EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Industry Standing Group (ISG) meeting, 26 June 2023

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

State of play for CECPs and PECPs

Submissions from 01 Apr 2021 – 1st June 2023 (**2 years**)

- **63 files submitted**

CECP

- **89%** class III implantable devices and **11%** class IIb active ARMP devices
- **35% new** MDR devices, **16%** devices with a **new intended purpose**, **49%** modified devices
- **10 opinions published**

Expert panels' thematic areas	Number of files submitted
Circulatory system	23
Orthopaedics, traumatology, rehabilitation , rheumatology	13
General and plastic surgery and dentistry	8
Respiratory system, anaesthesiology, intensive care	5 (all ARMP)
Neurology	11
Endocrinology and diabetes	1
Gastroenterology and hepatology	1
Nephrology and urology	1
Total	**63**

PECP

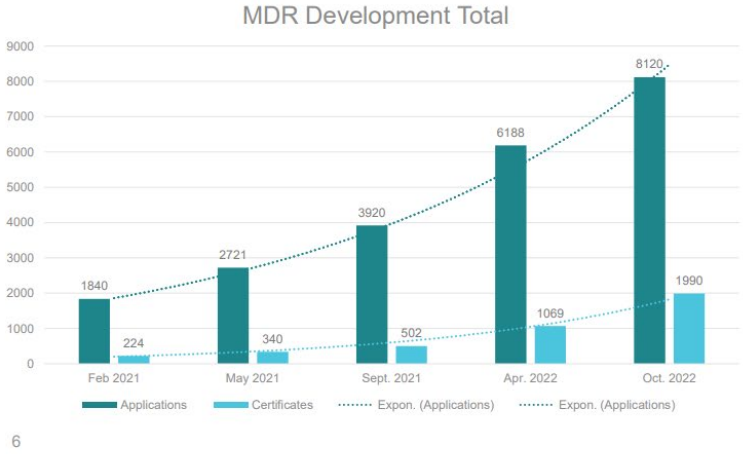
- **16 files submitted and published views**
- **No new PECPs since July 2022**

Notified Bodies Survey on certifications and applications (MDR/IVDR) – *24th October 2022*

MD

Survey on certifications and applications

MDR Applications filed and Certificates issued



6

October 2022

MDR Applications: 8.120

MDR Certificates: 1.990

Team –NB Dec2022

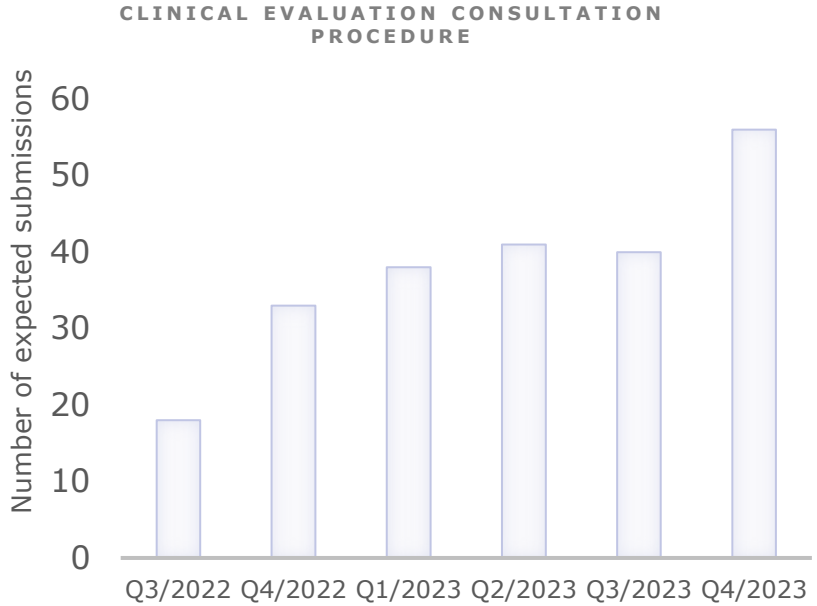
MDR Applications: 9615

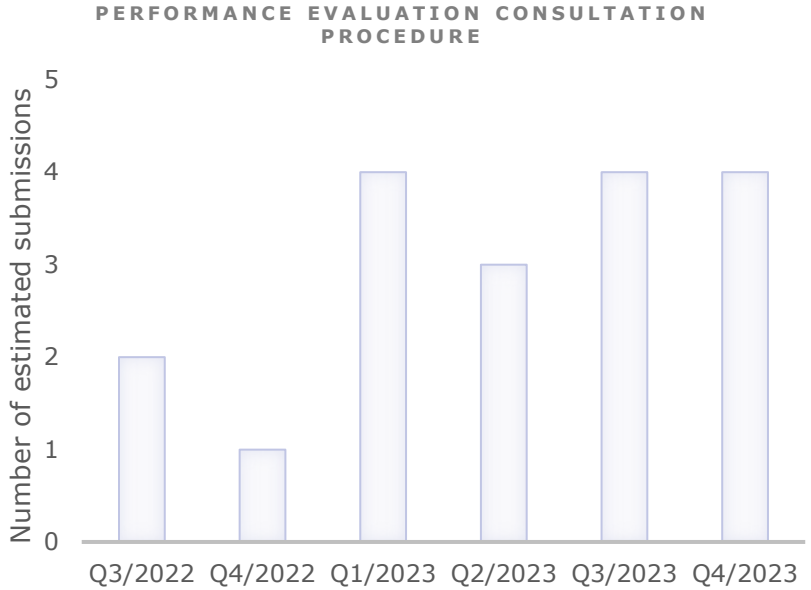
MDR Certificates: 2439

Directive certificates: 14993

European Commission

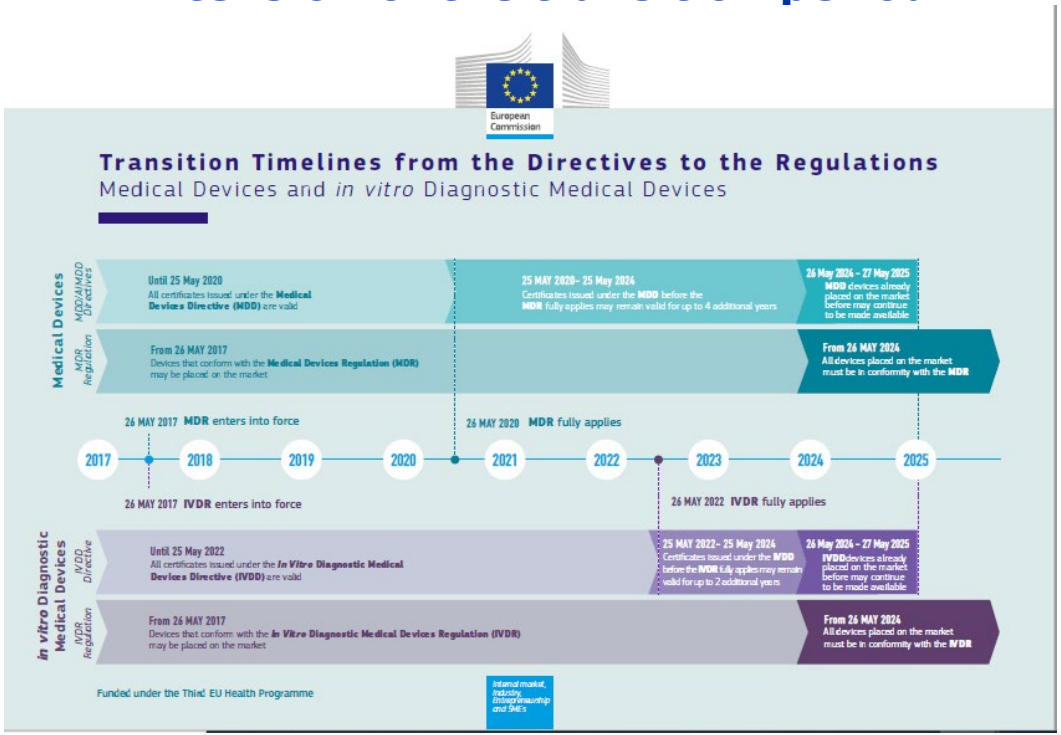
Estimation of the number of CECP and PECP in 2022/2023





Estimations of CECPs and workload for expert panels:

Extension of the transition period



REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 March 2023

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices

Devices	Limit date
All other devices covered by a certificate	31/12/2028
Class III and IIb implantable	31/12/2027
class III implantable custom-made devices	26/05/2026

Estimations of CECPs and workload for expert panels:

Extension of transition period

PART A – SCOPE OF THE EXTENSION OF THE MDR TRANSITIONAL PERIOD

1. Which devices can benefit from the extended transitional period?

Only 'legacy devices' can benefit from the extended transitional period. In line with MDCG 2021-25[2] 'legacy devices' should be understood as devices, which, in accordance with the MDR's transitional provisions, are placed on the market after the MDR's date of application (i.e. 26 May 2021) if certain conditions are fulfilled. Those devices can be:

- devices which are class I devices under Directive 93/42/EEC (MDD), for which an EC declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure under the MDR requires the involvement of a notified body;
- devices covered by a valid EC certificate issued in accordance with Directive 90/385/EEC (AIMDD) or the MDD prior to 26 May 2021.

The extension of the transitional period beyond 26 May 2024 only applies if the conditions laid down in Article 120(3c) MDR are fulfilled. In case of devices for which the relevant certificate has expired before 20 March 2023, also the conditions laid in the second subparagraph of Article 120(2), points (a) or (b), MDR need to be fulfilled (see below part C).

In: Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Future forecasting of procedures for CECP and PECP

- Need for a better understanding of the status of submitted applications for high risk devices for 2023
- New survey from the European Commission will be launched in July 2023 for estimation of applications for CECP and PECPs for 2024 and 2025
- Good forecasting = predictability
  - Important to get accurate information to be able to plan adequate resources and for ensuring predictability for the NB
- Implementation of the advice for high risk medical devices needs to be balanced with CECP activity

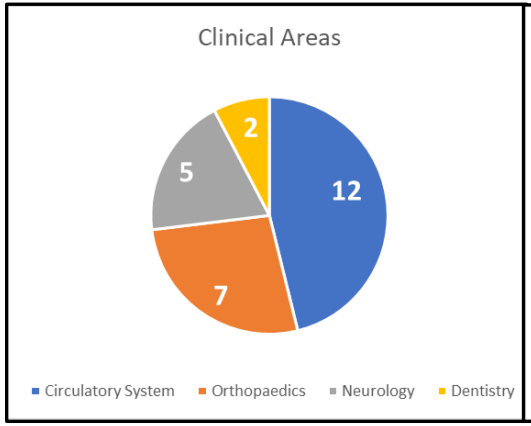
Advice from Expert Panels on high risk medical devices

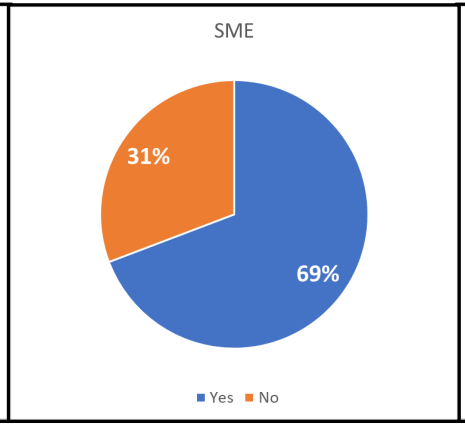
Pilot project Q1 2023 – Q2 2024

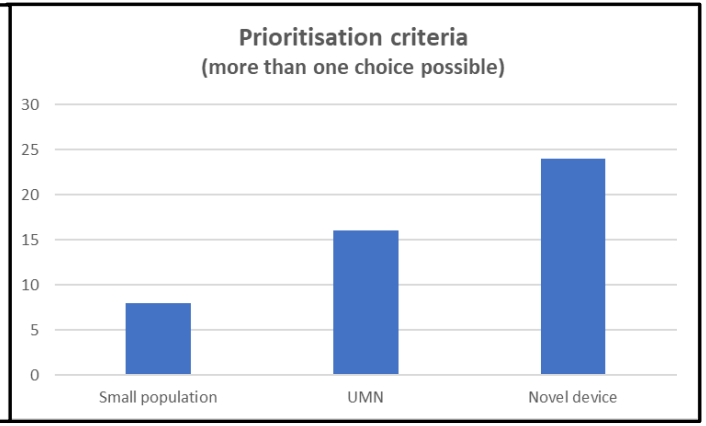
Pilot on advice to manufacturers – 1st selection phase

- **26 initial applications ("letters of interest")**
- **Selection criteria:**
  - ✓ 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**
- **Different clinical areas** and **types of devices** represented
- ***Currently:*** submission 1st phase closed (27th Feb to 15th April), selection of **6 applications**

Pilot on advice to manufacturers: 26 letters of interest







Different phases of development of the device:
• FIH / pilot studies
• Pivotal study
• Full clinical strategy (study designs for approval + PCMF plan (e.g., registry validation)
• Advice on ongoing studies

Take home messages

- Launch of the 2nd phase of the pilot on the **19th June 2023**, deadline for applications **15th September 2023**
- Launch of the European Commission **NB survey for forecasting of CECP and PECP** application in **July 2023**
- Both the mandatory scope and ad hoc advice are run in parallel, therefore accurate forecasting in needed for predictability

Any questions?

Further information: 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**