EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Expert Panels on Medical Devices and in vitro Diagnostics - State of Play

Industry Standing Group (ISG) meeting
25th March 2024

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Update to CECP and PECP and other advices

Period: 21st Apr 2021 – 28th Feb 2024

CECP

- **103 files submitted:**
  - **90%** class III implantable devices and **10%** class IIb active ARMP devices
  - **11 opinions** delivered

Expert panels' thematic areas	N.er of files submitted
Circulatory system	35
Orthopaedics, traumatology, rehabilitation , rheumatology	21
General and plastic surgery and dentistry	19
Neurology	16
Respiratory system, anaesthesiology, intensive care	7 (all AARMP)
Endocrinology and diabetes	1
Nephrology and urology	3
Gastroenterology and hepatology	1
Obstetrics and gynaecology, including reproductive medicine	0
Ophthalmology	0
Total	**103**

Number of CECP/Opinions/PECP

Year	2021	2022	2023	2024	Total
CECP	12	37	39	15	103
Opinions	*3*	*7*	*1*	*1*	*12*
PECP	15	1	2	(2)*	20

PECP

- **20 files submitted**
  - **19 views** delivered
  - **1** in preparation

MDCG Advice

- Influenza virus A(H1N1)pdm09 clinical epidemiology (transmissibility and disease severity)
- SARS-CoV-2 neutralizing antibodies
- Monkeypox virus clinical epidemiology (transmissibility and disease severity) – FU question
- Indirect antiglobulin tests

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Forecast from survey with NBs in 2023

Summary of the estimated number of CECP applications

- 2022: between 6-9 files / month
- 2023: between 13-15 files / month
- 2024: approx. 20 files per month

- The situation currently is manageable in terms of CECPs vs advice to manufacturers, however, this may change as most requests are in the circulatory system

Update on the Pilot for Advice to Manufacturers

Period:

- 1st Phase: started 27th February 2023;
- 2nd Phase: started 1st October 2023;
- 3rd Phase: starting 2nd April until 30th June 2024

Remit: Class III devices or IIb active devices to administer/remove medicines (MDR Art 61(2))

Area of advice: Clinical only (development of the clinical strategy and/or proposal for clinical investigations)

Fees: No fees during the pilot phase

Number of procedures: balance with CECPs/PECPs, focus will be on orphan devices

Pilot Scientific Advice - Prioritisation Criteria

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The following criteria will be considered – No priority order

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

-> Description of the target population of patients and quantitative estimate of this population in the EU

- **Devices for unmet medical needs** i.e., devices for 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 (see definition of "breakthrough devices" in MEDDEV 2.7/1 rev.4, Appendix 8)

-> Description of the disease(s)/condition(s) and the current standard medical treatments or diagnosis

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

-> Assessment of the novelty of the device and the expected clinical and/or health impacts resulting from that novelty cf. EC guidance for the medical device expert panels on the consistent interpretation of the decision criteria in the clinical evaluation consultation procedure

Advices for the 1st phase

Clinical field	Type of Device	Status
Circulatory system	ICED microcurrent inducer	In preparation (final drafting)
Circulatory system	Cardiovascular implant (others)	delivered (Dez 2023)
Circulatory system	Septal occluder device	in preparation (final drafting)
Neurology	Peripheral implantable nerve stimulator	delivered (Dez 2023)
Orthopaedics	Hip stem and cup implant system	delivered (Dez 2023)

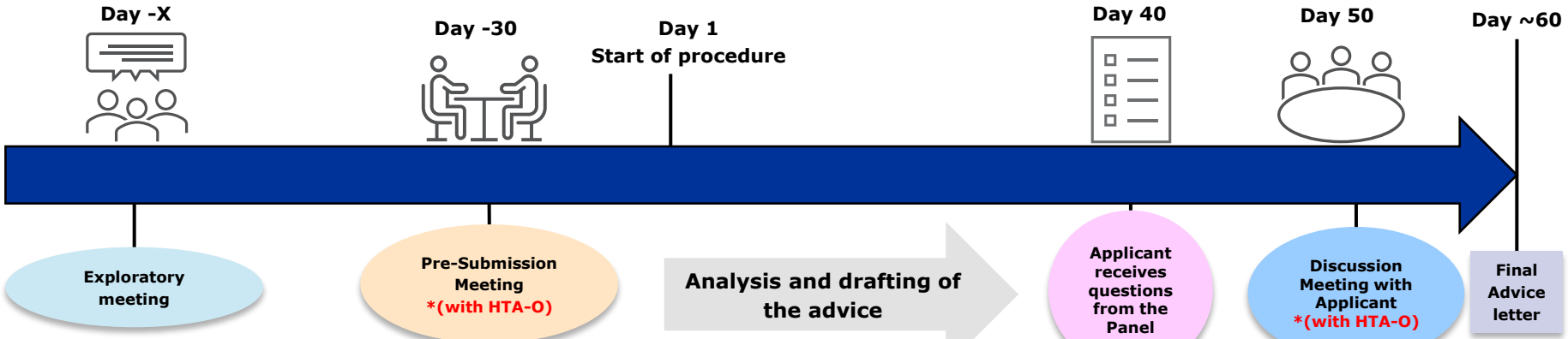
Extension of the pilot until the end of 2024

- 3rd phase to begin 2nd April 2024:
  - the submission portal will be open from 2nd of April to 30th of June 2024 for submission of letters of interest
- Prioritization criteria may apply
- Support to orphan device development will be under scope
- Observership from one or more HTA bodies might be a possibility, depending also on the willingness of the developer

Workshop with Notified Bodies

- Planned for the 22nd April 2024
- focus on clinical assessment alignment (advice to manufacturers and opinions)

Pilot on advice to medical device manufacturers: tentative procedural timeline



Prior to the start of every procedure:

- High-level discussion on the product and clinical development strategy
- Support in preparation of the briefing document

30 days prior to the start of every procedure:

- Pre-Submission meeting (PSM)
- Applicant submits draft application and briefing document
- Allocation of file (5 expert teams)

Day 40:

- Applicant receives questions to be addressed in writing and orally

Day 50:

- Discussion Meeting with Applicant on questions from the panel on the clinical strategy/ investigations

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General learnings from the Expert Panels advice pilot

- The earlier the advice is sought, the more beneficial is the advice:
  - Only limited advice can be provided if the study(ies) is(are) already ongoing
- Opportunities are different depending on the stage of the clinical development
  - Early advice on clinical development strategy helps steer the clinical evaluation plan
  - Once the studies have been completed, advice can still be provided on the PMCF plan
- Circulatory system has the highest number of interest for advice
  - In line with the clinical consultation procedure

Learnings from the Expert Panels advice pilot process

- Early dialogue through the **introductory meeting is critical**
  - To understand the stage of development of the product
  - Sets expectations from manufacturer on the scope of the advice
  - Critical discussion of the briefing package to be submitted
  - Secretariat of expert panels to provide relevant administrative, regulatory and scientific support for the briefing package and during the advice
  - Substance of the advice dependents on the comprehensiveness of the briefing package
- Advice procedure **excludes a pre-evaluation** of the clinical data for conformity assessment

Learnings from the Expert Panels advice pilot process

- Discussion Meeting with Applicant at the end of the process
  - Short timelines require good communication and coordination with the manufacturer
    - A response document with the slides for the meeting need to be sent the latest 3 days before the meeting
  - Final opportunity to interact with the expert panel before advice is delivered
    - Ensure that all responses are complete and ask questions if further clarification is needed on the questions

Future activities: Orphan devices

- In the EU, special regulatory considerations regarding the development and placing on the market of orphan devices are being discussed
- An Orphan device Task Force (ODTF) was set-up under the MDCG to address the issues and asked to prepare a guidance with procedural and scientific recommendations
- The secretariat of the Expert Panels, working closely with Commission, is involved in the work, as it is expected expert panels may be involved in future processes

Re-appointment of the experts

- New contracts and exercise of re-appointment of experts in **July/August 2023**
- Approximately **170 experts** have been (Re) – Appointed as members of the expert panels
- Experts are appointed based on the criteria set out in the current call for expression of interest
- Launch of the new call for expression of interest in **June 2024**

Take home messages

- Number of CECP applications well below the estimated forecast and surveyed NBs
  - Urgent need to have clarity on the potential number of applications in 2025
- Number of PECPs is low as expected after the publication of the first group of CSs
- Advice pilot is being extended
  - New application period of 2nd April – 30 June 2024
- Possibility to request HTA observers during the advice pilot
- Orphan devices will be a key future activity
- New 5-year call for expression of interest for experts launched in June 2024

Any questions?

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