



● Clinical Evaluation Consultation Procedure

A Guide to Article 54 of EU MDR 2017/745

23rd November 2022

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Head of Clinical Compliance/Clinical Regulatory Lead



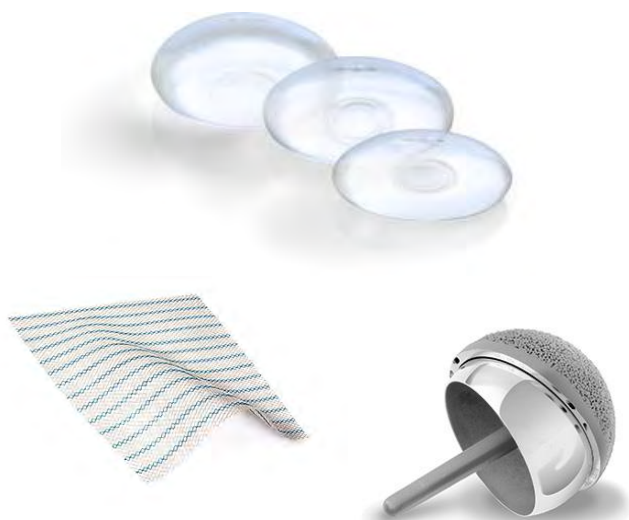
Contents of this Webinar

- Introduction to the EU Expert Panels
- Article 54
- The CECP Process
- Preparing your Submission
- Article 54.3
- Article 61 (2)
- BSI experience of CECP

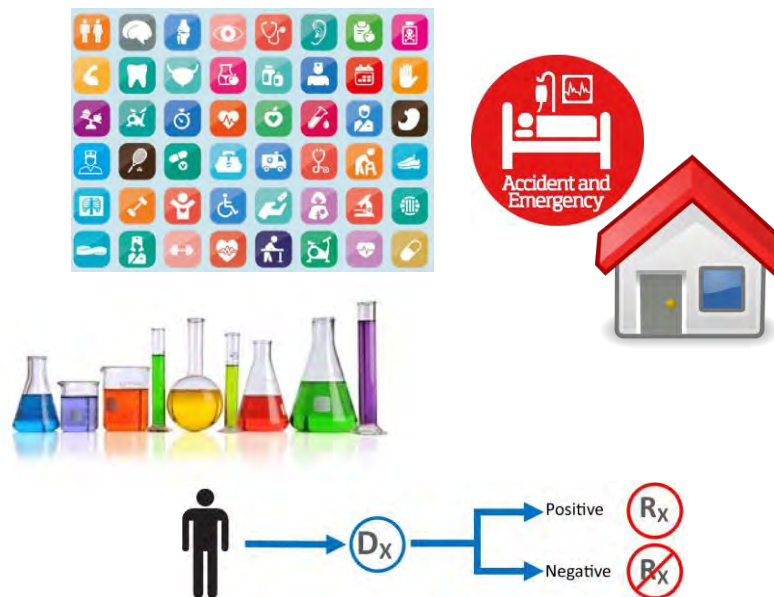


Expert Panels– Why?

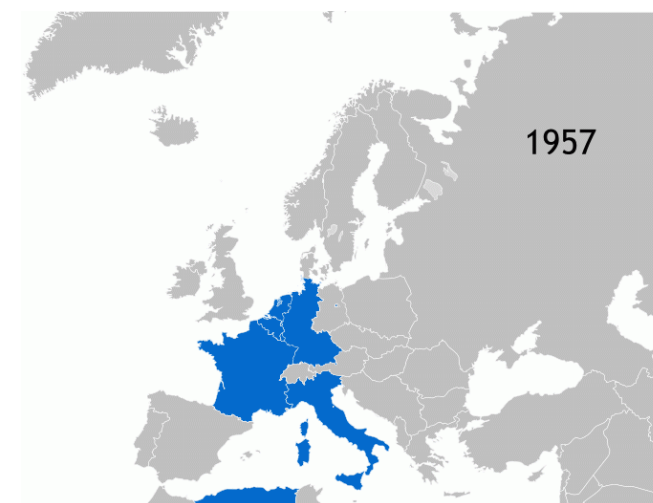
Response to 'scandals' to restore confidence in system



Keep pace with scientific and technical developments



Overcome divergence in interpretation and application



Expert panels are one of the key areas of the MDR focusing on 'Transparency' and 'Protection of public health and patient safety'

2017 EU Regulations – Why?

1. Protection of public health and patient safety

- Strict pre-market control
- Inclusion of certain aesthetic devices
- Reinforced designation and oversight of Notified Bodies
- Reinforced rules on clinical / performance evaluation and clinical investigation / performance studies
- Strict rules for substance-based devices
- Strict rules for use of hazardous substances
- Introduction of UDI

2. Legal certainty and innovation-friendly environment

- **Use of 'regulation' as a regulatory tool**
- Clarification of scope for both MD and IVDs
- Stronger role for the Commission on the regulatory status of products
- Clarification of regime applicable to devices manufactured and used in the same healthcare institution
- Clarification of responsibilities of economic operators
- New rules for software / apps

3. Increase transparency and patient empowerment

- Establishment of EU database on medical devices (EUDAMED) with a large part to be made publicly available
- Introduction of an implant card to be provided to patients
- Summary of safety and performance for all Class III and implantable devices available in EUDAMED
- New obligations for manufacturers and authorised representatives aimed at protecting consumers/ patients

Article 54 of EU 2017/745 addresses protection of public health and patient safety
Article 61 (2) of EU 2017/745 addresses innovation friendly environment.

Article 106 – Provision of scientific, technical and clinical opinions and advice

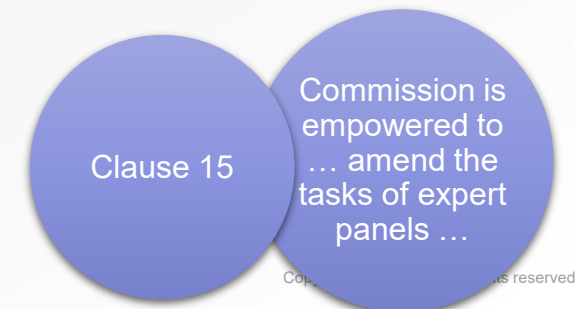
10. **Expert panels** and **expert laboratories** may have the following tasks, depending on the requisite needs:

(a) to provide **scientific, technical and clinical assistance** to the Commission and the MDCG in relation to the implementation of this Regulation;

(b) to contribute to the development and maintenance of appropriate **guidance and CS** for:

- clinical investigations,
- clinical evaluation and PMCF,
- performance studies,
- performance evaluation and post-market performance follow-up,
- physico-chemical characterisation, and
- microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing;

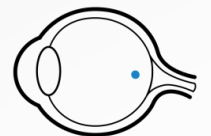
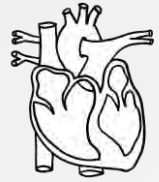
- c) to contribute to the development of **standards** at international level, ensuring that such standards reflect the **state of the art**;
- d) to provide **opinions in response to consultations by manufacturers in accordance with Article 61(2)**, notified bodies and Member States in accordance with paragraphs 11 to 13 of this Article.
- e) to contribute to **identification of concerns and emerging issues on the safety and performance of medical devices**;
- f) to provide views in accordance with Article 48(4) of Regulation (EU) 2017/746 on the performance evaluation of certain *in vitro* diagnostic medical devices.



Implementing Regulation (EU) 2019/1396



1. Orthopaedics, traumatology, rehabilitation, rheumatology
2. Circulatory system
3. Neurology
4. Respiratory system, anaesthesiology, intensive care
5. Endocrinology, diabetes
6. General surgery, plastic surgery, dentistry
7. Obstetrics, gynaecology, reproductive medicine
8. Gastroenterology, hepatology
9. Nephrology, urology
10. Ophthalmology
11. *In-vitro* diagnostic medical devices (IVD)



Expert Panels – Subgroups

MDCG 2020-13

CEAR

July 2020

Orthopaedics, traumatology,
rehabilitation, rheumatology

Joint replacements

Spinal devices

Non-articulating devices, rehabilitation

Other

Circulatory system

Prosthetic heart valves and devices for heart valve repair

Cardiovascular stents and vascular prostheses

Active implantable cardiac devices and
electrophysiological devices

Structural interventions and new devices (e.g. LAA/PFO
Occluders)

Cardiac surgery – extracorporeal membrane oxygenation,
cardiopulmonary bypass devices, artificial hearts, LVADs

Other

Expert Panels – Subgroups

Neurology

Central and peripheral nervous system devices

Implants for hearing and vision

Neurosurgical devices

Other

General surgery, plastic surgery, dentistry

Surgical implants and general surgery

Plastic surgery and wound care

Maxillofacial surgery

Dentistry

Other

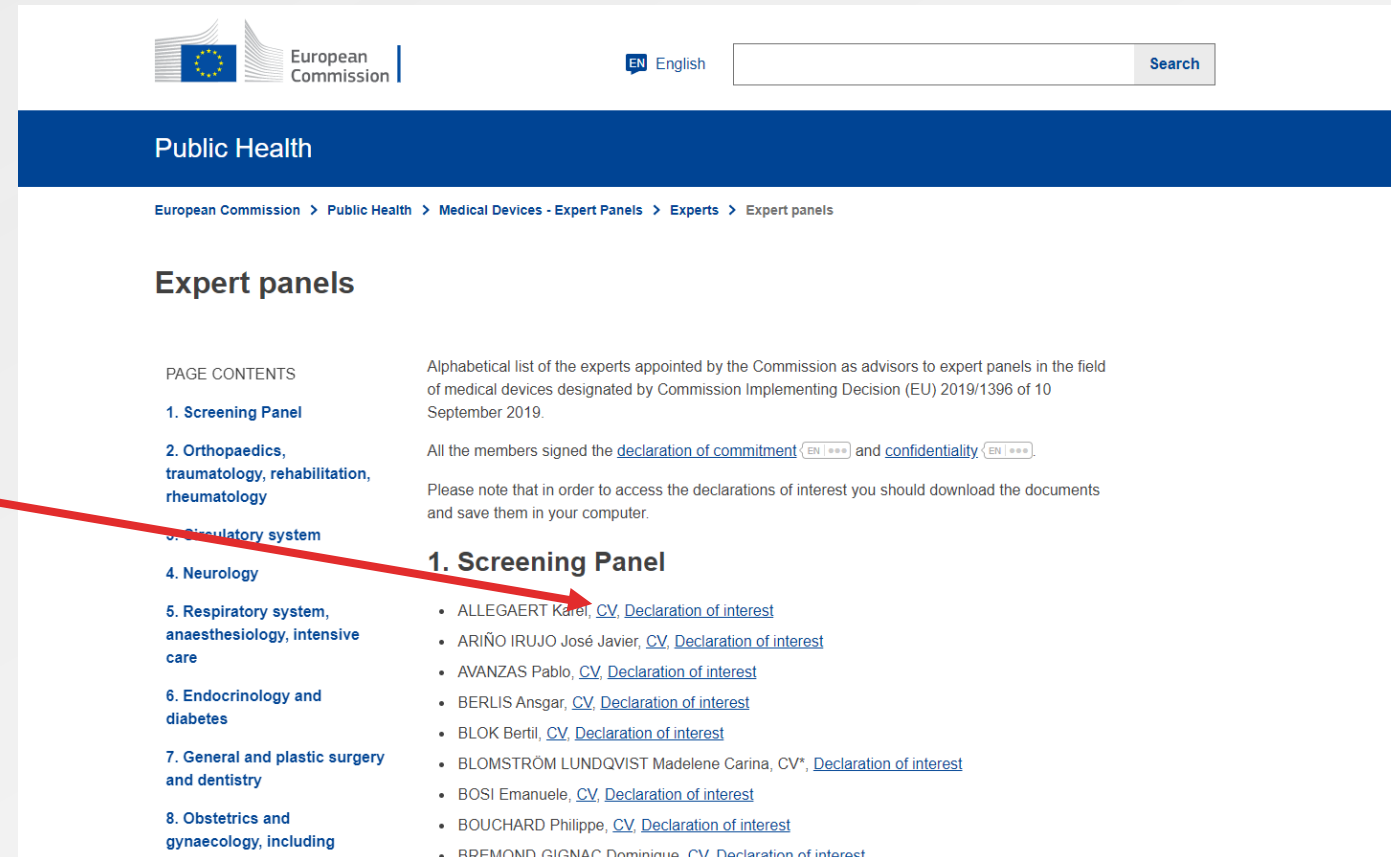
The Expert Panels

Members of the screening and expert panels per medical discipline are listed on the EU website.

Each name is accompanied with the experts CV and a Declaration of Interest.

These can be viewed here:

https://health.ec.europa.eu/medical-devices-expert-panels/experts/expert-panels_en



The screenshot shows the European Commission website page for 'Expert panels'. The page is titled 'Expert panels' and is part of the 'Public Health' section. It contains a list of expert panels, with the first panel, '1. Screening Panel', expanded to show a list of experts. Each expert's name is followed by a link to their CV and a link to their Declaration of Interest. A red arrow points from the text 'Each name is accompanied with the experts CV and a Declaration of Interest.' to the '1. Screening Panel' section of the list.

European Commission | English | Search

Public Health

European Commission > Public Health > Medical Devices - Expert Panels > Experts > Expert panels

Expert panels

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- 1. Screening Panel
- 2. Orthopaedics, traumatology, rehabilitation, rheumatology
- 3. Circulatory system
- 4. Neurology
- 5. Respiratory system, anaesthesiology, intensive care
- 6. Endocrinology and diabetes
- 7. General and plastic surgery and dentistry
- 8. Obstetrics and gynaecology, including

Alphabetical list of the experts appointed by the Commission as advisors to expert panels in the field of medical devices designated by Commission Implementing Decision (EU) 2019/1396 of 10 September 2019.

All the members signed the [declaration of commitment](#) ^(EN) and [confidentiality](#) ^(EN).

Please note that in order to access the declarations of interest you should download the documents and save them in your computer.

1. Screening Panel

- ALLEGAERT Karel, [CV](#), [Declaration of interest](#)
- ARIÑO IRUJO José Javier, [CV](#), [Declaration of interest](#)
- AVANZAS Pablo, [CV](#), [Declaration of interest](#)
- BERLIS Ansgar, [CV](#), [Declaration of interest](#)
- BLOK Bertil, [CV](#), [Declaration of interest](#)
- BLOMSTRÖM LUNDQVIST Madelene Carina, CV*, [Declaration of interest](#)
- BOSI Emanuele, [CV](#), [Declaration of interest](#)
- BOUCHARD Philippe, [CV](#), [Declaration of interest](#)
- BREMOND-GIGNAC Dominique, CV, [Declaration of interest](#)

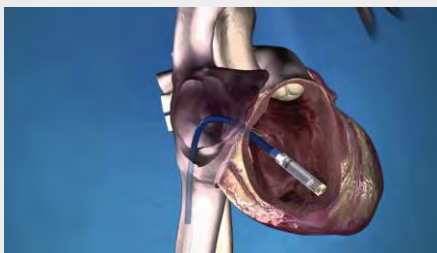
Article 54 Overview

Article 54

Clinical evaluation consultation procedure for certain class III and class IIb devices

1. 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).



Article 54(1) outlines the classifications of devices that are potential subject to Clinical Evaluation Consultation Procedure (CECP) as part of conformity assessment:

1. Class III Implantable Devices
2. Class IIb rule 12 active devices intended to administer and/or remove a medicinal product. (ARMS)

Important considerations for active devices intended to administer and/or remove a medicinal product.¹¹

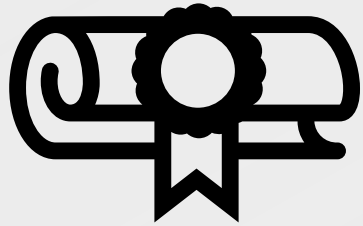
- Class III ARMS devices such as Closed Loop Systems e.g. Insulin delivery are not subject to CECP.
- The notified body will need to assess the clinical data of all rule 12 active ARMS devices before issuing a certificate and are unable to sample these throughout the certificate cycle

According to Article 54, Class IIb active devices intended to administer and/or remove a medicinal product falling into rule 12 of Annex VIII are subject to the clinical evaluation consultation procedure prior to issuing of the certificate. These devices can be subject to sampling but according to Articles 54(3) and 55 the notified body must ensure that at least the clinical evaluation assessment report (CEAR) for each device is uploaded in Eudamed prior to issuing the QMS certificate. This means that the sampling will not apply to the clinical evaluation as it has to be assessed for every device.

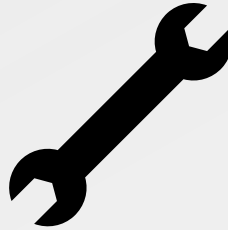
(MDCG 2019-13)



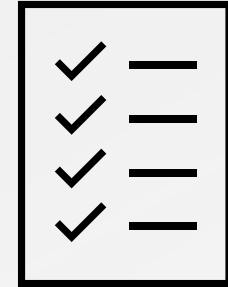
Article 54 (2) – Exemptions



(a) MDR Renewals are exempt from Article 54



(b) Modifications that do not adversely affect the benefit risk are exempt.



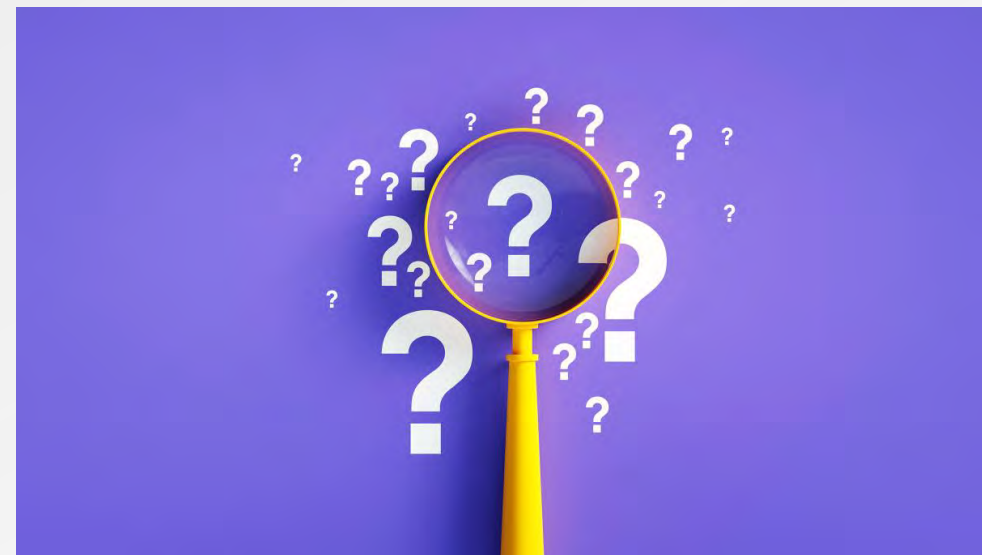
(c) If the manufacturer is compliant to the relevant common specifications of the clinical evaluation of the device

2. 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.

Poll Question - Legacy Device Changes

Q: What changes to legacy devices maybe subject to CECP upon MDR Application?

1. Expansion of indications
2. Significant design change with clinical data
3. Change in surgical procedure
4. Addition of a new variant



Poll Question - Legacy Device Changes

Q: What changes to legacy devices maybe subject to CECP upon MDR Application?

1. Expansion of indications
2. Significant Design change with clinical data
3. Change in surgical procedure
4. Addition of a new variant



Answer: All the above would be subject to CECP for a legacy device.

MDCG 2019-3

MDCG 2019-3 relates specifically to Interpretation of Article 54 (2)b.

- (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

Medical Devices

Medical Devices Coordination Group Document

MDCG 2019-3

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MDCG 2019-3

Interpretation of Article 54(2)b

March 2019

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.

Page 1 of 3

(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

MDCG 2019-3

This Guidance confirms that 'already marketed' includes the directives and the regulations

Legacy device modifications are intended to mean the additional requirements such as SSCP, Implant card etc to meet the new MDR requirements and **not** 'design or manufacturing changes' that will trigger a CECP review.

The following considerations seem to indicate that **the expression "device already marketed" cannot be intended to refer to a device already marketed uniquely under the new Regulation:**

- If the co-legislators had decided to restrict the application of point "b" to devices **marketed uniquely under the MDR**, they would have explicitly stated so, as they did for point "a";
- Article 54, together with other Articles (such as Article 61(6) and Article 120(3)), was written at the end of the negotiation process with a view to smoothen the implementation of the new Regulation. Therefore the interpretation of the exemption should be understood in line with the spirit and intention of **the co-legislators**.

It has to be noted that, in respect to **devices** that have been marketed already under the **relevant Directives**, the word "**modification**" shall be meant as limited only to those **modifications needed** in order to **comply** with the **new legal requirements** introduced by the **MDR**^{1 2}.

We will have to take a conservative approach to design/manufacturing modifications of legacy devices, until any further guidance is issued or as we begin to learn from the CECP screening process.

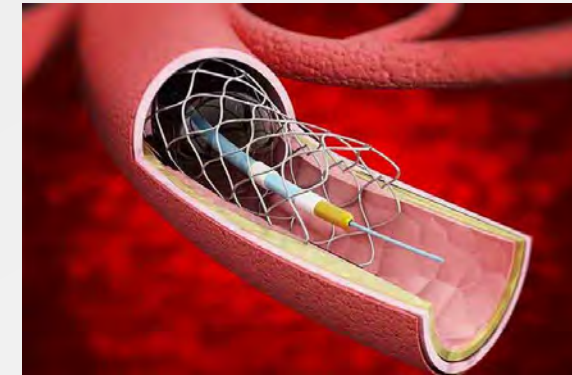
What triggers CECP for a legacy device?



Changes/additions to the intended purpose and/or indications



Additional populations of use



Additional sizes and/or variants outside of the MDD approved range



Major changes to clinical procedures and/or surgical technique



Changes to the device and/or its accessories that require the assessment of additional clinical data.

Annex IX 5.1 (a)

5.1. Assessment procedure for certain class III and class IIb devices

- (a) For class III implantable devices, and for 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), the notified body shall, having verified the quality of clinical data supporting the clinical evaluation report of the manufacturer referred to in Article 61(12), prepare a clinical evaluation assessment report which sets out its conclusions concerning the clinical evidence provided by the manufacturer, in particular concerning the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication or indications and the PMCF plan referred to in Article 10(3) and Part B of Annex XIV.

The notified body shall transmit its clinical evaluation assessment report, along with the manufacturer's clinical evaluation documentation, referred to in points (c) and (d) of Section 6.1 of Annex II, to the Commission.

The Commission shall immediately transmit those documents to the relevant expert panel referred to in Article 106.

Annex IX 5.1 (a) highlights the administrative and documentation steps for the notified body.

Please note assessments which have resulted in a positive recommendation by the notified body will be forwarded for CECP.

The CECP is not a 'disputes' mechanism.

Annex IX Section 5.1. (c) – Criteria of Screening for Opinion



Novelty of the device or the related clinical procedure and possible major clinical or health impact there of



A significantly adverse change in the benefit-risk profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in the case of failure of the device;



A significantly increased rate of serious incidents reported in accordance with Article 87 in respect of a specific category or group of devices

Published in August 2020 for the Expert Panel to allow for consistent interpretation of the decision criteria for CECP

Whilst this guidance is specific to Expert Panel Members, it does provide some helpful information in regards to the aspects of novelty and clinical or health impact, along with identifying scientifically valid concerns. These points are worth considering and ensuring they have been mentioned in your CER to aid the expert panels.

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C 259²⁰



English edition

Information and Notices

Volume 63

7 August 2020

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NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

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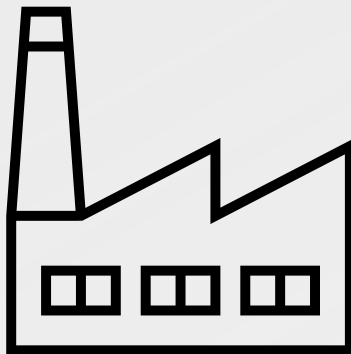
2020/C 259/01	Euro exchange rates — 6 August 2020	1
2020/C 259/02	Commission guidance for the medical devices expert panels on the consistent interpretation of the decision criteria in the clinical evaluation consultation procedure ⁽¹⁾	2
2020/C 259/03	Administrative Commission for the Coordination of Social Security Systems — Decision No H9 of 17 June 2020 regarding the postponement of deadlines mentioned in Articles 67 and 70 of Regulation (EC) No 883/2004 of the European Parliament and of the Council as well as in Decision No 59 due to the COVID-19 Pandemic ⁽¹⁾	9
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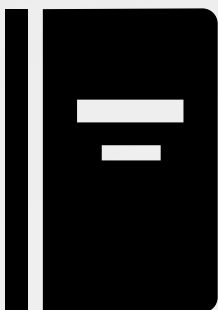
Commission guidance for the medical devices expert panels on the consistent interpretation of the decision criteria in the clinical evaluation consultation procedure ⁽¹⁾

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The CECP Process - What is submitted to CECP



Manufacturer Documentation



- Clinical Evaluation Plan
- Clinical Evaluation Report
- PMCF Plan*
- PMCF Evaluation Report*

*Or justification for why PMCF is not applicable.



Notified Body Documentation



- Clinical Evaluation Assessment Report (CEAR)

The CECP Process – Considerations of submitted documentation

Additional comments:

Although not requested, the whole expert panel would like to underline that the submission of numerous devices for approval in the same dossier and its structure have been perceived counterproductive for an efficient review in particular since part of the standard mandate of panels is to provide advice on the consistency of clinical evidence with the purpose including the medical indications.

- [CECP-2021-000205](#)

Good Documentation Practice

- Ideally, ensure the CER contains only the relevant devices for CECP that will be reviewed by the expert panels.
- The notified body will only submit a final and approved version of the CER and not a redline version.
- Ensure the data is presented and stratified accordingly per indication and variant/size.
- Ensure benefit-risk assessment is clear and based on evidence and is per indication.

PMCF Templates



- The manufacturers PMCF plan must follow the template as provided by MDCG 2020-7 or if submitting a PMCF evaluation report the template provided in MDCG 2020-8.
- Failure to follow the template will result in a refusal by the administrative screening process of the EMA.
- This template is to allow for consistent ease of use/readability for the expert panels for the multiple manufacturer submission they will receive.
- The expert panels have been trained on reviewing this specific document.
- This principle also applies to the notified body's clinical evaluation assessment report (CEAR) as provided by MDCG 2020-13.

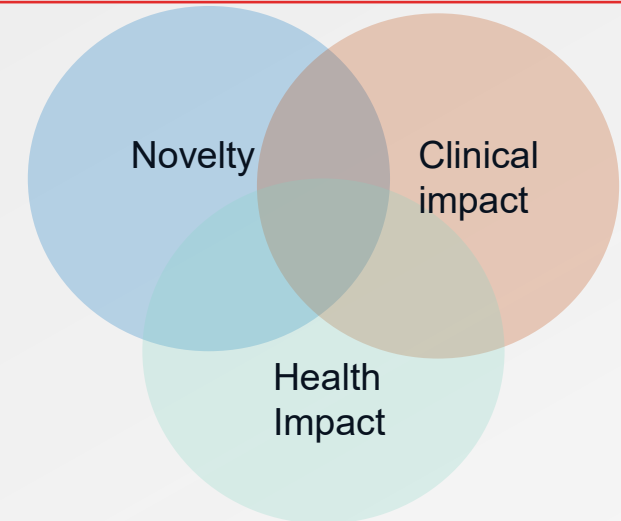
The CECP Process – Considerations within the CER

Clinical or Surgical Procedure Novelty Dimensions

- Mode of Use or Treatment Option
- Device-Patient Interface
- Interaction and Control
- Deployment Methods

Device Related Novelty Dimensions

- Medical Purpose
- Design
- Mechanism of Action
- Materials
- Site of Application
- Components
- Manufacturing Process



It is critical that manufacturers address **ALL** these aspects in a section of the CER, indicating if the device has any novelty in relation to these areas.

If the device has these novel features it is paramount the manufacturer adequately describes with scientific justification why there would be no impact to safety or performance and overall benefit/risk.

Failure to address these aspects in the CER/CEAR may trigger an unnecessary CECP Opinion.

Do Not Use the ANSM Card – Requested by Secretariat

Novelty Table – Consider using this table

Clinical or Surgical Procedure Novelty Dimensions		
	Is there novelty? Yes /No	If Yes – Specifically describe novel features and any potential clinical or health impact. If <u>No</u> – provide evidence/justification to demonstrate non-novel features
Mode of Use or Treatment Option		
Device-Patient Interface		
Interaction and Control		
Deployment Methods		
Device Related Novelty Dimensions		
Medical Purpose		
Design		
Mechanism of Action		
Materials		
Site of Application		
Components		
Manufacturing Process		

You can download this from the Handouts section of the GoTo Webinar Taskbar

Snow Screen ▾ Stop Showing Screen Give Keyboard & Mouse Change Presenter

Start Recording 55.4 GB remaining Settings

- Webcam
- Audio
- Dashboard
- Attendees: 5 of 1001 (max)
- Polls (0/2)
- Select a Poll... ▾ Launch
- Questions
- Handouts: 1
- Manufacturer Novelty Table for CECP.do...
- Chat

Understanding the Clinical Evaluation Cons

Poll Question - Legacy Device Changes

How many days are required for the CECF process?

1. 21 days
2. >21days
3. 60 Days
4. >60 Days



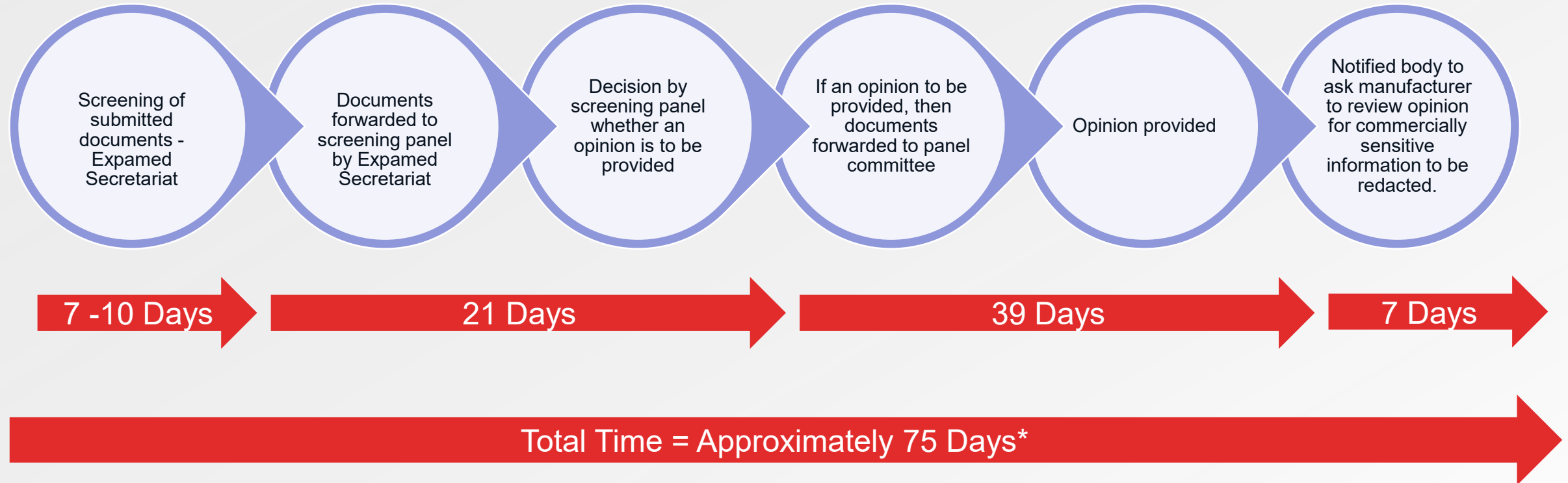
Poll Question - Legacy Device Changes

How many days are required for the CECF process?

1. 21 days
2. >21days
3. 60 Days
4. >60 Days



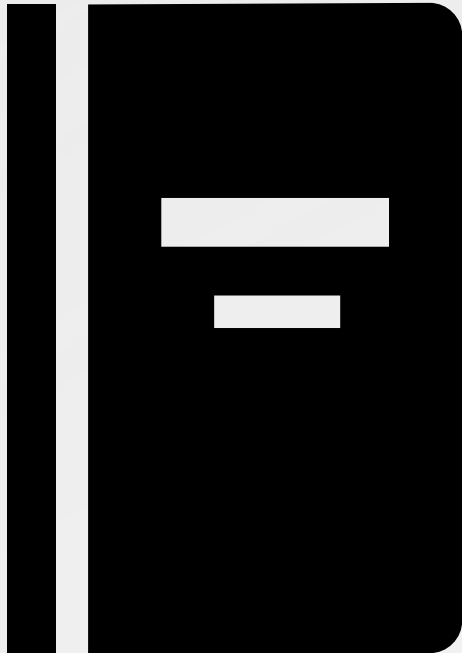
The CECP Process – Timelines



*Typically calendar days and does not include holidays. Notified body will consider the expert panel opinion at the end of the process and decided on any additional necessary actions.

The CECP Process – Pre-submission point

Screening of submitted documents - Expanded Secretariat

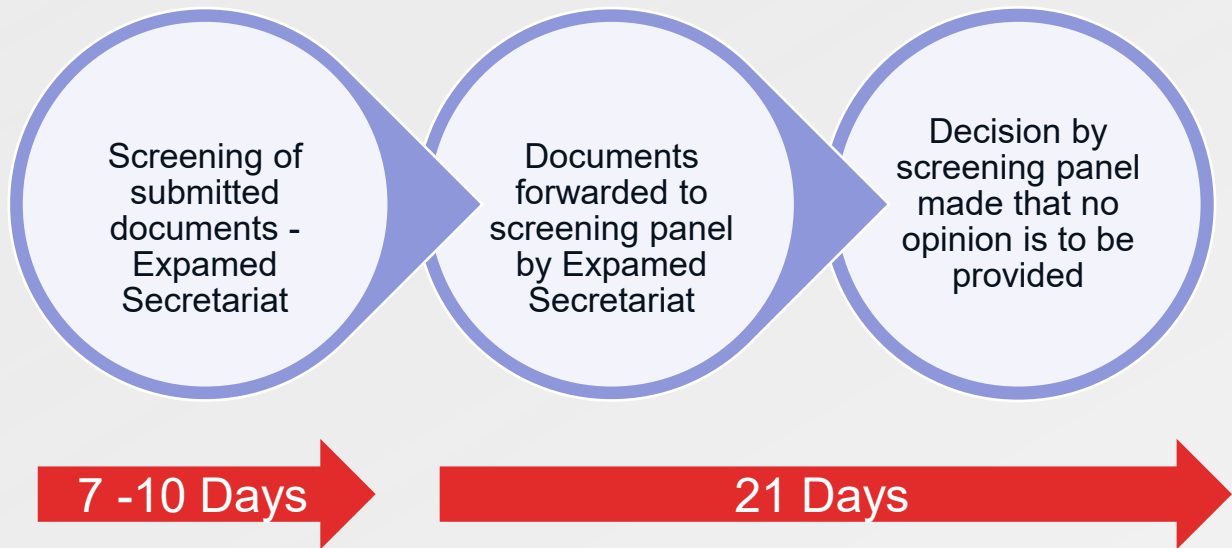


Documents are reviewed by Expanded Secretariat of the European Medicines Agency to ensure that there are no administrative or inconsistencies in the documentation which could result in delays for the expert panel to make their opinion.

This sometimes includes requests for additional documentation to support the review that maybe mentioned in the CER, e.g., Statical Analysis Plans or clarity on the device description/novelty.

The Secretariat are typically people with scientific background and include former notified body staff.

The CECP Process – No opinion to be provided.

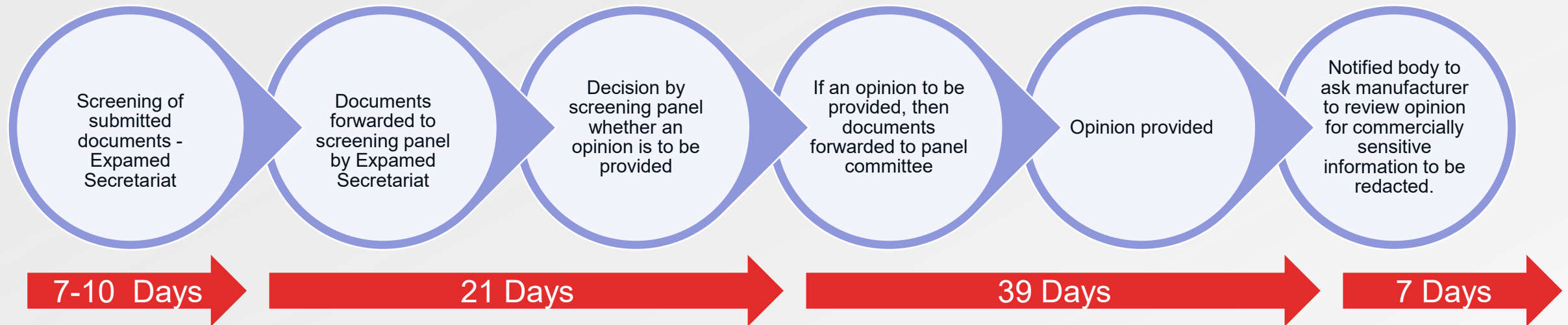


In this scenario, the notified body can go ahead continue with the issuing of the certificate.

No information is made public from this process.

Notified body are provided with the views of the screening panel as to why no opinion is to be provided.

The CECP Process – Opinion to be provided.



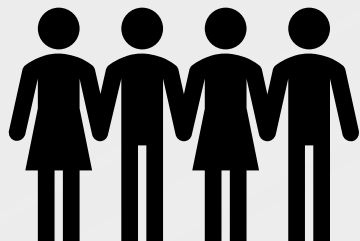
When an opinion is to be provided the notified body are told the reasons why an opinion has been decided. The notified body will inform the manufacturer that it has been sent for opinion.

During this process the notified body may be required to answer any questions of the expert panel. – Not typically seen.

Once the opinion has been provided the notified body has as strict timeline of 7 days to ask the manufacturer to review the opinion and provide details of any commercially sensitive material in the opinion. – Please note that is not an opportunity to challenge the opinion.

Example of opinion – how it works

Screening Panel

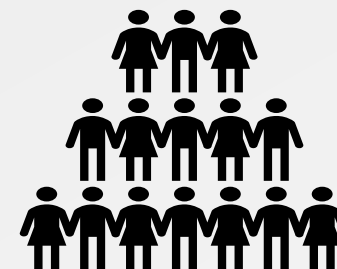


Information from the screening panel is sent to the expert panels with their concerns related to:

- Novelty
- Health Impact
- Clinical Impact



Expert Panel



The Expert Panels provide a specific opinion on:

1. Overall opinion of the NB's assessment of the adequacy of the manufacturer's clinical evaluation report.
2. Opinion on the NB's assessment on
 - I. the sufficiency of the clinical evidence provided by the manufacturer
 - II. Manufacturer's benefit-risk determination
 - III. Consistency of the manufacturers clinical evidence and intended purpose
 - IV. Consistency of the manufacturers clinical evidence and PMCF plan
3. Any additional information
4. Summary of divergent opinions.

Notified body consideration of the expert panel view

Annex IX, Chapter II Section 5.1 (g)

Restrict Intended Purpose

- Restrict to specific patient populations
- Restrict to limited indications

Limit Certificate

- Limit Certificate Duration
- Limit to PMCF Release Only
- Limit Certificate to align with PMCF Studies

Change to Technical Documentation

- Update the IFU
- Update the SSCP
- Update any Necessary Documentation

The NB will provide full justification why it has not followed the advice of the expert panel, this justification along with the findings of the expert panel will be made publicly available via Eudamed.

Publication of the CECP Opinion

- The opinion is published on the EU Commission Website.
- It is anticipated once Eudamed is available these opinions will be published there.
- The redaction of information is only temporary.
- Once the certificate has been issued the full opinion will be made available.

1 ADMINISTRATIVE INFORMATION

Date of reception of the dossier	01/08/2022
Notified Body number	2797
Internal CECP dossier #	2022-000227
Medical device type	██████████ is a fully resorbable mesh with a resorbable hydrogel coating. It is a sterile mesh device designed for the reinforcement and reconstruction of soft tissue deficiencies, co-knitted using poly-4-hydroxybutyrate (P4HB, < 60%) and polyglycolic acid (PGA, < 15%) fibers.
Intended purpose	The device is indicated for use in the reinforcement of abdominal soft tissue, where weakness exists, in ventral and hiatal hernia repair procedures.
Risk class / type	<input checked="" type="checkbox"/> class III implantable <input type="checkbox"/> class IIb active device intended to administer or remove medicinal product(s)
Screening step: medical field / competence area	General and plastic surgery and dentistry

A full list of opinions can be located here: https://health.ec.europa.eu/medical-devices-expert-panels/experts/list-opinions-provided-under-cecp_en

The CECF Process – Is there an appeals process?

There is no appeals process for opinions.

It is critically important that the manufacturer and the notified body provide full and complete information at time of submission.

The notified body can choose not to follow the opinion of the expert panels but will have to provide a justification for not following the opinion and this will also be publicly made available.



Is there a fee associated with expert panels?

36



There is currently no fee associated with the CECP process.

The EU commission have provided funding for this service for the next few years.

Article 106 - Clause 13

The Commission **may require manufacturers and notified bodies to pay fees for the advice provided by expert panels** and expert laboratories.

The structure and the level of fees as well as the scale and structure of recoverable costs shall be adopted by the Commission by means of implementing acts, taking into account the objectives of the adequate implementation of this Regulation, protection of health and safety, support of innovation and cost-effectiveness and the necessity to achieve active participation in the expert panels. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

Article 106 - Clause 14

The fees payable to the Commission in accordance with the procedure under paragraph 13 of this Article shall be set in a transparent manner and on the basis of the costs for the services provided.

The **fees payable shall be reduced in the case of a clinical evaluation consultation procedure** initiated in accordance with point (c) of Section 5.1 of Annex IX **involving a manufacturer who is a micro, small or medium-sized enterprise** within the meaning of Recommendation 2003/361/EC.



Article 54.3. Consideration

The notified body is required to notify the Commission for all certificates issued for class III implantable or IIb rule 12 active ARMS device that are not sent for CECP. This notification includes a copy of the clinical evaluation assessment report.



3. 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 (3)

Article 54 (2) - exemptions

2. 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.



**Clarity
Point**

Therefore we still need to notify the competent authority and upload the CEAR prior to certificate issue for all these exemptions to Article 54 (2) (a, b, c). This includes legacy devices.

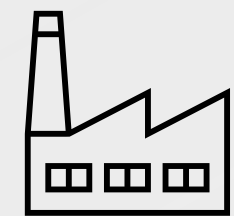
Pre-Market Consultation & Expert Panels

- (57) For class III devices and for certain class IIb devices, a manufacturer should be able to consult voluntarily an expert panel, prior to that manufacturer's clinical evaluation and/or investigation, on its clinical development strategy and on proposals for clinical investigations.

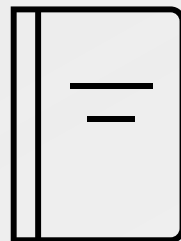
Recital 57

The MDR has a provision for voluntary consultation of the evaluation of manufacturers clinical development strategy

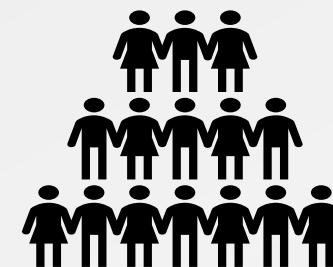
Article 61 (2) -



Manufacturer



Clinical
Development
Strategy



Expert Panels

Article 61 (2) allows for the provision for manufacturers to contact the expert panels for an opinion on the clinical strategy plan.

This is expected to be for all class III (including non-implantable) and IIb rule 12 active ARMS device.

This availability is expected after May 2024. There are plans to allow for 10 devices to reviewed in 2023 as part of a trial on a *'first come, first serve'* basis.

Please note this is an independent procedure between the manufacturer and the EU commission and does not involve the notified bodies.

BSI experience of CECP – Lessons Learned

Timelines

- The 21-day timeline for screening has always been achieved
- The 60-day timeline for opinion has always been achieved

Opinions

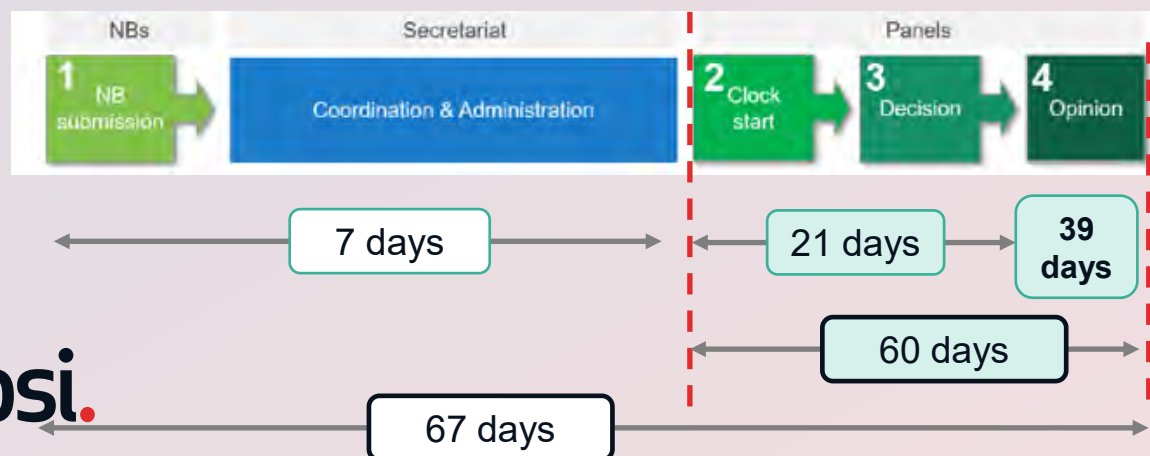
BSI has had two opinions published

- [CECP-2022-000227](#)
- [CECP-2021-000205](#)

Type of Submission	Number
CECP Submissions	11
CECP Submissions led to opinion	2
Article 54.3 Notifications	221

Opinion CECP - 2022-000205

- NB2797 – BSI NL
- Acetabular cups/inserts for total hip Implant
- Legacy device. CECP process triggered by the change to the PMMA spacer material grade for the Contemporary Flanged Cup
- Opinion was required based on the preclinical documentation regarding the changes in the PMMA spacers are not available, and the expert panels were unable to judge the degree of novelty of this device.
- Panel - Orthopaedics, traumatology, rehabilitation, rheumatology– Subgroup 1. Joint Replacement (Hip, Knee and Shoulder)
- Positive commentary in relation to the NB assessment – some concerns about the amount of information from other devices in the documentation.
- Some commentary on pre-clinical data and manufacturing aspects such as changes in sterilisation method and impact and some of these changes were approved under MDD.
- Positive Opinion with the Expert Panel agreeing with the NB's conclusions.



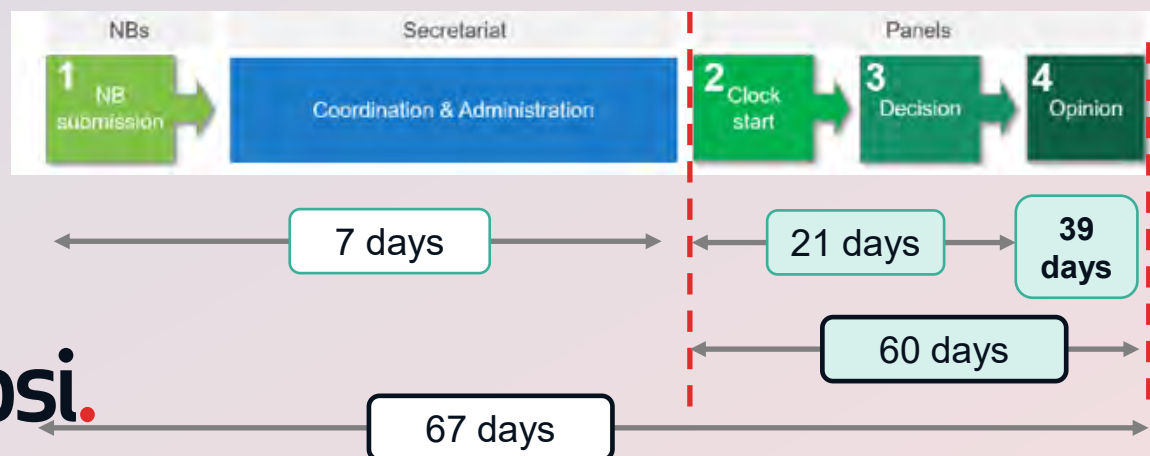
Major changes in UHMWPE manufacturing ("novel aspects", CEAR document, page 37): changes in the raw material processing from compression molding (CM) to ram extrusion (RE) and sterilization from gas plasma to ethylene oxide (EtO) may have clinically significant influence on future clinical performance of polyethylene (different oxidation/chemical evolution and mechanical properties).

After the evaluation of the provided data, the expert panel concurs with the NB's assessment of the manufacturer's conclusions on benefit-risk determination for the change in PMMA spacer material grade.

Longitudinal monitoring of clinical outcomes as proposed in the manufacturer's PMCF plan is considered adequate to detect unexpected mechanisms of failure, insufficient performance, and a survival rate below the acceptable rate for clinical excellence.

Opinion CECP - 2022-000227

- NB2797 – BSI NL
- Resorbable Hernia Mesh
- Legacy device. CECP process triggered by the addition of an indication for ventral hernia repair.
- Opinion was required based on screening criteria 3 - scientifically valid health concerns (clinical use and literature show that complications occur over time with use of this device)
- Panel - General and plastic surgery and dentistry – Subgroup 1. Surgical Implants & General Surgery
- Positive commentary in relation to the NB assessment and the way it was presented in the CEAR.
- Shortcomings with the clinical data were identified as relatively low number of patients enrolled in studies and registries especially for the extended indication and relatively short follow-up period with most of the available data covering a follow-up 2 years. The Expert Panel accepted that the PMCF plan would address both of these concerns.
- Positive Opinion with the Expert Panel agreeing with the NB's conclusions.



The notified body (NB) performed a thorough and sufficiently detailed assessment of the manufacturer's clinical evaluation report (CER) and all the clinical evidence presented.

The clinical evaluation assessment report (CEAR) is considered adequate and detailed.

The clinical evidence provided by the manufacturer in the CER and associated documents, namely the PMCF Report, were analysed extensively by the NB and evidence of that exercise was extensively provided in the CEAR.

We agree with the NB's conclusion that there is sufficient clinical evidence to support the current indication of hiatal hernia repair and the extended indication for open ventral use. In addition, data collection for both hiatal and open ventral use will be ongoing by the defined PMCF Plan.

Lessons Learned

- The expert panels are focusing on ‘novelty’
- The expert panels have been trained to review the CEAR and PMCF templates published by the Commission.
- Expert panels are also considering pre-clinical data.
- Failure to document adequate clear information in the CER and CEAR can result in an unnecessary opinion.
- Expired MDD certificates for legacy devices **DO NOT** trigger CECP if there are no modifications.



Useful Links



Opinions can be viewed here:

https://ec.europa.eu/health/medical-devices-expert-panels/experts/list-opinions-provided-under-cecp_en



Training Modules for experts


Training modules delivered to the members of the expert panels. Launch the presentation in full screen to hear the narration (Available for Modules 2-5).

- [Module 1: Legislation & regulatory framework](#) EN | ...
- [Module 2: Conflict of interests \(COI\) management](#) EN | ...
- [Module 3: Roles and tasks of panels and experts](#) EN | ...
- [Module 4: Screening decision criteria](#) EN | ...
- [Module 5: Operations](#) EN | ...

The training materials of the expert panels can be located here:

https://health.ec.europa.eu/medical-devices-expert-panels/work-expert-panels/practical-information-experts_en

Clinical Masterclass Series 2023 – Register for our webinars now!



The graphic features the title "BSI New Clinical Masterclass Series 2023" in red text at the top. Below the title, five topics are listed in a sequence from left to right. The first topic, "Preparing a Clinical Evaluation Plan", is in black text. The second, "Preparing a Clinical Evaluation Report (Part I)", is in red text and is enclosed in a white circular highlight. The third, "Preparing a Clinical Evaluation Report (Part II)", is in black text. The fourth, "Preparing a Post Market Clinical Follow Up Plan & Evaluation Report", is in red text and is also enclosed in a white circular highlight. The fifth, "Preparing a Summary of Safety and Clinical Performance (SSCP) Report", is in black text.

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Webinars

MDR Conformity Assessment Routes webinar

MDR - What we know

Source: Halliday & Jay Katta
BSI Medical Devices
Mar 2020

Download the presentation >

White Papers and Articles

Person responsible for regulatory compliance (PRRC) - MDR/IVDR Article 15

With the MDR and IVDR, European regulators aim to ensure companies have a regulatory expert – a Person Responsible for Regulatory Compliance (PRRC) – at their disposal, to ensure that the company is meeting certain specific EU requirements.

Software as a medical device - A comparison of the EU's approach with the US's approach

The International Medical Device Regulators Forum (IMDRF) aims to accelerate international medical device regulatory convergence. Through the IMDRF, regulators reached consensus on what software is considered a medical device. Regulators call it 'software as a medical device' (SaMD). This paper provides a comparison of how SaMD is regulated in the US and in the EU.

Machine learning AI in medical devices

How is AI different from traditional medical devices and medical software and what are the implications of those differences? What controls are necessary to ensure AI in healthcare is safe and effective?

Medical device clinical investigations – What's new under the MDR?

The conduct of a clinical investigation is one of the most time consuming and resource intensive activities that a medical device manufacturer can face. This paper discusses important new requirements for pre-market and post-market clinical investigations under the European MDR.

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