Medical Device Regulation:
Expert panels on medical devices

ISPOR
2 December 2021

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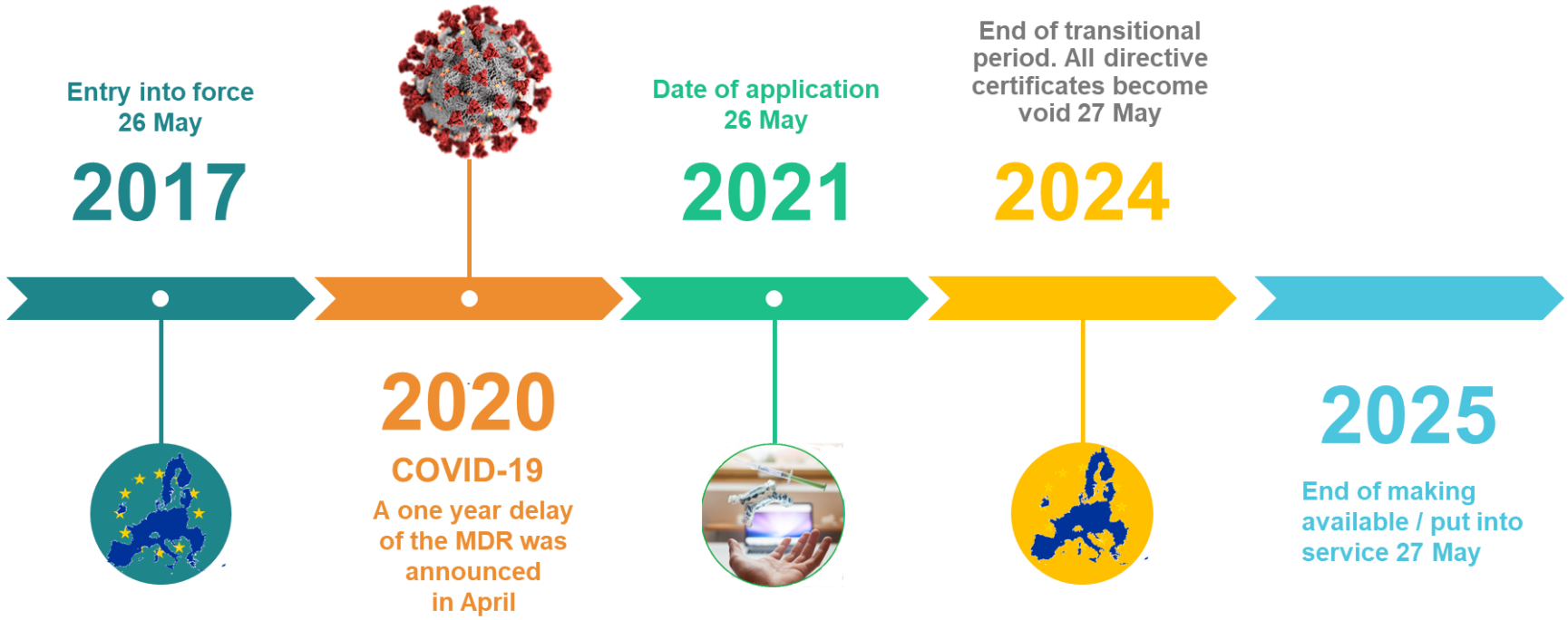
European Commission, DG SANTE, Unit B6

New EU regulatory framework for MDs

Regulation 2017/745 on medical devices

date of application 26 May 2022



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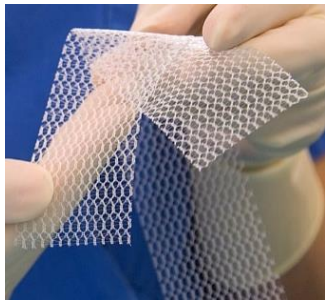
Why the revision and main objectives of the new legislation

- Adaptation to technological and scientific progress
- Better protection of public health and better patient safety
- Legal certainty and innovation-friendly environment
- More transparency and patient empowerment
- A more European approach
- Restore the trust of the patients and clinicians



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Key changes & improvements

- ✓ **Stricter pre-market control of high-risk devices** with the involvement of a pool of experts at EU level.
- ✓ **Stricter** requirements related to the use of **hazardous substances** for certain devices
- ✓ **Inclusion** of certain **aesthetic devices** within the scope
- ✓ **Reinforced** designation and oversight processes of **notified bodies.**
- ✓ **Reinforcement** of the rules on **clinical evaluation** and **clinical investigation**
- ✓ **Upgraded classification** system based on international guidance.
- ✓ Improved **transparency** via comprehensive EU database on medical devices (EUDAMED) & device **traceability** system based on (UDI)
- ✓ Introduction of an **“implant card”** for patients
- ✓ Enhanced **post-market surveillance**, market surveillance and vigilance requirements

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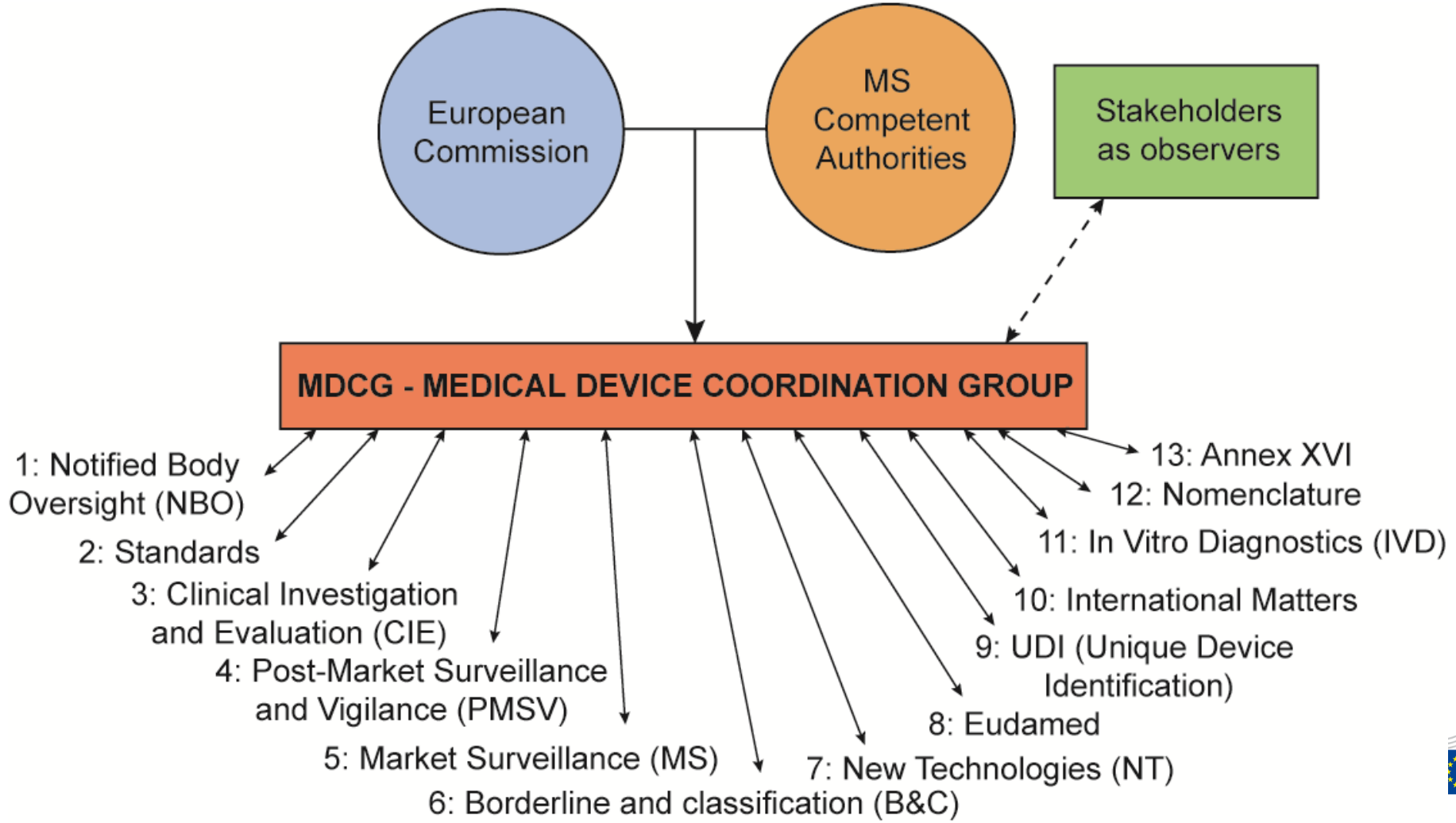
How we work on implementation of medical device legislation



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Legislation and COM guidance

- Implementing Decision (EU) 2019/1396 of 10 September 2019 on designation of expert panels in the field of medical devices
- Implementing Decision (EU) 2019/939 of 6 June 2019 designating issuing entities designated to operate a system for the assignment of Unique Device Identifiers (UDIs) in the field of medical devices
- Guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are CMR or have ED properties
- Commission guidance for the medical devices expert panels on the consistent interpretation of the decision criteria in the clinical evaluation consultation procedure 2020/C 259/02

Guidance documents under the MDR

- app 47 documents, 51 revisions cumulatively in 18+ years
- 91 documents, a few revisions in 4+ years
  +12 factsheets

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Monitoring the developments

- MDCG work in progress
- Implementation rolling plan
- CAMD roadmap

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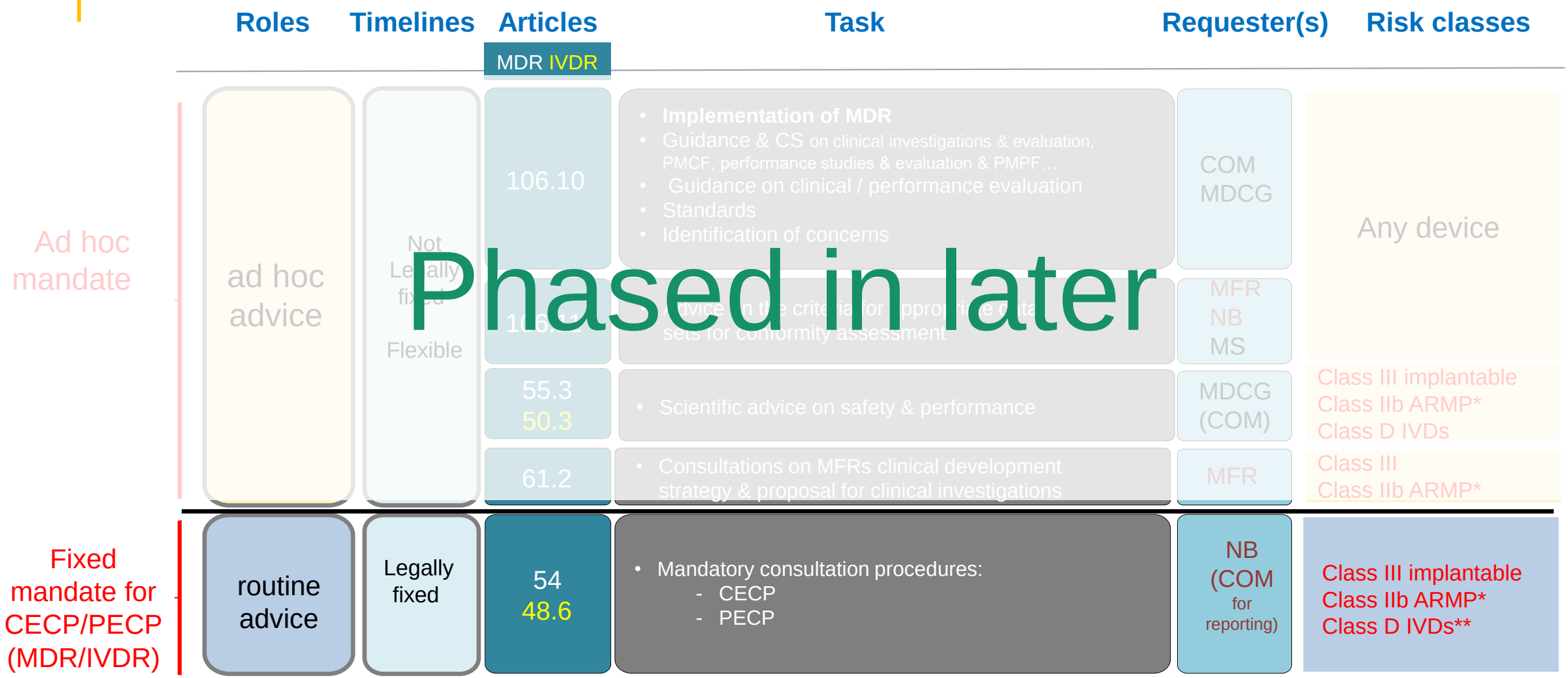
Overview of the roles of expert panels



* ARMP = Administer and/or Remove Medicinal Products

** class D IVDs for which no common specifications exist and where it is the first certification for that specific type of device

Coordination Comm

Template part 1: decision

Screening Panel

Templa scientif

Orthopaedics

1. Joint replace (load bearing)

2. Joint replace load bearing)

Circulatory

1. Prosthetic va heart valve rep

2. Cardiovascul

Neurology

1. CNS & PNS d

Respiratory…

Endocrinology

Surgery

1. Surgical impl general surgery

Gynaecology / Obstetrics

Gastroenterology

Nephrology / Urology

Ophthalmology

SCREENING PANEL	POLYDOROU Olga	STANZIONE Paolo
	THEMATIC PANELS	
THEMATIC PANELS AND SUBGROUPS	CHAIR	VICE-CHAIR
1. Circulatory system	CIARKA Agnieszka	TASCHNER Christian
A) Prosthetic heart valves and devices for heart valve repair	MORENO SAMOS Jose Carlos	PARMA Radoslaw
B) Cardiovascular stents (metallic and bio-resorbable) & vascular prostheses	TASCHNER Christian	STEFANINI Giulio
C) Active implantable cardiac devices & electrophysiological devices	LENNERZ Carsten	PEZAWAS Thomas
D) Structural interventions and new devices	GORI Tommaso	-
E) Cardiac surgery	CIARKA Agnieszka	OOSTERLINCK Wouter
2. Orthopaedics, Traumatology, Rehabilitation, Rheumatology	NELISSEN Rob	WILLIAMS Dan
A) Loadbearing joint replacements	BOBAK Peter	PERINO Giorgio
B) Non-loadbearing joint replacements	NELISSEN Rob	WILLIAMS Dan
C) Spinal devices	MENCHETTI PierPaolo Maria	-
D) Non-articulating devices and rehabilitation	MACHAIRAS Georgios	-
3. Neurology	HELBOK Raimund	DIETZ Aarno
A) Central & peripheral nervous system devices	DIETZ Volker	LEOCANI Letizia
B) Implants for hearing and vision	DIETZ Aarno	-
C) Neurosurgical devices	HELBOK Raimund	-
4. General & plastic surgery and dentistry	KLAR Ernst	PAGANELLI Corrado
A) Surgical implants & general surgery	KLAR Ernst	MISEREZ Marc
B) Plastic surgery & wound care	CEDIDI C. Can	-
C) Maxillofacial surgery & Dentistry	PAGANELLI Corrado	SCHMALZ Gottfried
5. Obstetrics & gynaecology	COSTANTINI Elisabetta	-
6. Gastroenterology & hepatology	AABAKKEN Lars	LOPES Luís
7. Respiratory & anaesthetic devices, intensive care	ZENKER Sven	KARIMOVA Ann
8. Endocrinology & diabetes	BIESTER Torben	DOVC Klemen
9. Nephrology & urology	MUSCHTER Rolf	RASSWEILER Jens
10. Ophthalmology	NARDI Marco	SCIALDONE Antonio

Five core principles governing the work of the expert panels

- Scientific competence and expertise
- Independence, impartiality and objectivity
- Transparency
- Confidentiality
- Commitment

Declaration of interests (DOI)
Declaration on confidentiality
Declaration on commitment

To be completed and signed by the experts

Term of office & renewal of term

TERM OF OFFICE AND RENEWAL OF TERM

EXPERT PANELS

- Experts are appointed for a maximum of 3 years and their term can be renewed if the conditions for membership are still fulfilled.
- If experts resign before end of term: Secretariat seeks to assign experts from central list for the remaining duration of the term

CENTRAL LIST

- Validity - 5 years from the date of its establishment
- Date of validity will be published on the Commission webpage

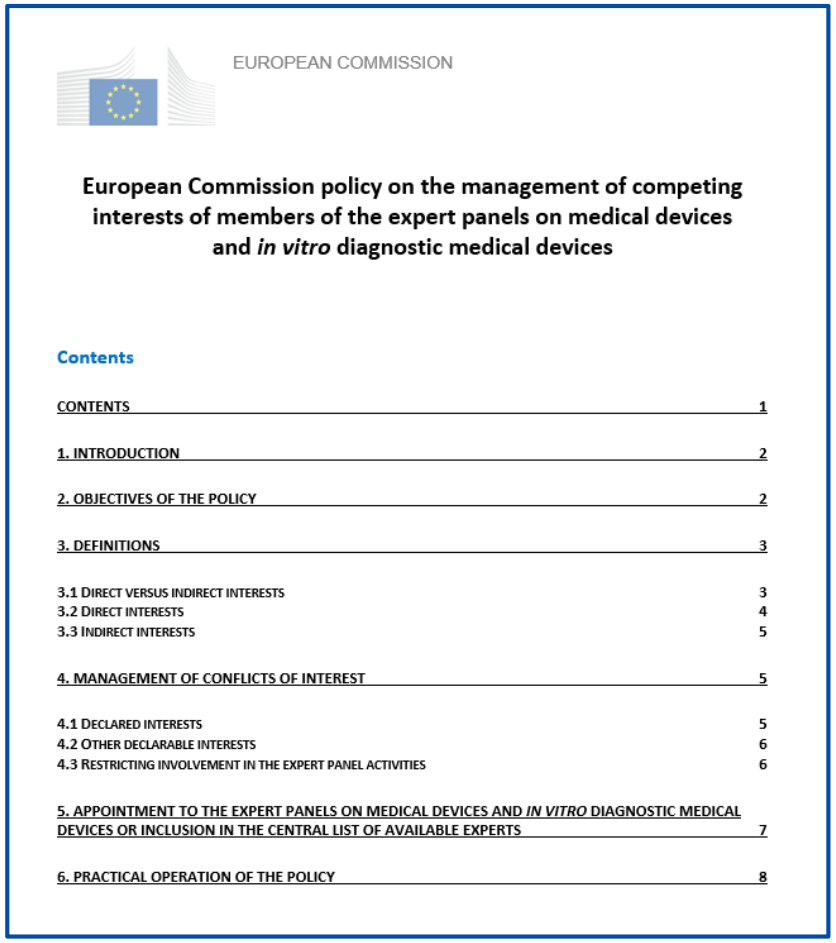
Fundamental obligations of experts

- Active & substantial contribution to **remote work** and **meetings**
- Adhere to **Terms of Reference, Rules of Procedure** and **Handling Instructions of confidential information**
- Follow **Commission guidance** on the consistent interpretation of the screening decision criteria
- Use **secured IT tools** (CIRCABC platform, Eudralink) and follow the **Operational procedures**
- Use the **templates and forms** for **delivering output via CIRCABC**

Roles within thematic panel

Chair	• Coordinates the expert panel work • Manages decision making (consensus or majority) • Assigns, in collaboration with the Secretariat, a rapporteur and co-rapporteur for each dossier (rotating roles) based on the DOI assessment of the Secretariat • Requests additional expertise if needed (interaction with Secretariat)
Vice-Chair	• Replaces the Chair when he/she cannot fulfil his/her role • May support the Chair in fulfilling his/her responsibility (useful for larger panels) • Otherwise: can act as rapporteur, co-rapporteur or reviewing member
Rapporteur / co-rapporteur	• Rapporteur and co-rapporteur draft scientific opinion/view under supervision of chair • Rapporteur is responsible for providing the draft documents to the Chair within time for consensus decision making. • Rapporteur uploads final opinion/view on CIRCABC (=deliverable)
Reviewing members	• Panel members supporting the rapporteur / co-rapporteur with their expertise and have voting rights in regard to the dossier
Temporarily assigned expert	• Assigned by the Secretariat from central list/other panel on ad hoc basis for limited period based on workload/expertise
Notified Bodies representatives	• Permitted by the Chair in agreement with Secretariat to present their conclusions on the clinical evaluation from the manufacturer – Annex IX 5.1 (b)

European Commission policy on the management of conflict of interests



EUROPEAN COMMISSION

European Commission policy on the management of competing interests of members of the expert panels on medical devices and *in vitro* diagnostic medical devices

Contents

- Securing the best expertise while ensuring that interests do not interfere with impartiality, objectivity & independence.
  - Dossier-specific **exclusion** of experts with conflicting interests in regard to certain companies or medical devices
  - In other cases **restriction** of experts' in regard to the the role they can play

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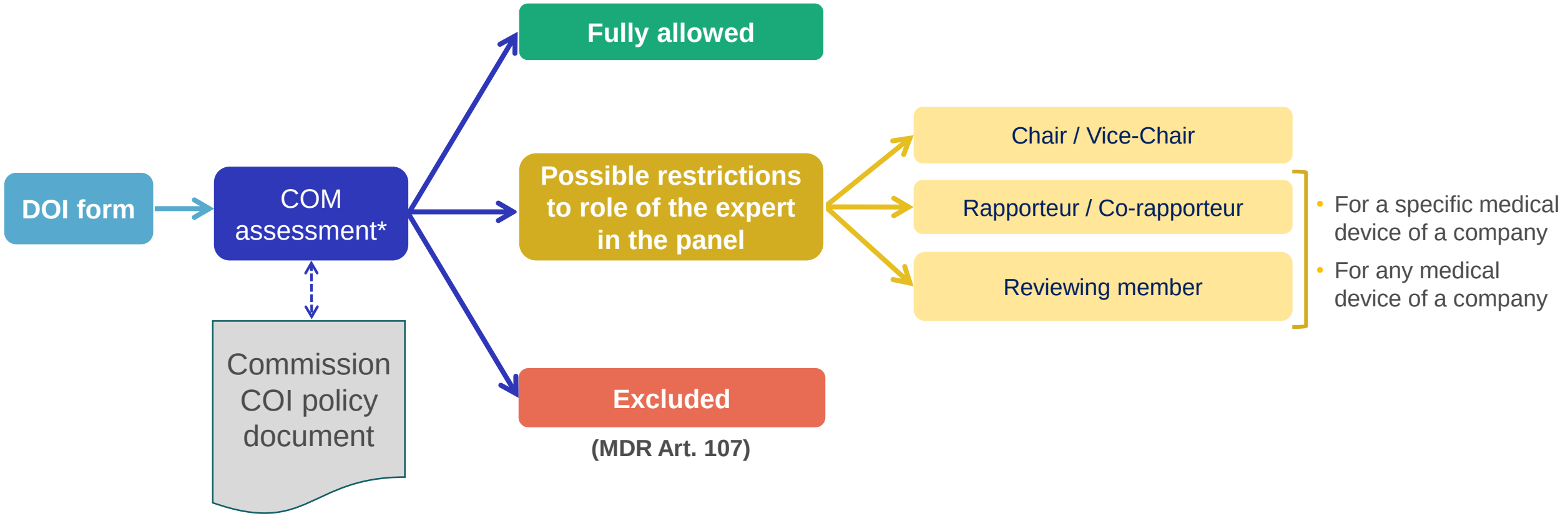
Assessment of experts' DOI and possible restrictions



** based on the Commission CoI management policy*

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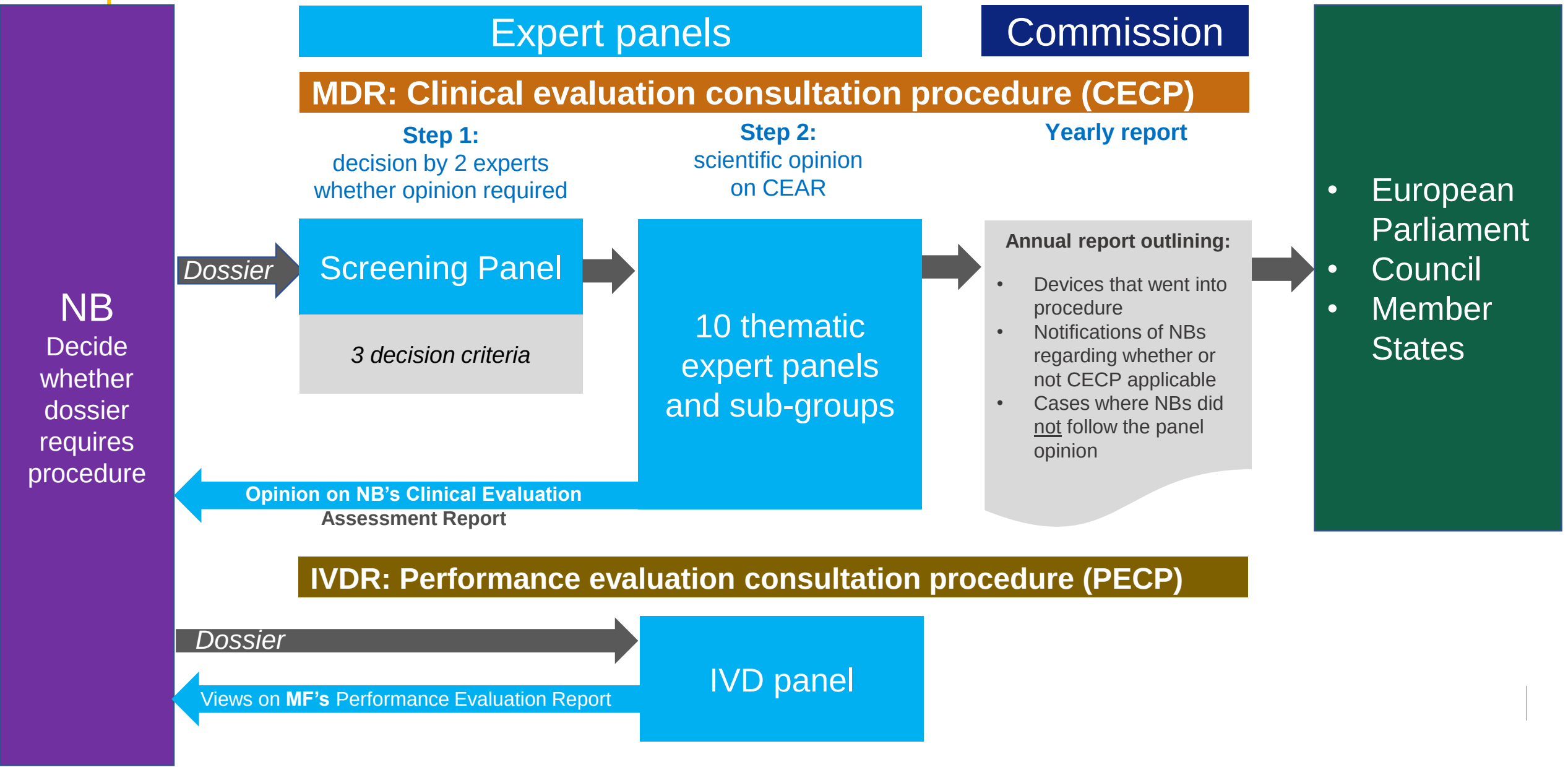
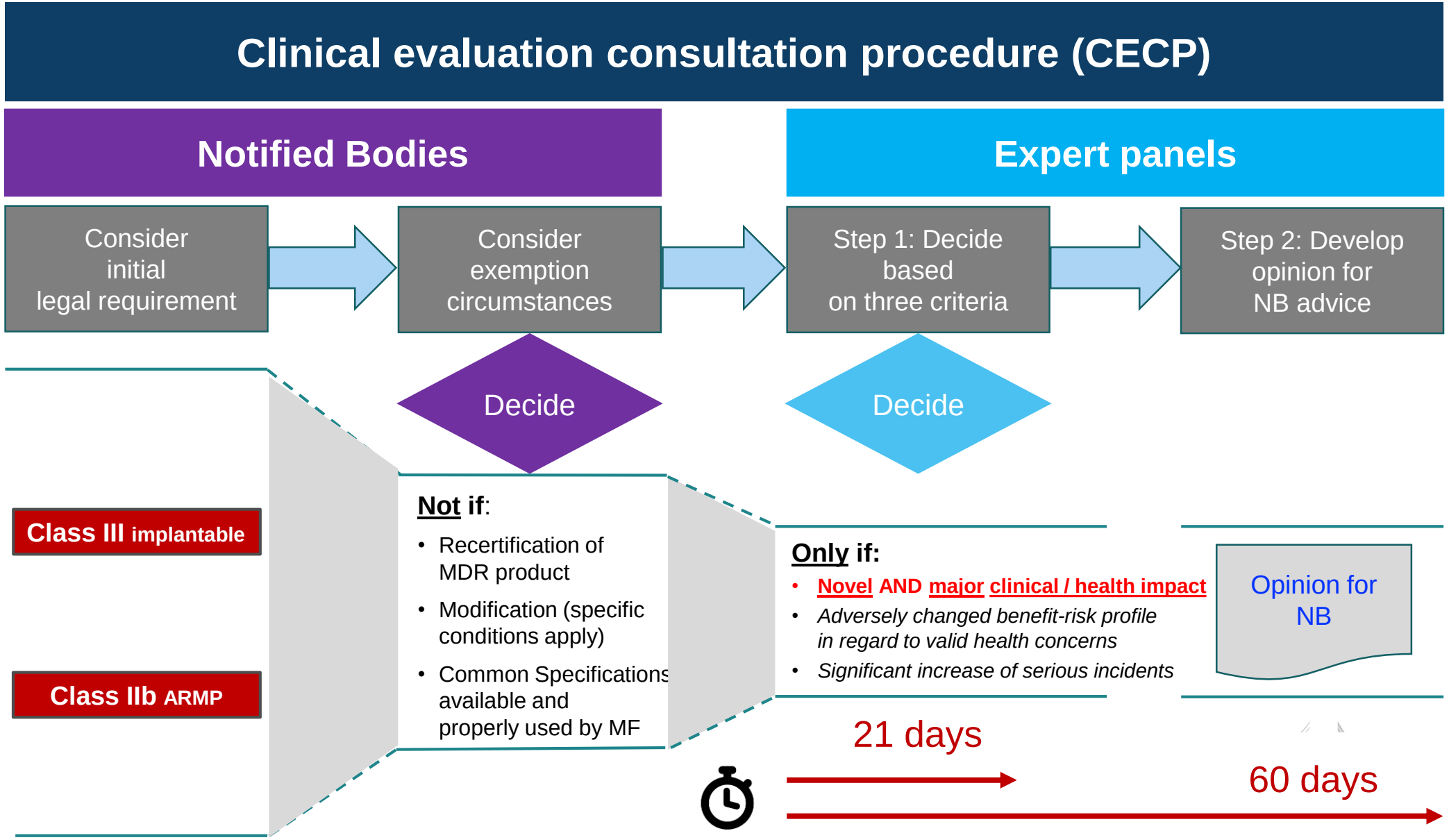
CECP/PECP and expert panels

- In the context of their conformity assessments, **notified bodies (NBs) are legally obliged to consult expert panels** for specific high-risk devices:
  - **For medical devices**:
    clinical evaluation consultation procedure (CECP)
  - **For in vitro diagnostic devices**:
    performance evaluation consultation procedure (PECP)
- However, the advice by expert panels is not legally binding. NBs have to consider the advice but may decide not to follow it (fully). However, in such cases NBs need to justify why they did not follow the expert panel advice.
- In case there is no opinion within the legal timeline, the NB can continue with conformity assessment.

Clinical evaluation consultation procedure (CECP) for medical devices and Performance evaluation consultation procedure (PECP) for diagnostics



Actors and steps of the CECP for medical devices



Notified Body Decision: which dossiers need to undergo the CECP ?

Risk class requirements

- Class III implantable devices
- Class IIb devices for administering and/or removing medicinal products (‘ARMP’ devices)

Circumstances under which dossiers are exempt from CECP:

- Exemption 1: Renewal of a certificate issued under the Medical Devices Regulation - MDR
- Exemption 2: Modified devices, subject to an assessment of adverse changes of the risk-benefit determination
- Exemption 3: Common Specifications for device type exist and specific requirements are fulfilled

Exemptions 1 and 3 will, in the beginning, not be relevant:
MDR becomes applicable only in May 2021 and currently there are no Common Specifications.

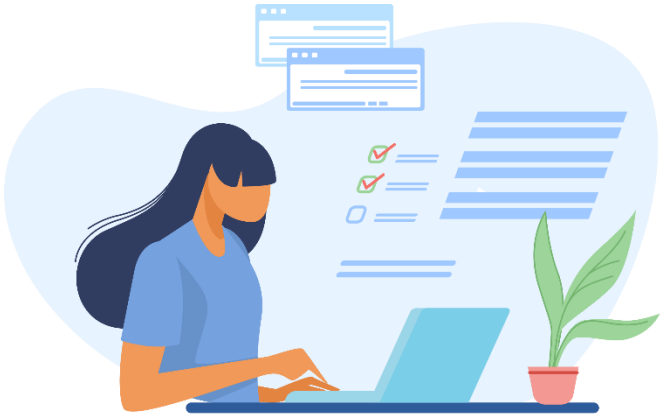
Exemption 2 will not be relevant initially for modifications of MDR products.
However also products marketed under the Directives (‘legacy products’) may fall under exemption 2.

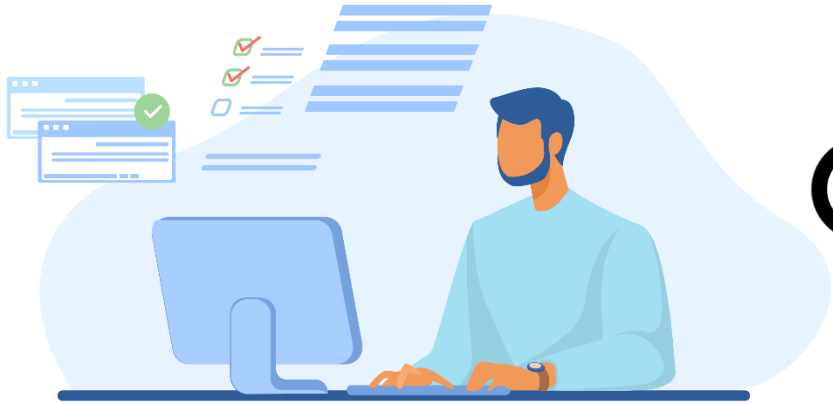
Screening panel experts (only CECP)

2 experts per dossier:

RAPPORTEUR / CO-RAPPORTEUR

- Selected by the Secretariat among the screening panel experts based on medical area/expertise required for the specific dossier
- Experts decide whether or not an opinion is required and complete the relevant part of the template with the decision. If no consensus: specific provisions in Rules of Procedure
- Rapporteur delivers the decision by uploading the template on CIRCABC





21 days

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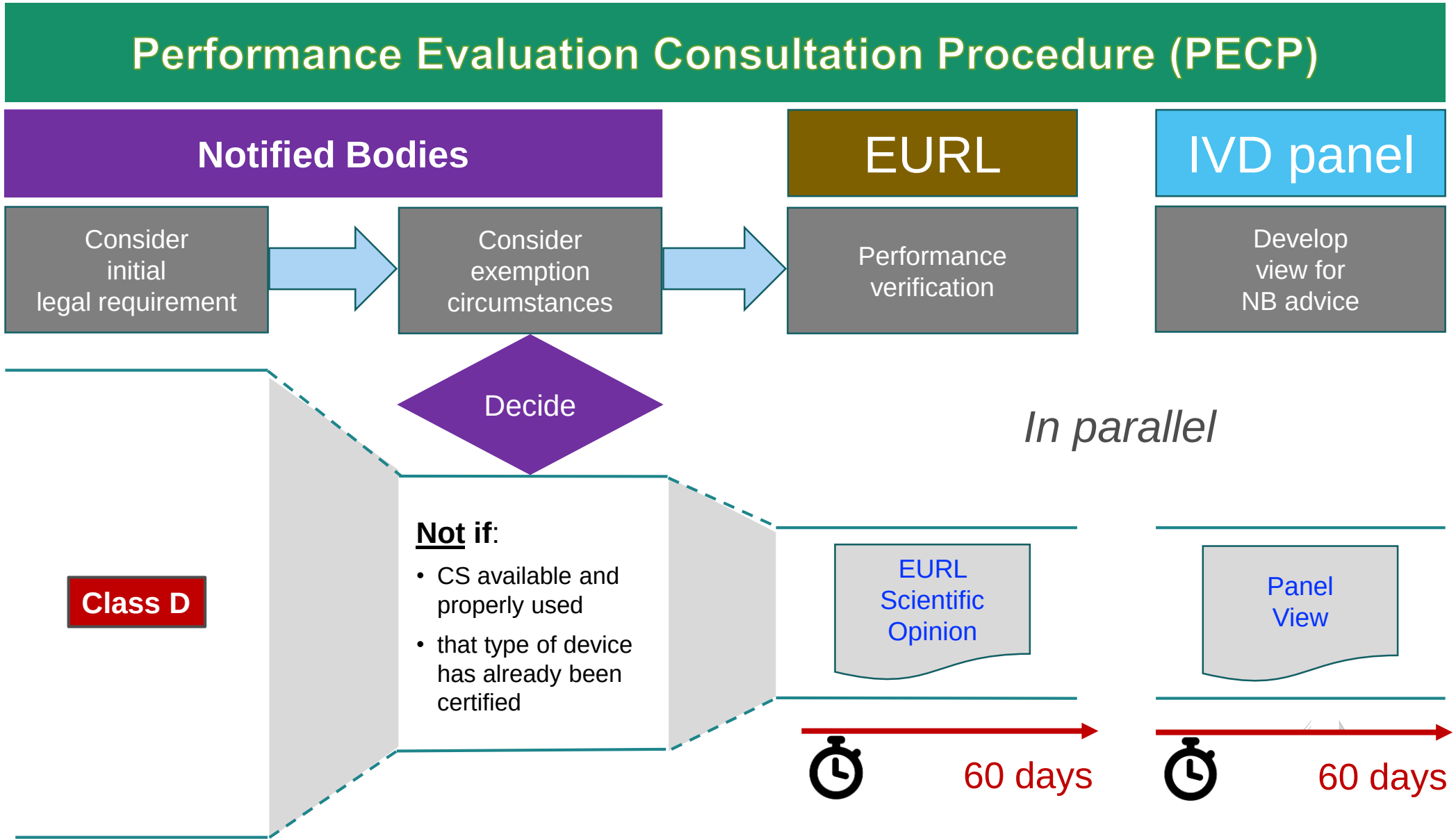
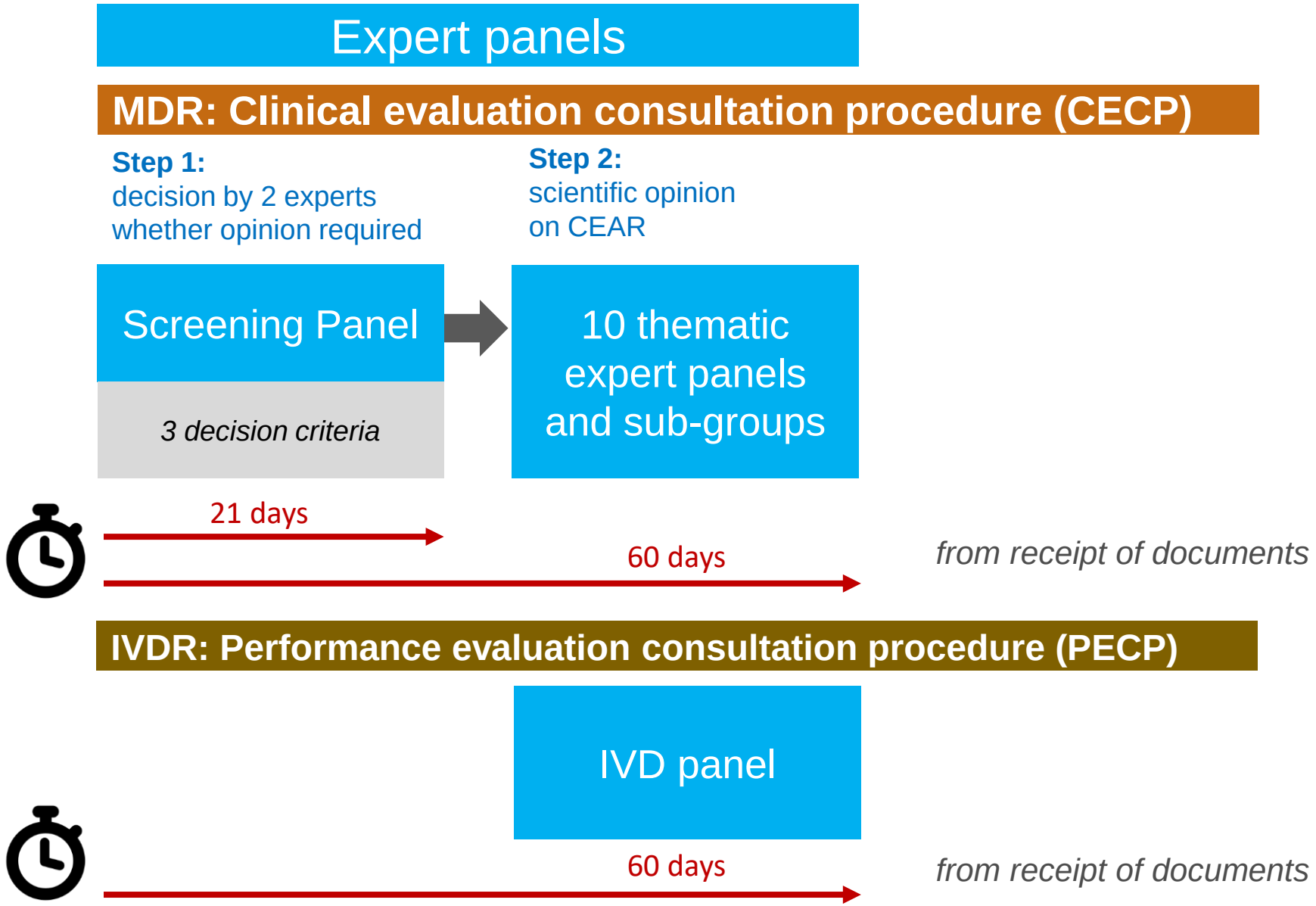
Actors and steps of the PECP for IVD devices



Timelines for CECP and PECP



CECP and PECP compared

CECP (medical devices)

Expert panel review

NB's clinical evaluation assessment report (CEAR)

based on MF's clinical evidence

- The clinical evaluation report (CER)
- The clinical evaluation plan (CEP)
- The post-market follow-up plan (PMCF)
- The PMCF evaluation report (where available)

PECP (in vitro diagnostic devices)

Expert panel review

MF's performance evaluation report (PER)

based on MF's

- Scientific validity report
- Analytical performance report
- Clinical performance report

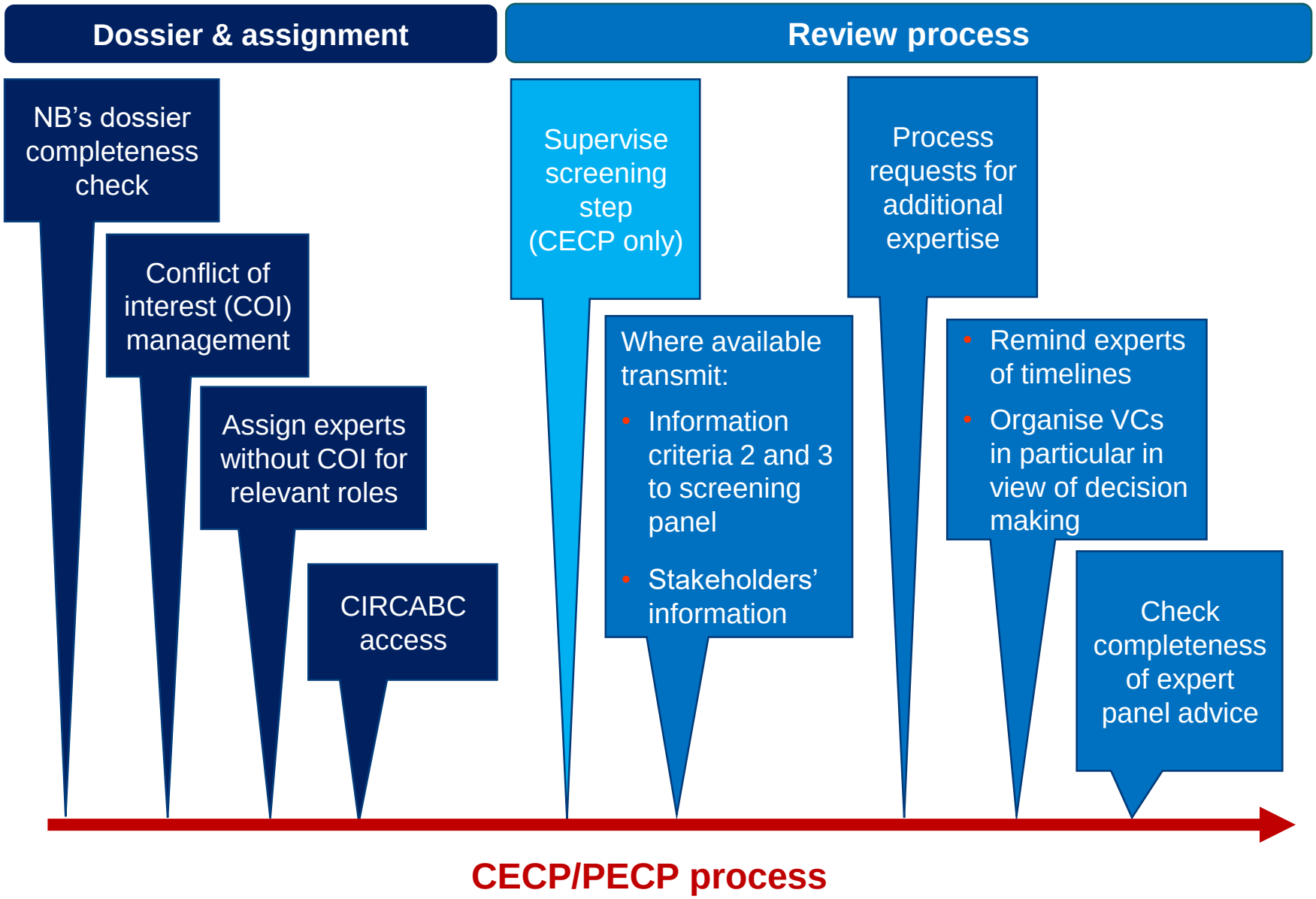
Taking into consideration:

Stakeholder information received from the Secretariat (where available)

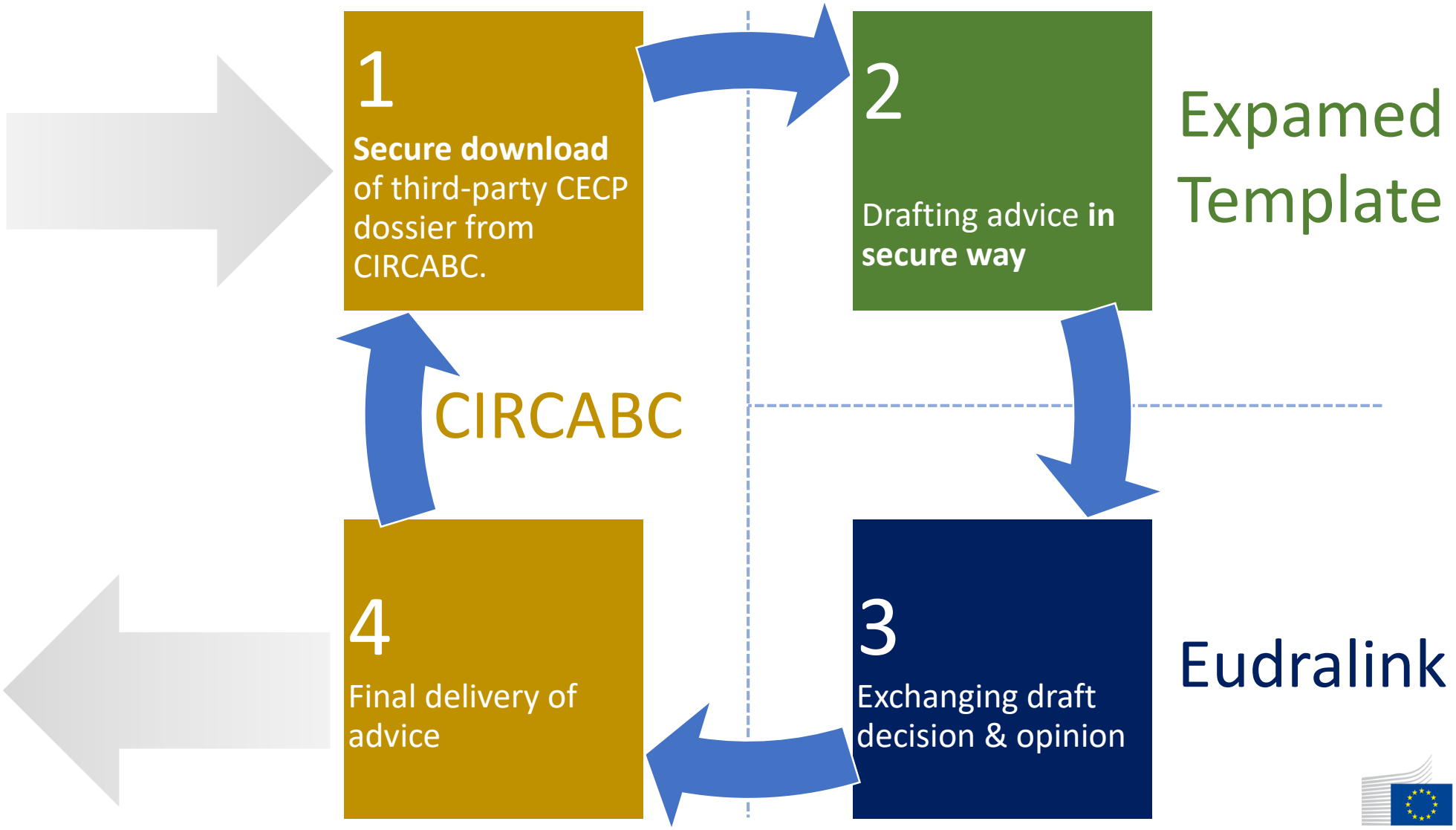
Roles of the Commission secretariat

Horizontal roles

- Monitor compliance with Rules of Procedure
- Publish scientific advice of panels and, where necessary, justifications of notified bodies in case these do not follow expert advice
- Continuous monitoring of expert engagement & dossiers
- Issuing of contracts & budgetary planning & reimbursement depending on timely and satisfactory delivery
- Chair panels/sub-groups in case of duly justified cases & emergencies
- Organize and chair meetings of Coordination Committee
- Collect information on devices for yearly report by Commission (CECP only)



Importance of document management: confidentiality, sensitive information, publication



Data management

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CECP & PECP: key documents

CECP dossier

Expert documents

NB	CEAR (NB)	MDCG 2020-13 template
NB	Metadata (NB)	*On NB's CIRCABC space*
MF	CER (MF)	
MF	CEP (MF)	
MF	PMCF plan (MF)	MDCG 2020-7 template
MF	PMCF evaluation report* (MF)	MDCG 2020-8 template

Decision notification (CIRCABC)

Template
part 1) completed by Screeners

Opinion notification (CIRCABC)

Template
part 1) completed by Screeners
part 2) on scientific opinion

PECP dossier

NB	Metadata (NB)	*On NB's CIRCABC space*
MF	CER (MF)	

View notification (CIRCABC)

Template: Expert panel view on PER

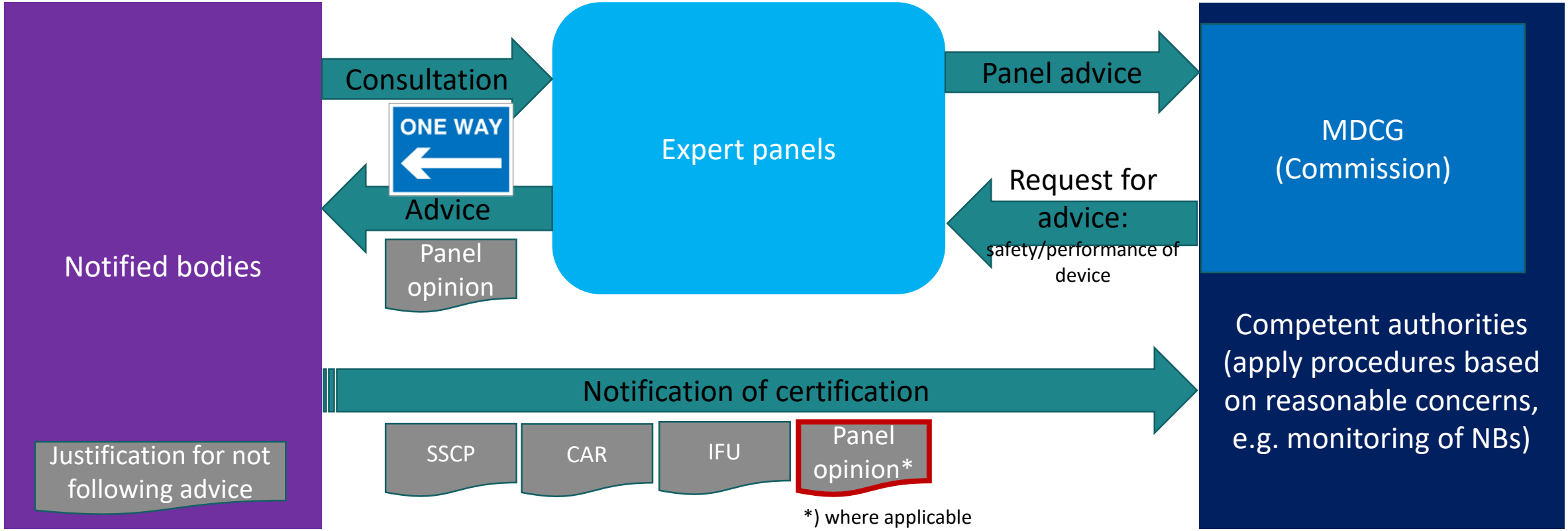
Experience so far

- Files submitted: 9 CECP, 10 PECP
- Opinions/views: 2 CECP, 1 PECP

https://ec.europa.eu/health/md_expertpanels/list-opinions-cecp_en

https://ec.europa.eu/health/md_expertpanels/list-opinions-pecp_en

Expert panel consultation & mechanism for scrutiny of specific high-risk devices



Consultation (Article 54):

- Harmonised evaluation of high risk devices by
  - sharing expertise
  - developing CS
- COM report to Parliament, Council, MS

Mechanism for scrutiny (Article 55):

- Scrutiny of high – risk devices
- Governance of NB work

Future regulation on HTA

- Joint clinical assessments

  medical devices classified as class IIb or III pursuant to Article 51 of Regulation (EU) 2017/745 for which the relevant expert panels have provided a scientific opinion in the framework of the CECP

  in vitro diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746 for which the relevant expert panels have provided their views in the framework of the PECP

  on decision of the Coordination Group by IA

Future regulation on HTA

- Joint scientific consultations

  Health technology developers - in order to obtain guidance on the information, data, analyses and other evidence that are likely to be required from clinical studies

  In parallel with those under Article 61(2) of Regulation (EU) 2017/745

  Joint scientific consultations on medical devices may take place in parallel with the consultation of the expert panels pursuant to Article 61(2) of Regulation (EU) 2017/745

  Health technology developers of medical devices may request that the joint scientific consultation takes place in parallel with the consultation of an expert panel– may include selection by Coordination Group

  Result - joint scientific consultation outcome document

Thank you