EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on medical devices expert panels implementation

Industry Standing Group (ISG) meeting, 26th Sept 2022

Presented by Silvy da Rocha Dias – EPG/EMA

EMA's slide from the last ISG meeting – 21st June

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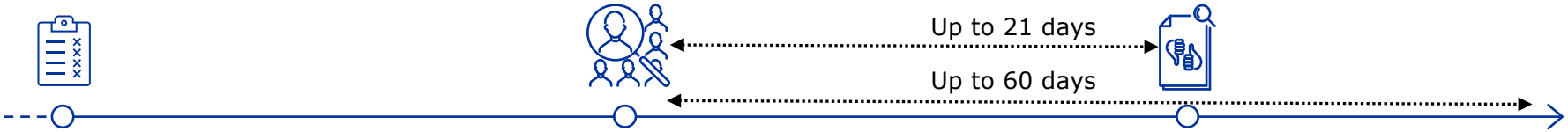
CLINICAL EVALUATION CONSULTATION PROCEDURE (CECP)

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**

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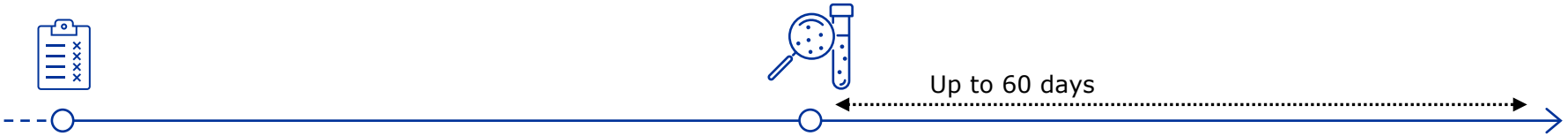
PERFORMANCE EVALUATION CONSULTATION PROCEDURE (PECP)

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

TEAM-NB's slide from the last ISG meeting – 21st June

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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

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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)

Publication of 1st group of Common Specifications for IVDs (04/07/2022)

- Blood group antigens in the ABO, Rh, Kell, Duffy and Kidd blood group systems.
- Markers for infection by:
  - human immunodeficiency virus (HIV) or T-cell lymphotropic virus (HTLV).
  - hepatitis C virus (HCV), hepatitis B virus (HBV) infection or hepatitis D virus (HDV).
  - variant Creutzfeldt-Jakob disease (vCJD).
  - Cytomegalovirus (CMV).
  - Epstein-Barr virus (EBV).
  - *Treponema pallidum*.
  - *Trypanosoma cruzi*.
  - Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

State of play regarding CECPs and PECPs

CECP

- **37 applications** received from notified bodies (NB)
  - **9 decisions** of the screening experts that an opinion is needed
- Most of the applications are in **Circulatory System (18) and Orthopedics, traumatology, rehabilitation, rheumatology (6).**

PECP

- **16 applications** received from manufacturers (via NBs)
  - **16 views** delivered by the IVD panel
- Most of the applications were for devices for **SARS-CoV-2 detection**

100% of decisions/opinions/views delivered within the deadlines and with full compliance with the MDR/IVDR **– Integrity of the process**

CLARIFICATIONS

- **Opinions/views are not negative nor positive, but they are the expression of the advice of the Expert Panels' members (not the EMA).**
- **The opinions and views are grouped in the EC website per thematic areas of the expert panels (the IVD panel is a single area).**
- **Notifications under Art. 54 (3): the change that was mentioned was introduced based on feedback received from NBs to simplify the process of notifications by the NBs.**
- **The Annual Report mentioned in Art. 54(4) is a responsibility of the European Commission.**

LESSONS LEARNED

- **EMA is fully committed to predictability:**
  - **Process was changed to always inform NBs of the date of start of the procedure and the following steps.**
- **EMA is responsible for ensuring the integrity of the procedure according to the Regulation (e.g., DoI checks, expertise, availability of experts, role assignment).**
- **CECP and PECP are still relatively new procedures for all stakeholders. Improvements and simplifications are very welcomed whenever identified.**
- **The Expert Panels Secretariat is open to further expand dialogue with the NBs.**

Any questions?

Further information

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