices' clinical development

- Expert panels' activities focused first on the mandatory consultation procedures while a*d hoc* activities were to be gradually implemented depending on needs and resources
- **Stakeholders feedback** highlighted the need for scientific support from the Expert Panels on the clinical development of medical devices => **pilot for scientific advice** for manufacturers in 2023
- The pilot will help **shape the future scientific advice procedure**, adapted to the specificities of the **MedTech** sector, including adjusted timelines
- This activity will foster **innovation development** in Europe and promote **faster access** to safer and more effective devices to EU patients

European Commission

European Health Union:
Supporting the transition to the new medical device framework

Measures for a successful transition in the longer term

- Pilot project on **scientific advice for clinical development strategies** for high-risk devices
- Targeted **support for SMEs** through the Enterprise Europe Network
- Tailored **solutions for orphan devices**

Orphan devices are crucial for treating relatively small group of patients, especially children.

Small and Medium sized Enterprises (SMEs) represent around **95% of medical device manufacturers** in Europe.

https://health.ec.europa.eu/system/files/2023-01/mdr_proposal_factsheet_0.pdf

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Expert panels' advice to medical device manufacturers pilot: overview and updates

Industry Standing Group (ISG) meeting, 21 March 2023

Presented by Miguel Antunes - Expert Panels and Groups Office

Expert Panels' Advice - Legal basis

Article 61(2) MDR: 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' Advice - Format

Period: February 2023 to Q1 2024

Fees: No fees will be charged during the pilot phase

Applicants: manufacturers/authorised representatives established in the EEA

Number of procedures: 10 requests organised in 2 rounds of 5 applications

- Limited number to ensure availability of experts for CECPs
- Possibility to submit several proposals but only one can be selected per company
- Proposals not selected at the 1st round will automatically be considered for the 2nd round

Expert Panels' Advice - selection process

- **If > 10 applications, the following criteria will be applied**:

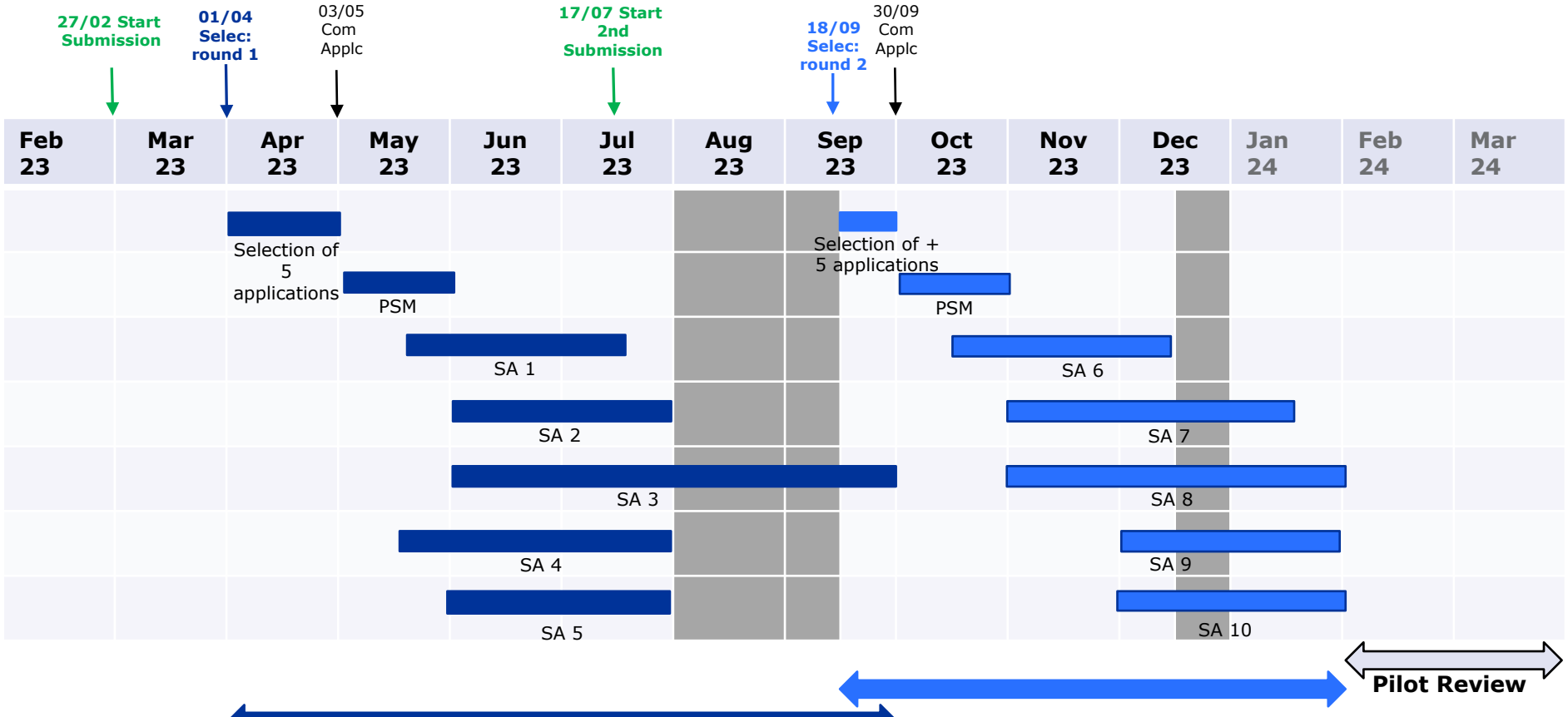
  ✓ Devices intended to benefit a relatively **small group of patients** in the treatment or diagnosis of a disease or condition (e.g. "orphan devices", devices for paediatric use)

  ✓ Devices for **unmet medical needs** i.e., medical conditions that are life-threatening or cause permanent impairment of a body function AND for which current medical alternatives are insufficient or carry significant risks ("breakthrough device" - MEDDEV 2.7/1 rev.4, Appendix 8)

  ✓ **Novel devices** with a possible **major clinical or health impact**

- Ideally, **different clinical areas and types of devices** should be represented

Pilot advice timeline (tentative)



Expert Panels' advice

- The Expert Panels will review the applicant's **clinical development strategy** and/or proposals for **clinical investigation**. Although the advice is **not on the preclinical development** strategy, some preclinical information might be relevant. This will be discussed with the applicant on a case-by-case basis
- The advice is given based on the best scientific information available at the time. However, scientific advice is **prospective** in nature
- Expert Panels **do not perform pre-assessment** of data or of study results. The advice is based on the scientific strategy under discussion, not the results
- Advice request in a **question-and-answer format** (question followed by the applicant's position)
- The advice delivered in this pilot phase will **not be published**

Expert Panels' advice – process overview

≈ 30 days before:
- Applicant submits a draft application

Day 1:
- Applicant submits the final application

Day 60-X: The expert group discusses the draft final advice with the applicant before it is delivered

*No publication during the pilot

* The process **timeline may vary slightly**, depending on expert's availability and the nature of the request

12

Information session on the pilot for expert panels' scientific advice to manufacturers of high-risk medical devices - 25/01/2023

Documents

Question and Answer information session on the pilot for expert panels' scientific advice to manufacturers of high-risk medical devices (PDF/164.09 KB) (new)

First published: 24/02/2023
EMA/81171/2023

Letter of interest template for online application - Information session on the pilot for expert panels' scientific advice to manufacturers of certain high-risk medical devices (PDF/173.08 KB)

First published: 06/02/2023

Presentation - Information session on the pilot for expert panels' scientific advice to manufacturers of certain high-risk medical devices (PDF/656.48 KB)

First published: 06/02/2023

https://www.ema.europa.eu/en/events/information-session-pilot-expert-panels-scientific-advice-manufacturers-high-risk-medical-devices

Expert Panels' advice – assessment phase

- **Outcomes to be assessed**
  - Satisfaction with the process (applicants and experts)
  - Time needed for the different steps and adequacy
  - Application form
- **Meeting with stakeholders** to discuss potential changes to be implemented in the design of the advice process
- **Survey of manufacturers** to estimate their needs in terms of advice process and plan the resources in the expert panels

Any questions?

Further information

E-mail: EU-OPERATIONS-EXPAMED@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

Follow us on **@EMA_News**