EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SESSION 3

Coordinating expert panels on high-risk medical devices and *in vitro* diagnostics

Introduction by topic lead

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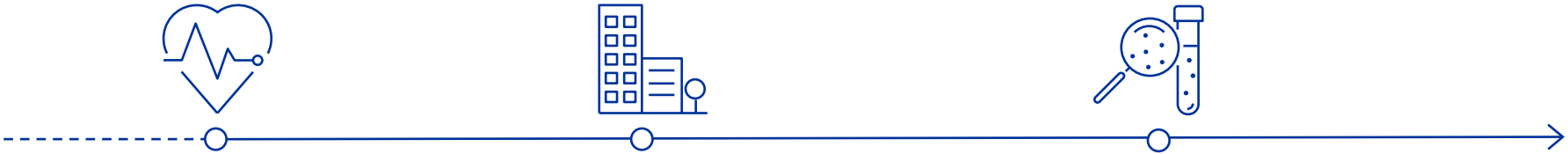
Outline

1. Medical Device Regulation
2. The Expert Panels in the framework of Medical Devices Regulation
3. Expert Panels – 1 year review
4. EMA’s new mandate on coordination of the Expert Panels
5. Conclusion

New Medical Device Regulation

More than 500,000 types of medical devices and in-vitro diagnostic medical devices on the EU market.

The previous regulatory framework of three Directives was replaced by the regulations on medical devices and in-vitro diagnostics:



With effect from:

26 May 2021

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices **(MDR)**

1 March 2022

Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

26 May 2022

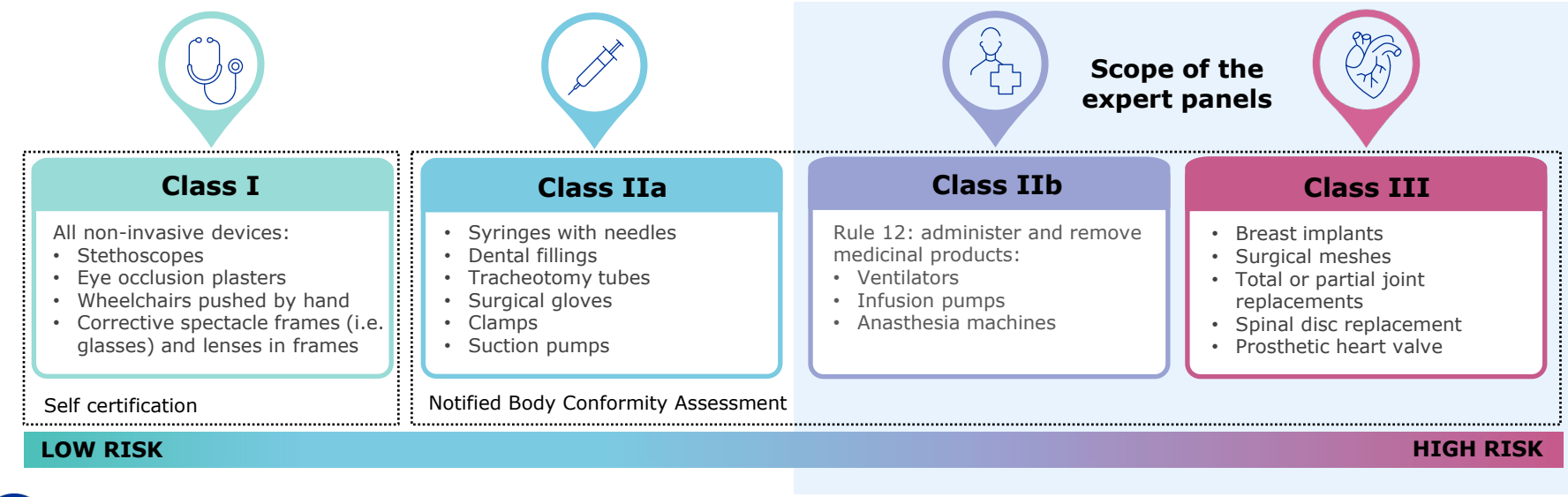
Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices **(IVDR)**

MEDICAL DEVICES

Overview of the types of medical devices

Medical device classification rules adopts a risk-based approach taking into account the risks associated with the use, technical and manufacture characteristics of the device.

The MDR (EC) 2017/745 divides the devices into 4 risk classes and 22 rules on classification of medical devices.



Recent safety issues with medical devices

Metal-on-Metal (MoM) hip replacement implant
2010

Recall of MoM hip replacements due to device failure of metal wearing and release of metal particles into the bloodstream and soft tissues.


'Metal-on-metal' hip implant patients recalled for tests over toxicity fears

Alert issued by regulatory agency calls for for MRI scans and blood tests on expanded pool from 56,000 patients using devices believed to be at risk of bone or muscle damage

Patients previously considered low risk using the 'metal-on-metal' hip implants are now being called for tests. Illustration: Ellen Wishart

Thousands of patients with "metal-on-metal" hip implants will be recalled for a battery of tests, including MRI scans and blood tests, due to concerns over toxicity.

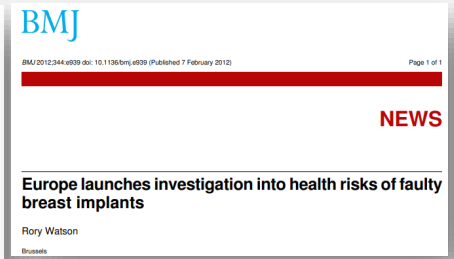
Poly Implant Prothese (PIP)
2012

Breast implants from the manufacturer PIP used low-grade industrial silicone that had not been approved by health authorities. Many of these implants ruptured, with no traceability.


Breast implants: 'There are some very frightened women'

Hospitals are facing a flood of inquiries from patients concerned they may have been given faulty products

Miles Dickson, a surgeon at Spire's hospital in Harpenden, says he never used PIP products, but has had 'loads of emails' from concerned former patients. Photograph: Sarah Lee for the Guardian



New tools of the Medical Device Regulation

Regulation (EU) 2017/745 and Regulation (EU) 2017/746 introduce stricter monitoring and certification procedures to ensure full compliance and traceability of medical devices, such as breast or hip implants.

Some new tools introduced with the new regulation:

- Pre-market obligation for consultation on **clinical evaluation** for certain high-risk devices – Expert panels
- EUDAMED - **Life cycle monitoring** with post-market clinical follow up (PMCF) data
- More **transparency, visibility and traceability** to patient and healthcare professionals

Pre-market control

- Stricter pre-market control with the introduction of Expert panels
- Provides mechanism of scrutiny for assessment of certain class III and class IIb devices

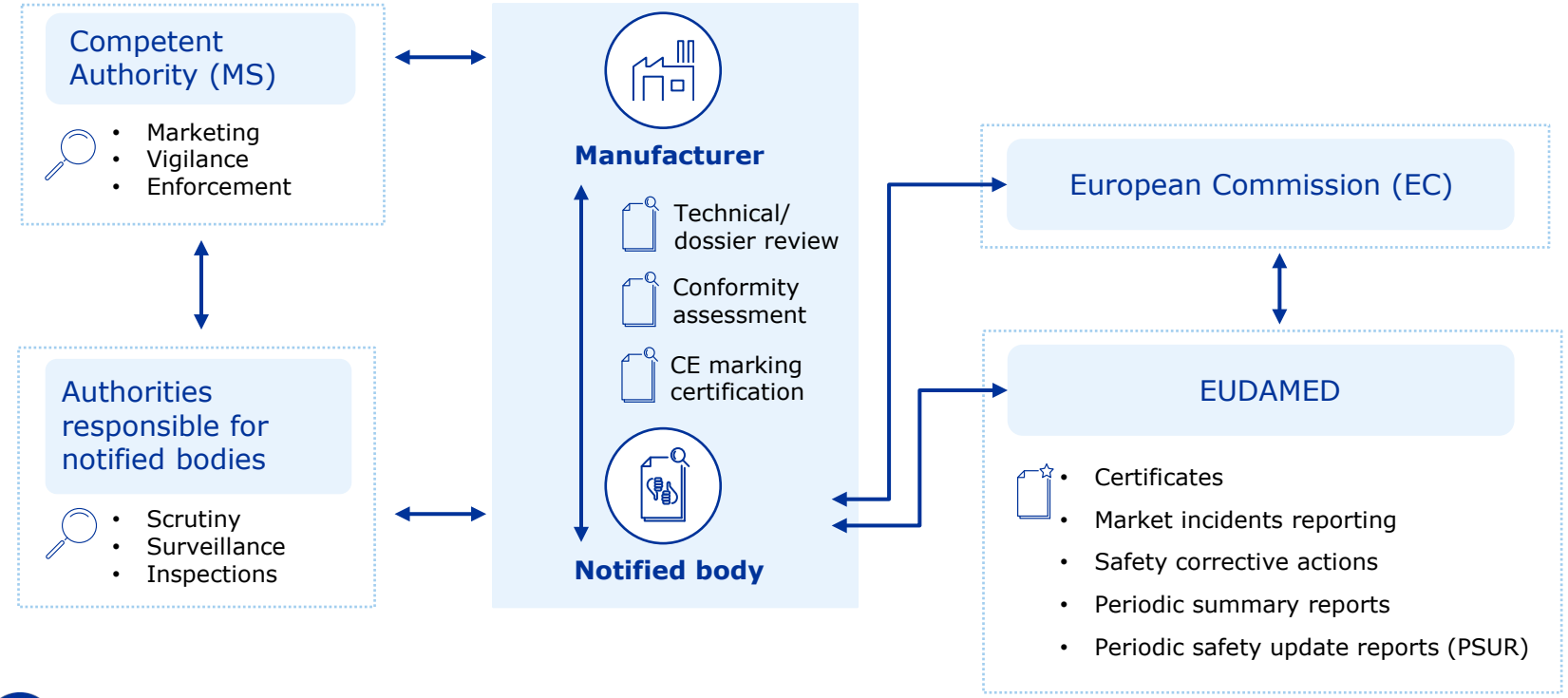
EUDAMED

- Improved market surveillance with the EU DAtabase on MEDical Devices
- Lifecycle of all products on the EU market

Traceability

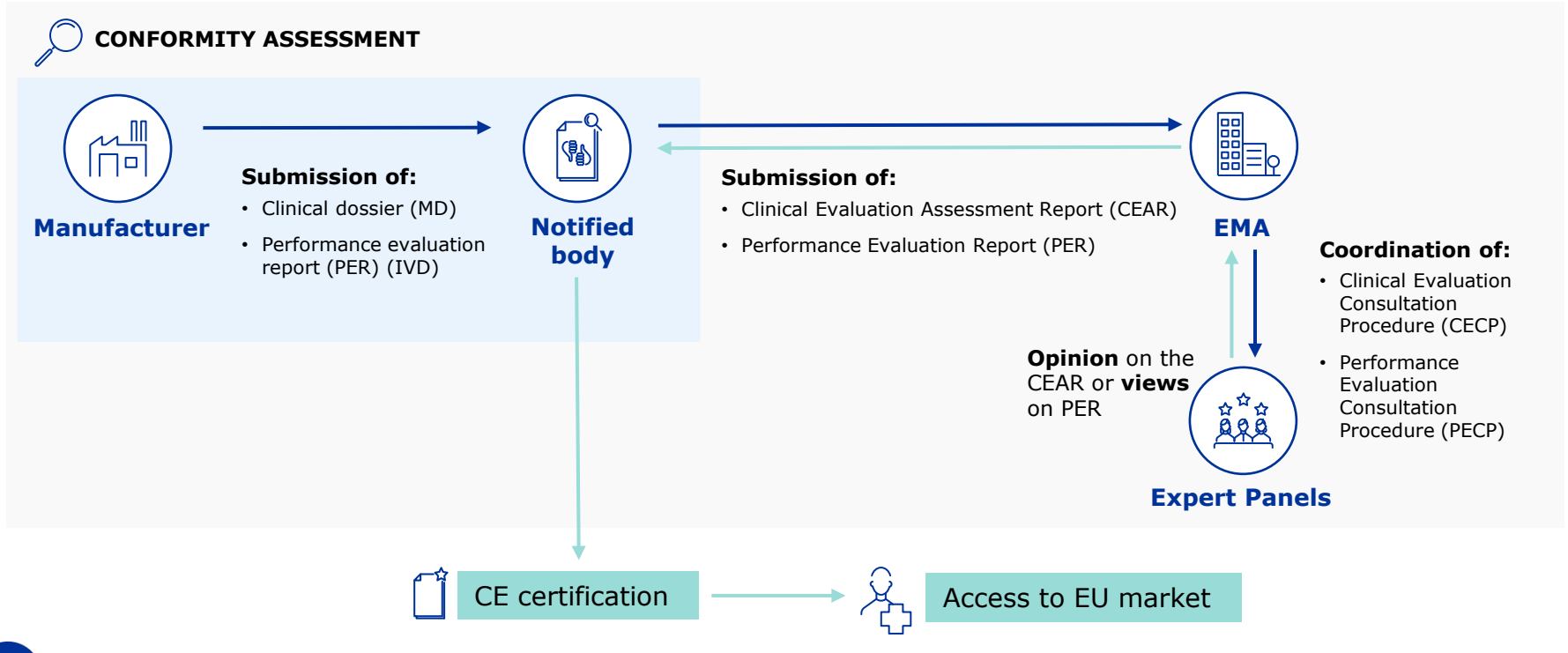
- Unique Device Identification (UDI) system
- Implant card for patients

Approval pathway for medical devices



NEW STRUCTURE

Expert Panels for medical devices



How are the Expert Panels organised

Coordination committee

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

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

Central list of available experts

Temporary assignment of experts to panels.

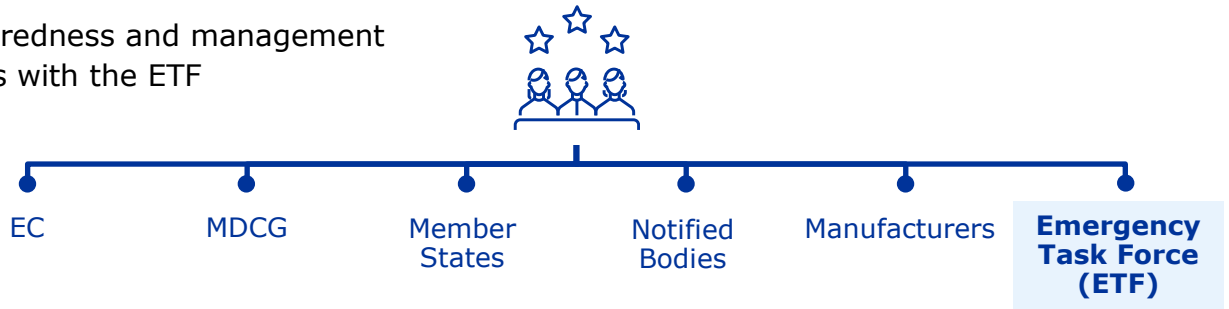
Reserve list for appointments.

Role of the Expert Panels

Focus: Provide opinion on notified bodies' assessment of clinical evaluation of certain high-risk medical devices and views on the performance evaluation of certain *in vitro* diagnostics

To further implement:

- Advisory role on technical, scientific and clinical matters
- Contribution to the development of common specifications for clinical evaluation of device categories, guidance documents or international standards
- Contribute to the identification of concerns and emerging issues on safety and performance of medical devices
- Play a relevant role in preparedness and management of public health emergencies with the ETF



NEW: CLINICAL EVALUATION CONSULTATION PROCEDURE (CECP)

Provide opinion on notified bodies' assessment of clinical evaluation of certain high-risk medical devices

Consider the legal requirements

Type of device

- For class III implantable eg. Pacemakers, joint replacement devices, breast implants
- For class Iib administer/ remove medicinal product eg. Infusion pumps, ventilators

Consider exemptions

No Expert Panel if:

- Re-certification of MDR product
- Modification does not affect B/R
- Common Specification available for the type of device

Phase I: Screening Panel

Decide on 3 criteria:

- Novel AND major clinical / health impact
- Adversely changed benefit-risk profile in regard to valid health concerns
- Significant increase of serious incidents

Phase II: Thematic Panel

Provide an Opinion

- Non-binding opinion which is publicly available on EC website
- The Competent Authorities will be notified of the opinion

Notified body | **Expert Panel**

Overview of output of Expert Panels for medical devices

The EC started receiving applications for the CECP on **1 April 2021**

During their first year of operation:

- 25 dossiers on high-risk devices and in vitro diagnostics were submitted
- 3 scientific opinions for CECP
- 15 scientific views for PECP

The EMA is coordinating the expert panels since **1 March 2022**

Currently:

- 3 applications ongoing
- 2 recently submitted

Example of the work of the Expert Panel

CECP#	Medical Device	Intended purpose
2021-000201	**An implantable device in contact with bone which is mainly resorbed.** It consists of porous granules of hydroxyapatite derived from porcine teeth.	A medical device intended to be used as a bone graft material for the repair or augmentation of bone defects in dental procedures.

The expert panel challenged adequacy of clinical evidence assessment by the notified body and commented on:

- Length of study duration
- Endpoint of the study
- Possible immune adverse reaction from the source material
- Adequacy of the dataset to support the intended use of the medical device

The expert panel recommended additional measures to implement in the post-market clinical follow-up (PMCF) plan

NEW: PERFORMANCE EVALUATION CONSULTATION PROCEDURE (PECP)

Views on the performance evaluation of certain in vitro diagnostics

Consider the legal requirements

Type of device

- For Class D: Intended for detection of presence/ exposure to, a transmissible agent

Consider exemptions

No Expert Panel if:

- Common Specification available for the type of device
- The type of device is already been certified

***In vitro* Diagnostic Panel**

Provide a View

- Non-binding view which is publicly available on EC website

Notified body

Expert Panel

Overview of the *in vitro* diagnostic Expert Panel work

The EC started receiving applications since **3 September 2021**

Views provided under PECP: testing kits for detection/screening of Parvovirus B19, Hepatitis E, West Nile Virus, Babesia, Zika, chikungunya virus (CHIKV) and dengue virus, Epstein Barr Virus, Trypanosoma cruzi, Treponema pallidum and SARS-Cov-2

PECP#	In vitro diagnostic medical device
IVD-2021-000007	The device is a qualitative double-antigen sandwich assay for the detection of Antibodies to **SARS-CoV-2** in serum/plasma
IVD-2021-000008	The device is a qualitative real-time PCR test for the simultaneously detection and differentiation of **SARS-CoV-2, Influenza A, and Influenza B** in respiratory specimens (Nasopharyngeal swab/nasal swab)
IVD-2021-000010	This test is an in vitro nucleic acid amplification test intended for qualitative detection of **SARS-CoV-2** genomic RNA by real-time polymerase chain reaction (PCR) method.
IVD-2021-000012	Chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of IgM antibodies to **SARS-CoV-2** in human serum and plasma
IVD-2021-000013	Chemiluminescent microparticle immunoassay (CMIA) used for the qualitative and quantitative determination of IgG antibodies to **SARS-CoV-2** in human serum and plasma

Advisory role on technical, scientific and clinical matters

Expert panels to provide scientific advice

Long term activity

- To Medical Device Coordination Group (MDCG) and EC concerning **safety and performance** of high-risk medical devices and in vitro diagnostics
- To manufacturers on their **clinical development strategy and proposals for clinical investigations** for certain high-risk medical devices
- To manufacturers, notified bodies and Member States on the **criteria for appropriate data sets for clinical evaluation** as part of conformity assessment of medical devices

Benefits of the Expert Panels

Benefit by improving public health and safety and supporting harmonization and standardization of device specifications:

- Provides **greater transparency** for patients and healthcare professionals on the clinical assessment done by the Notified Bodies
- Provides the **reinforcement of the supervisory** role of the Competent Authorities regarding the use of these medical devices
- Issues **critical opinion** on the clinical evidence provided at the time of certification and recommendations on future clinical data collection
- Help with **developing common specifications** which will support manufacturers to standardise the quality and performance of their devices and play a relevant role in crisis preparedness during public health emergencies eg SARS-Cov-2 IVDs (detection or quantification of SARS-CoV-2 nucleic acid and antibodies)

KEY BENEFIT

Increased transparency and public information on medical devices used across the EU

Handover Roadmap of the Expert Panels

Expert Panels' have been set up, managed and coordinated by the Joint Research Center and DG-SANTE for the past year.

Q2 2021

Role of the Expamed secretariat

Expanded EMA mandate for the coordination and administration of CECP and PECP

Q3 2021

Expert database management

Review of the EC policy on the management of competing interests for MD

Q4 2021

Expert selection

Managing pool of applications of experts and assignment into thematic panels based on workload

End Q4 2021

Expert engagement and payments

Assignment of rapporteurships and assessment team

Q1 2022

Final transfer steps

Preparatory work for official handover 1st March 2022

Terms of references and Rules of procedure

Legal provisions that have led to the process design

Conflict of interest declaration (CoI)

CoI evaluation based on the EMA policy, however with some adaptation

Call for expression of interest

Open call for applications and appointment of experts by the EC

IT tools

Internal workflow for CECP and PECP, CIRCABC for dossier management with notified body

Handover activities

Training, knowledge transfer and expert onboarding

How will EMA support the Expert Panels?

WHAT IS THE ADDED VALUE OF THE EXTENDED MANDATE

Bring considerable know-how in managing experts from all across the EU to ensure impartiality

Offer excellence in the best available scientific knowledge in the EU for scientific opinions and advice for pre-market and post market clinical development plans

Encourage innovation through support structures for SMEs and timely access for patients of innovative products

Management of competing interests and providing independent opinions, views and scientific advices on products

Increase transparency with the publication of scientific opinions to allow for public scrutiny

Conclusion

- Expert panels are one of the tools in the new MDR to **improve safety and performance** of MDs and IVDs as well as transparency for patients and healthcare professionals
- Under the new Extended Mandate, expert panels **activities are under the coordination** of the EMA and implementation is done on a step-wise approach
- **With its extensive experience in coordinating expert groups**, EMA will be able to meet its new role's expectation which would complement EMA's mission
- EMA's new mandate **strengthens the preparedness for major public health crisis and provides further resilience** for the availability of medical devices through its advisory role on critical medical devices
- EMA's coordination of the expert panels will lead to a **more integrated and synergistic approach** to the management of the scientific panels for medical devices that will help improve public health protection for the entire Union