Industry Standing Group Meeting

Team NB

Notified Body experience with the Medical Device Expert Panels

26th September 2022

Introduction

- Expert Panels in place since April 2021.
- In the absence of EUDAMED, uploads being made via the Circabc platform
- Expert Panels transferred from JRC to EMA in March 2022
- To date hundreds of Article 54(3) notifications have been submitted and a total of 5 opinions provided under the CECP process and 16 under the PECP process
- The aim of this presentation is to provide some feedback based on initial NB experience with the process.
- The areas which will be covered include timelines, need for discussions between NB's and the Expert Panels during the review process, administrative comments and some questions.

Predictability – Timelines for Expert Panel Consultation

Annex IX – 5.1:
*(e) The expert panel shall within **21 days** of receipt of the documents from the Commission notify the Commission, through Eudamed whether it intends to provide a scientific opinion, pursuant to point (c), or whether it intends not to provide a scientific opinion, pursuant to point (d).*

*(f) Where no opinion has been delivered within a period of **60 days**, the notified body may proceed with the certification procedure of the device in question.*

NB Upload for CECP	Transferred to Screening Panel	Screening Deadline	Deadline for Opinion	Review of Commercially Sensitive Information
14/June/2022	Day 9	Day 31	Day 69	Day 74
01/Aug/2022	Day 7	Day 28	Day 67	Day 74
25/Aug/2022	Day 13	Day 34	Day 73	Day 76

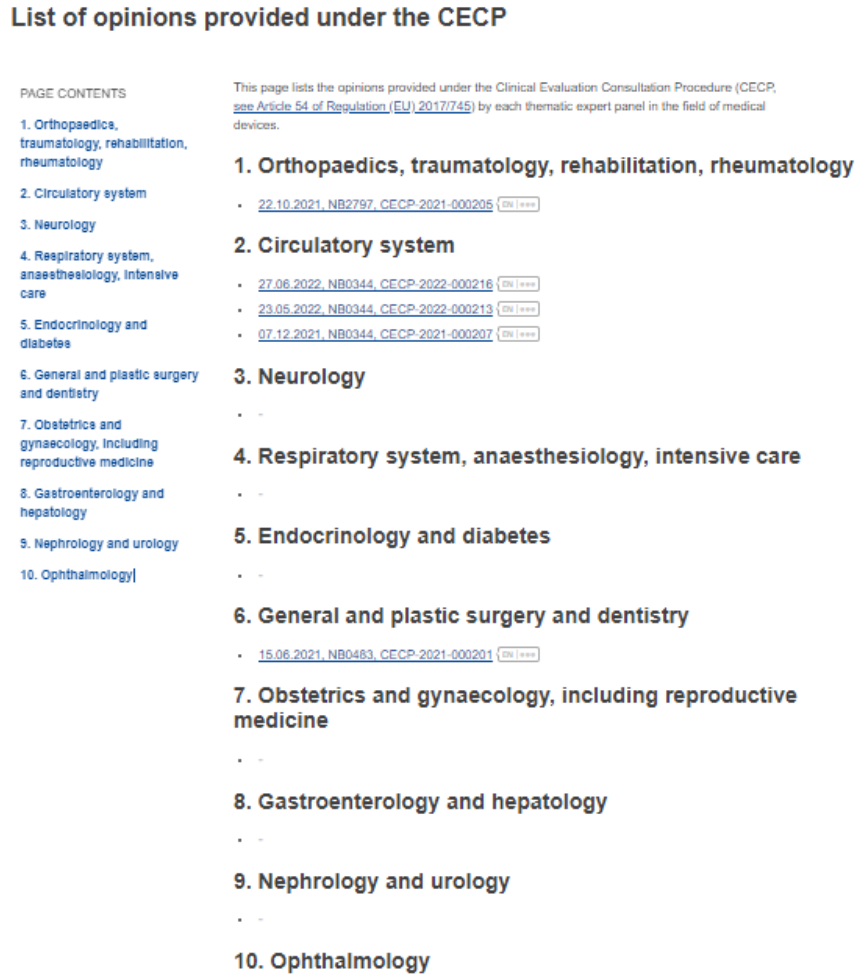
- The communications from the secretariat are clear with due dates stated for the various stages however it is noted that the timelines for each step across reviews is variable.
- Predictable, worst-case timelines are needed for all steps involved in the process including the administrative time at the start and end of the process.
- Whereas manufacturers are expecting an opinion within 60 days, the actual process has more steps than expected and is typically taking longer than 60 days.

CEAR Conclusions & Opportunity to Present

Annex IX – 5.1:
(b) The notified body may be requested to present its conclusions as referred to in point (a) to the expert panel concerned.

- Notified Bodies would welcome this opportunity to present, particularly in cases where a negative opinion is to be published.
- The Clinical Evaluation Assessment Report (CEAR) document's the Notified Bodies conclusions of its clinical assessment.
- Whereas every effort is made to include detail in the CEAR, it is effectively a summary of a comprehensive assessment and it is difficult to convey every detail which was taken into consideration to reach the conclusions stated within the report.
- If a negative opinion is to be published, Notified Bodies see a real benefit to having an open dialogue to ensure that all presented data has been considered and that conclusions drawn by the expert panel are accurate.
- Whereas there is limited experience to date in these situations, one Notified Bodies attempt to engage in discussion within this type of scenario was rejected.

Administrative – Groupings / Categories for PECP Opinions



List of opinions provided under the CECP

PAGE CONTENTS

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

This page lists the opinions provided under the Clinical Evaluation Consultation Procedure (CECP, see Article 54 of Regulation (EU) 2017/745) by each thematic expert panel in the field of medical devices.

1. Orthopaedics, traumatology, rehabilitation, rheumatology

- 22.10.2021, NB2797, CECP-2021-000205

2. Circulatory system

- 27.06.2022, NB0344, CECP-2022-000216
- 23.05.2022, NB0344, CECP-2022-000213
- 07.12.2021, NB0344, CECP-2021-000207

3. Neurology

-

4. Respiratory system, anaesthesiology, intensive care

-

5. Endocrinology and diabetes

-

6. General and plastic surgery and dentistry

- 15.06.2021, NB0483, CECP-2021-000201

7. Obstetrics and gynaecology, including reproductive medicine

-

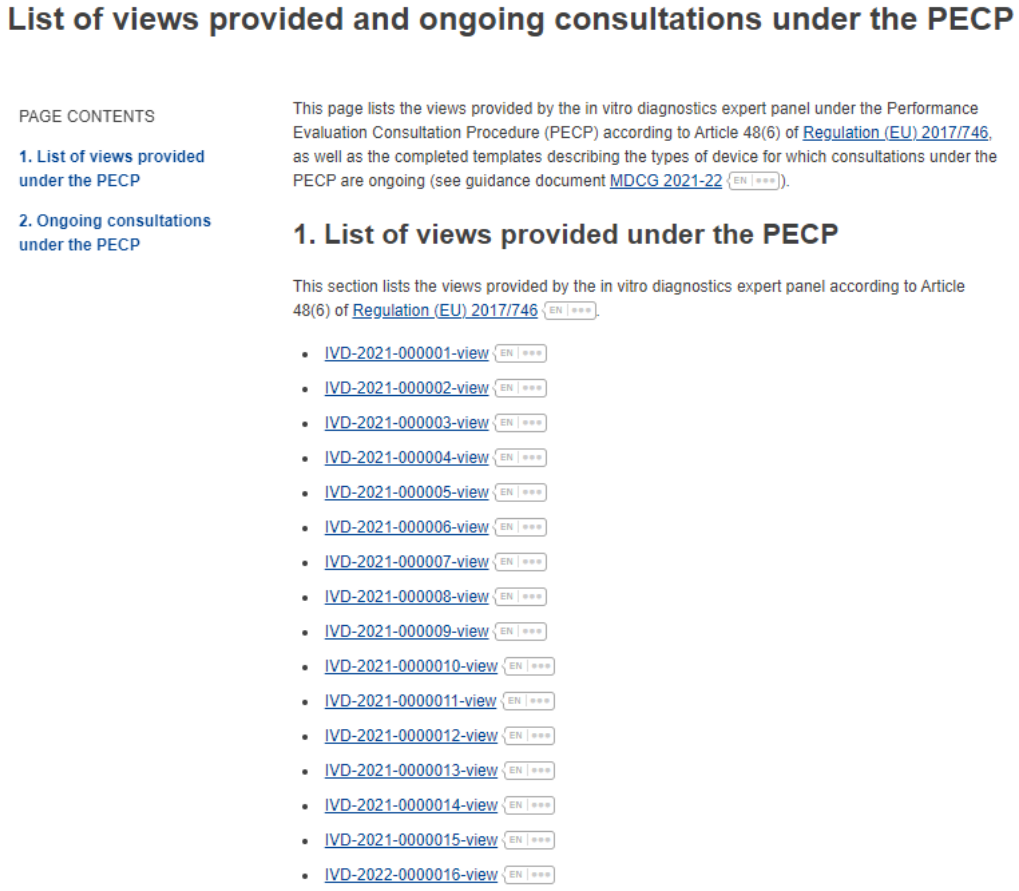
8. Gastroenterology and hepatology

-

9. Nephrology and urology

-

10. Ophthalmology



List of views provided and ongoing consultations under the PECP

PAGE CONTENTS

1. List of views provided under the PECP
2. Ongoing consultations under the PECP

This page lists the views provided by the in vitro diagnostics expert panel under the Performance Evaluation Consultation Procedure (PECP) according to Article 48(6) of Regulation (EU) 2017/746, as well as the completed templates describing the types of device for which consultations under the PECP are ongoing (see guidance document MDCG 2021-22).

1. List of views provided under the PECP

This section lists the views provided by the in vitro diagnostics expert panel according to Article 48(6) of Regulation (EU) 2017/746.

- IVD-2021-000001-view
- IVD-2021-000002-view
- IVD-2021-000003-view
- IVD-2021-000004-view
- IVD-2021-000005-view
- IVD-2021-000006-view
- IVD-2021-000007-view
- IVD-2021-000008-view
- IVD-2021-000009-view
- IVD-2021-0000010-view
- IVD-2021-0000011-view
- IVD-2021-0000012-view
- IVD-2021-0000013-view
- IVD-2021-0000014-view
- IVD-2021-0000015-view
- IVD-2022-0000016-view

The list of CECP Opinions appearing online are well organised with each opinion categorised based on the field of the Expert Panel.

The views provided under the PECP have no such groupings or attributes which makes it difficult to differentiate the reviews. It would be helpful to categorise the PECP views in some way, for example based on disease condition.

Administrative – Article 54(3) Notifications Summary Table

Date of notification	NB internal dossier #	NB	Manufacturer	Name of device	Device type	Class of risk	CECP applies	Reason for CECP exemption	CECP dossier #	Expert opinion
									2021-000203	
									2021-000205	

- The table used by Circabc to summarize all Article 54(3) and communications from the Expert Panels use the CECP dossier number for identification purposes.
- When the dossier number is used as reference number, it is not always obvious which device or certificate an upload or communication relates to.
- A suggestion would be to add a column to this table include an identifier such as the MDR certificate number.
- More generally, some transparency for all stakeholders including the CA's as to what is available in the Circabc space would be beneficial.

Administrative - Circabc Process

- Whereas it is accepted that the overall process is relatively new and will take some time to stabilize, it is worth highlighting that frequent changes to the Expert Panel process including the administrative aspects make it difficult to successfully implement related processes within the NB.

- One example is the Article 54(3) Notification Form which was requested along with every Article 54(3) notification for a period of time, before being withdrawn in mid 2022.

- Changes which promote efficiency and improvement are welcome but some degree of stability is required, as every change has an impact on the training and process implemented within each Notified Body.

Notification to be provided by notified bodies to the competent authorities, the authority responsible for notified bodies and the Commission whether or not the clinical evaluation consultation procedure (CECP) applies

1. Purpose of this document and legal provisions

This document is aimed at giving guidance to the notified bodies regarding the notification they shall provide to the competent authorities, the authority responsible for notified bodies and the Commission regarding the application of the clinical evaluation consultation procedure (CECP).

Article 54(3) of Regulation (EU) 2017/745 (MDR) provides: *"The notified body shall notify the competent authorities, the authority responsible for notified bodies and the Commission through the electronic system referred to in Article 57 of whether or not the procedure referred to in paragraph 1 of this Article is to be applied. That notification shall be accompanied by the clinical evaluation assessment report"*

Article 54(1), MDR refers to the scope of application of the CECP. It provides: *"In addition to the procedures applicable pursuant to Article 52, a notified body shall also follow the procedure regarding clinical evaluation consultation as specified in Section 5.1 of Annex IX or as referred to in Section 6 of Annex X, as applicable, when performing a conformity assessment of the following devices: (a) class III implantable devices, and (b) class IIb active devices intended to administer and/or remove a medicinal product, as referred to in Section 6.4 of Annex VIII (Rule 12).*

Moreover, Article 54(2), MDR refers to the devices that are exempted from CECP. It provides: *"The procedure referred to in paragraph 1 shall not be required for the devices referred to therein: (a) in the case of renewal of a certificate issued under this Regulation; (b) where the device has been designed by modifying a device already marketed by the same manufacturer for the same intended purpose, provided that the manufacturer has demonstrated to the satisfaction of the notified body that the modifications do not adversely affect the benefit-risk ratio of the device; or (c) where the principles of the clinical evaluation of the device type or category have been addressed in a CS referred to in Article 9 and the notified body confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant CS for clinical evaluation of that kind of device."*

2. Information to be provided in the notification referred to in Art. 54(3)

For each device under the scope of Art. 54 (1), the notified body should send a notification available to the competent authorities, the authority responsible for notified bodies and the Commission through Eudamed and until it becomes available, through the CIRCABC electronic system with a justification whether or not the CECP applies to this device. The upload of this notification should be done in the following CIRCABC space (https://classified.circabc.europa.eu/ui/group/de99b4e5-6c1f-45cb-a064-59a70821c61d) and should follow the same approach as the one used for a CECP file.

The notification should include the following information:

Notified body name and number	*Name and NANDO Number*
Manufacturer(s) name and SRN	
Medical device name model and type	*General description* *Basic UDI-DI(s) (if available)* *Certificate number (if applicable)*
Risk Class	
Does CECP apply to this device?	☐ Yes ☐ No

Question: Annual Overview as per Article 54(4)

Article 54:
4. The Commission shall draw up an annual overview of devices which have been subject to the procedure specified in Section 5.1 of Annex IX and referred to in Section 6 of Annex X. The annual overview shall include the notifications in accordance with paragraph 3 of this Article and point (e) of Section 5.1 of Annex IX and a listing of the cases where the notified body did not follow the advice from the expert panel. The Commission shall submit this overview to the European Parliament, to the Council and to the MDCG.

It would be helpful for Notified Bodies to get some additional information about this annual overview. For example has this process started? Will any information from the report be shared with Notified Bodies or the public?

Industry Standing Group Meeting

Team NB

Thanks for your attention.