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**

...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

CONFORMITY ASSESSMENT

Manufacturer -> Notified body

Submission of:
- Clinical dossier (MD)
- Performance evaluation report (PER) (IVD)

Submission of:
- Clinical Evaluation Assessment Report (CEAR)
- Performance Evaluation Report (PER)

Coordination of:
- Clinical Evaluation Consultation Procedure (CECP)
- Performance Evaluation Consultation Procedure (PECP)

Opinion on the CEAR or Views on PER

CE certification -> Access to EU market

Manufacturer
Notified body
EMA
Expert Panels

Manufacturer Notified body EMA Expert Panels

Submission of:
- Clinical dossier (MD)
- Performance evaluation report (PER) (IVD)

Submission of:
- Clinical Evaluation Assessment Report (CEAR)
- Performance Evaluation Report (PER)

Coordination of:
- Clinical Evaluation Consultation Procedure (CECP)
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Opinion on the CEAR or Views on PER

CE certification -> Access to EU market

Manufacturer Notified body EMA Expert Panels

Submission of:
- Clinical dossier (MD)
- Performance evaluation report (PER) (IVD)

Submission of:
- Clinical Evaluation Assessment Report (CEAR)
- Performance Evaluation Report (PER)

Coordination of:
- Clinical Evaluation Consultation Procedure (CECP)
- Performance Evaluation Consultation Procedure (PECP)

Opinion on the CEAR or Views on PER

CE certification -> Access to EU market
Clinical Evaluation Consultation Procedure (CECP) only applies to certain high-risk medical devices

Class I
- Examples:
  - Stethoscopes
  - Wheelchairs pushed by hand
  - Corrective spectacle frames (i.e., glasses) and lenses in frames

Class IIa
- Examples:
  - Syringes with needles
  - Dental fillings
  - Tracheotomy tubes
  - Surgical gloves

Class IIb
- Part of Rule 12: active devices to administer/remove medicinal products.
  - Examples:
    - Infusion pumps
    - Anaesthesia machines

Class III
- Class III implantable
  - Examples:
    - Breast implants
    - Total or partial joint replacements
    - Prosthetic heart valve

Scope of the expert panels

LOW RISK
- Self certification* (exp. Is or Im)
- Notified Body Conformity Assessment

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

**Class A**
- **Examples:**
  - Products for general laboratory use
- **LOW RISK**
  - Self certification*

**Class B**
- **Examples:**
  - Self-testing devices for pregnancy, cholesterol or glucose in urine
  - All others
- **Notified Body Conformity Assessment**

**Class C**
- **Examples:**
  - Companion diagnostics
  - Screening, diagnosis, or staging of cancer
  - Human genetic testing
  - Self-testing (majority)

**Class D**
- **Examples**
  - HIV, HTLV, HBV, vCJD, SARS-CoV-2
  - Blood groups AB0, Rhesus, Kell, Duffy and Kidd

**Scope of the expert panels**

*Low risk*
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

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**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
Up to 21 days
Up to 60 days
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

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**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

**In vitro Diagnostic Panel**

**Provide a View**
- View published on the EC website
- The notified body shall give due consideration to the views expressed
Role of the Secretariat: ensuring the integrity of the procedure under the legal timeframe

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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