EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Notified Body Conformity Assessment including EMA coordination of Clinical Evaluation Consultation Procedure (CECP) and Performance Evaluation Consultation Procedure (PECP)

Industry Standing Group (ISG) meeting, 21 June 2022

Presented by Alexey Shiryaev, Sabina Hoekstra - Team-NB
Silvy da Rocha Dias, Miguel Antunes - EMA

Notified Body Conformity Assessment Overview: interfaces with the CECP and the PECP

Presented by Alexey Shiryaev, Sabina Hoekstra - Team-NB

Introduction

- Important area of improvement in MDR/IVDR as compared to ‘old’ Directives: clinical substantiation of market access of medical devices/IVDs
- New elements: Clinical Evaluation Consultation Procedure (CECP) in MDR resp. Performance Evaluation Consultation Procedure (PECP) in IVDR.
- NBs good experiences with cooperation with expert panels under ‘JRC umbrella’
- Invitation for today reflects mutual EMA/NBs intention to continue this constructive cooperation under EMA’s extended mandate
- NBs looking forward to it!

CECP in the context of conformity assessment

9-18 months

N months	~ 7-10 days	60 days	7 days	N days - weeks	
ASSESSMENT OF TECHNICAL DOCUMENTATION INCLUDING ROUNDS OF NON-CONFORMITIES HANDLING CONSULTATION FOR MEDICINAL SUBSTANCES CONSULTATION FOR ANIMAL/HUMAN TISSUE	EXPERT PANELS SECRETARIAT	EXPERT PANEL	REVIEW OF COMMERCIALLY SENSITIVE INCLUDING CONTACT WITH MANUFACTURER	REVIEW OF OPINION	FINALIZATION OF CONFORMITY ASSESSMENT INCLUDING DECISION AND CERTIFICATE ISSUANCE

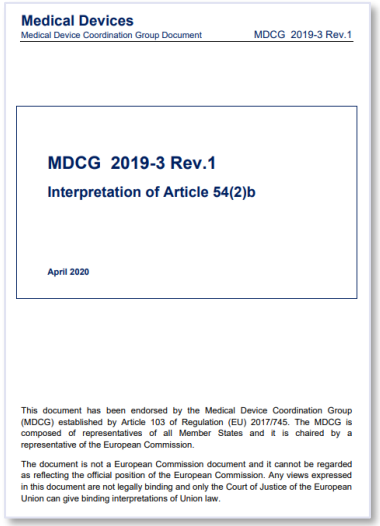
Clinical Evaluation Report – stand alone document

Exemptions from CECP

a) Renewal of a certificate issued under MDR

b) Already marketed device modified without adversely affecting benefit-risk ratio

c) Common Specification availability



Medical Devices
Medical Device Coordination Group Document MDCG 2019-3 Rev.1

MDCG 2019-3 Rev.1
Interpretation of Article 54(2)b

April 2020

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

*…The expression "**device already marketed**" cannot be intended to refer to a device already marketed uniquely under the new Regulation…*

Manufacturers requested to submit with application:

- a statement that it has marketed the device in question for the same intended purpose under the relevant Directive,
- copy of the last issued certificate(s) together with the certificate history, and
- a description of the modifications introduced to comply with the MDR

PECP in the context of conformity assessment

Type of device has already been certified

Common Specification availability

9-12 months

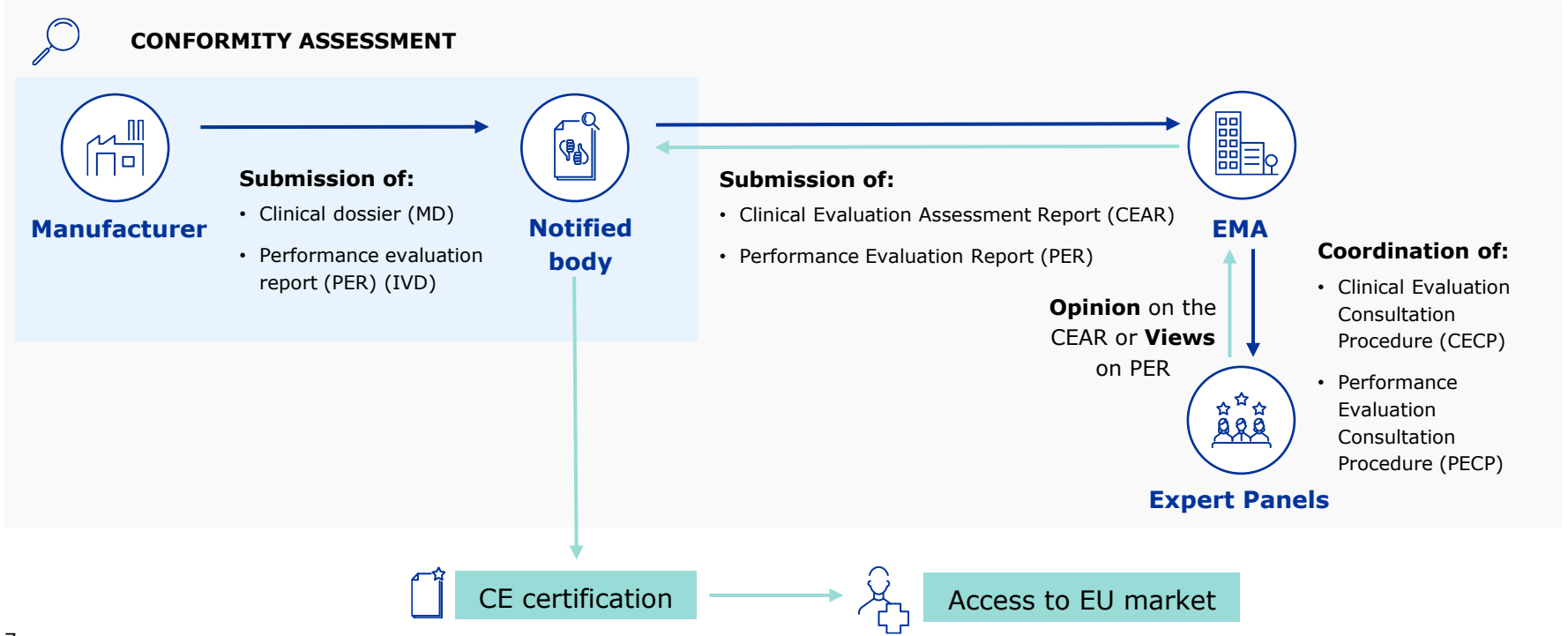
5 days	~ 7-10 days	60 days	7 days	N weeks-months	
NOTIFIED BODY SUBMISSION TO EXPERT PANELS	SECRETARIAT	EXPERT PANEL	REVIEW OF COMMERCIALLY SENSITIVE INCLUDING CONTACT WITH MANUFACTURER	REVIEW OF OPINION	FINALIZATION OF CONFORMITY ASSESSMENT INCLUDING DECISION AND CERTIFICATE ISSUANCE

Performance Evaluation Report – variable content from manufactures – review is only as good as the data provided (and IFU is needed)

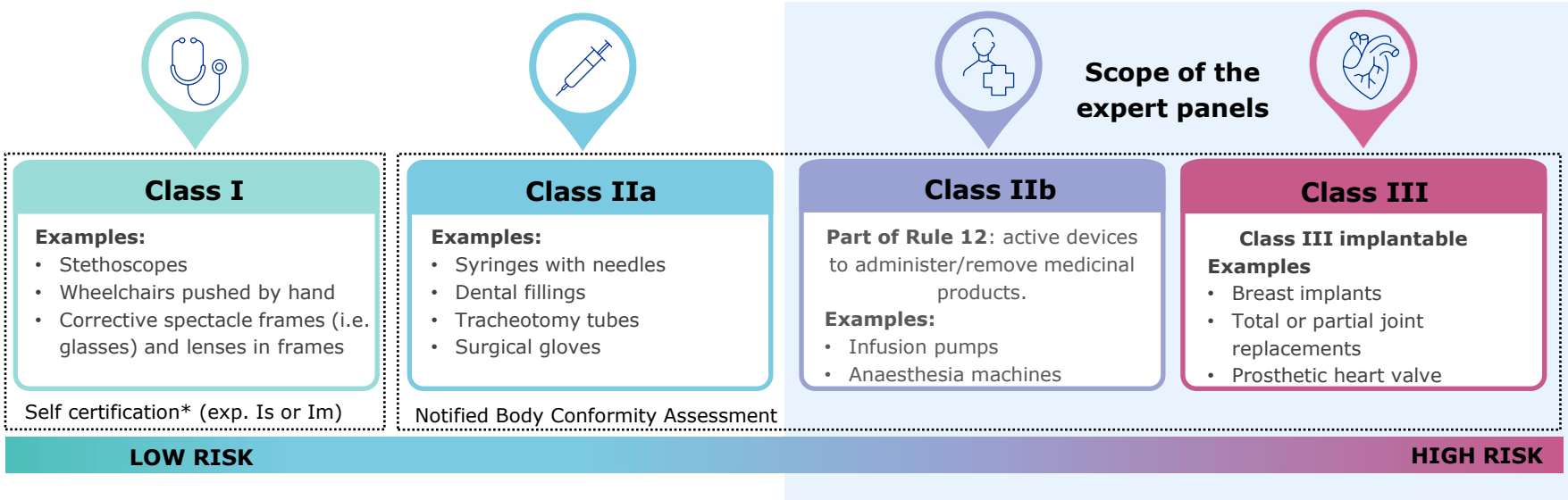
EMA coordination of Clinical Evaluation Consultation Procedure (CECP) and Performance Evaluation Consultation Procedure (PECP)

Presented by Silvy da Rocha Dias and Miguel Antunes – EPG

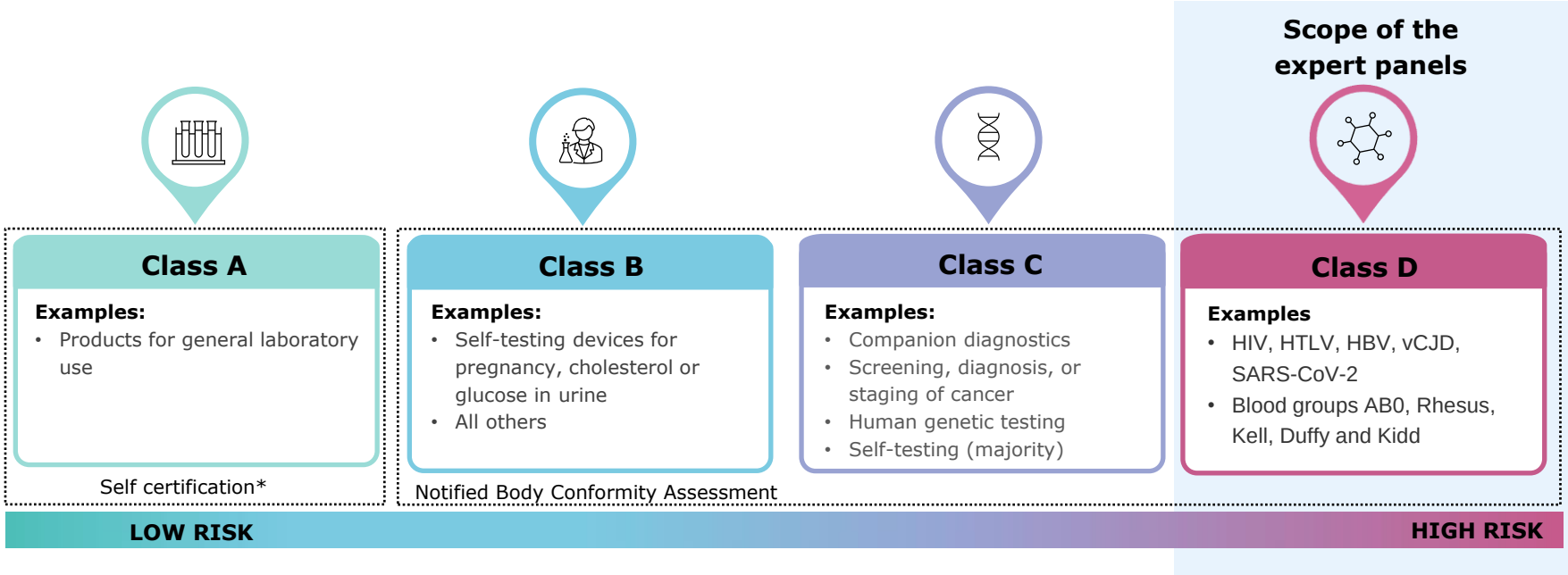
Expert Panels for medical devices in the context of the conformity assessment process



Clinical Evaluation Consultation Procedure (CECP) only applies to certain high-risk medical devices



Performance Evaluation Consultation Procedure (PECP) only applies to certain high-risk *in vitro* medical devices



How are the Expert Panels organised

Medical devices regulation

1. Screening panel

***Thematic expert panels and possible sub-groups*:**

2. Orthopaedics, traumatology, rehabilitation, rheumatology (sub-groups)
3. Circulatory system (sub-groups)
4. Neurology (sub-groups)
5. Respiratory system, anaesthesiology, intensive care
6. Endocrinology and diabetes
7. General and plastic surgery and dentistry (sub-groups)
8. Obstetrics and gynaecology, incl. reproductive medicine
9. Gastroenterology and hepatology
10. Nephrology and urology
11. Ophthalmology

***In vitro* diagnostics regulation**

12. *In vitro* diagnostics devices panel

Coordination committee

Chairs & Vice Chairs of 10 MDR panels + IVD panel and representatives of screening panel.

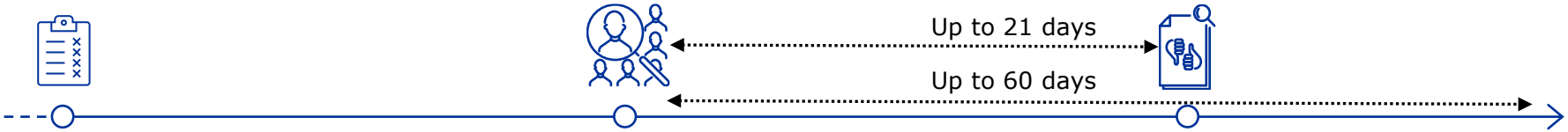
Central list of available experts

Temporary assignment of experts to panels.

Reserve list for appointments.

CLINICAL EVALUATION CONSULTATION PROCEDURE (CECP)

Provide opinion on notified bodies' assessment of the clinical evaluation (Clinical Evaluation Assessment Report - CEAR) of certain high-risk medical devices



Submission of the application by the NB:

- Checking the submission file's completeness
- Assigning experts according to areas of clinical expertise and checking for absence of competing interests
- Checking availability from the experts

Phase I:
Screening Panel
3 criteria:

- Novelty of device/procedure AND major clinical/health impact
- Significant adverse change in the B/R profile for group of device
- Significant increase rate of serious incidents for a category or group of devices

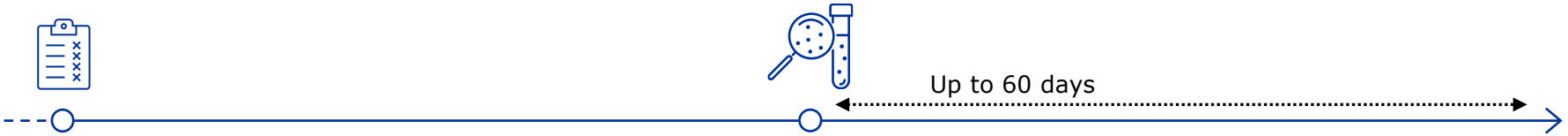
Phase II:
Thematic Panel
Provide an Opinion

- Publicly available on EC website
- If not followed by NB, a full justification needs to be provided

EMA Secretariat | **Expert Panels**

PERFORMANCE EVALUATION CONSULTATION PROCEDURE (PECP)

Provide a view on the manufacturer's performance evaluation (Performance Evaluation Report – PER) for certain high-risk *in vitro* medical devices



Submission of the application by the NB:

- Checking the submission file's completeness
- Assigning experts according to areas of laboratorial expertise and checking for absence of competing interests
- Checking availability from the experts

EMA Secretariat

***In vitro* Diagnostic Panel**

Provide a View

- View published on the EC website
- The notified body shall give due consideration to the views expressed

IVD Expert Panel

Role of the Secretariat: ensuring the integrity of the procedure under the legal timeframe

Expert panels Secretariat

Support of Notified Bodies:

- Drafting and updating guidance documents on the CECP and PECP processes
- Checking the completeness of the file submitted
- Procedure management and contact point for key dates and decisions
- Clarification of queries of the submission and throughout the procedure

Support to the experts

- Drafting and updating guidance documents on the CECP and PECP processes
- Training on expert panel procedure
- Information regarding conflicts of interest management and on commercially confidential information
- Assigning experts according to areas of clinical expertise and checking for absence of competing interests
- Harmonization of decisions, opinions and views

State of play regarding CECPs and PECPs

CECP

- **24 applications** received from notified bodies (NB)
  - **5 decisions** of the screening experts that an opinion is needed
- Most of the applications are in **Cardiology** and **Orthopaedics**

PECP

- **15 applications** received from NBs
  - **15 views** delivered by the IVD panel
- Most of the applications were for devices for **SARS-CoV-2 detection**

Advisory role on technical, scientific and clinical matters

Expert panels to provide advice

Activities to be implemented

- To the Medical Device Coordination Group (MDCG) and EC concerning
  - **safety and performance** of high-risk medical devices and *in vitro* diagnostics
  - development and maintenance of appropriate **guidance, and Common Specifications**
- To manufacturers on their **clinical development strategy and proposals for clinical investigations** for all **class III devices** and **class IIb active devices intended to administer and/or remove a medicinal product**
- Cooperation with the **ETF** in relation to preparedness and management of public health emergencies.

Advisory role to manufacturers

Expert panels to provide advice

Activities to be implemented

- The **expert panels** can provide to manufactures, at their request, scientific advice (SA) on their clinical development strategies for high-risk medical devices
- The SA process needs to developed in collaboration with the relevant stakeholders, including the **medical device industry**, to ensure that it is tailored to the **sector's specificities**.
- The EMA is already providing SA for very different types of medicinal products. Based on this experience and feedback received from stakeholders, the EMA aims to develop this new SA process to support the generation of the **best possible evidence** on the safety and effectiveness of medical devices under development.

Any questions?

Further information

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