



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medical Device Regulation

- Expert panels for medical devices: role and function
- Patient and HCP potential involvement

Implications for EMA

PCWP/HCPWP joint meeting, 3 March 2023

Presented by Miguel Antunes – Experts Panels and Groups Office - EMA





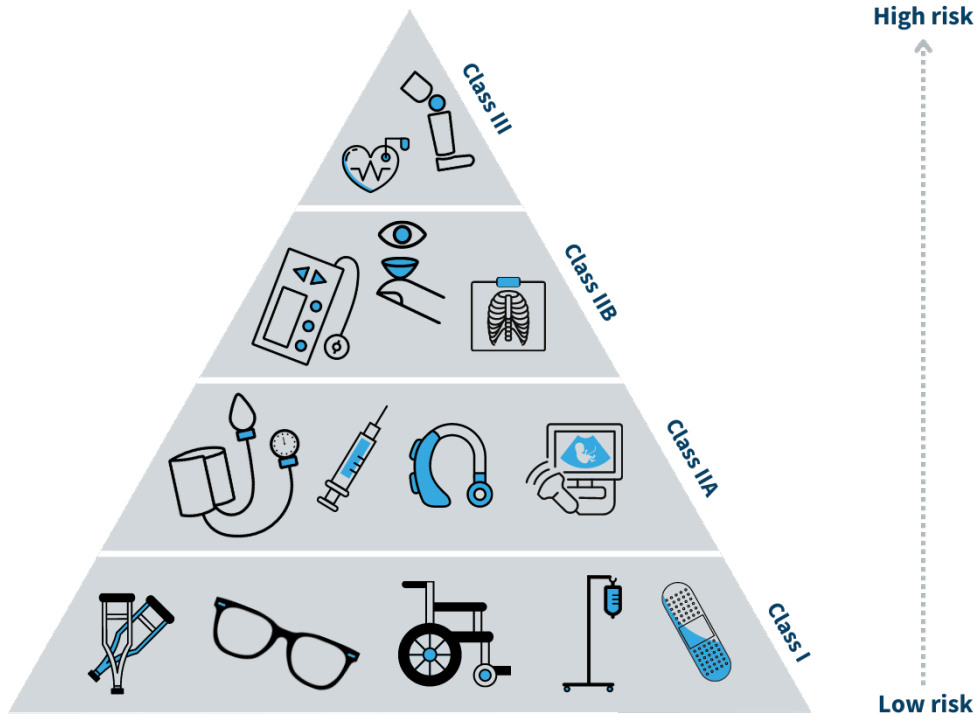
Outline

- Brief introduction to medical devices and *in vitro* medical devices
- Expert Panels' main activities
- Pilot on advice from the Expert Panels to manufacturers
- Discussion on patients and HCP potential involvement in EP activities



Brief introduction to medical devices and in vitro medical devices

Medical devices



<https://laegemiddelstyrelsen.dk/en/devices/>

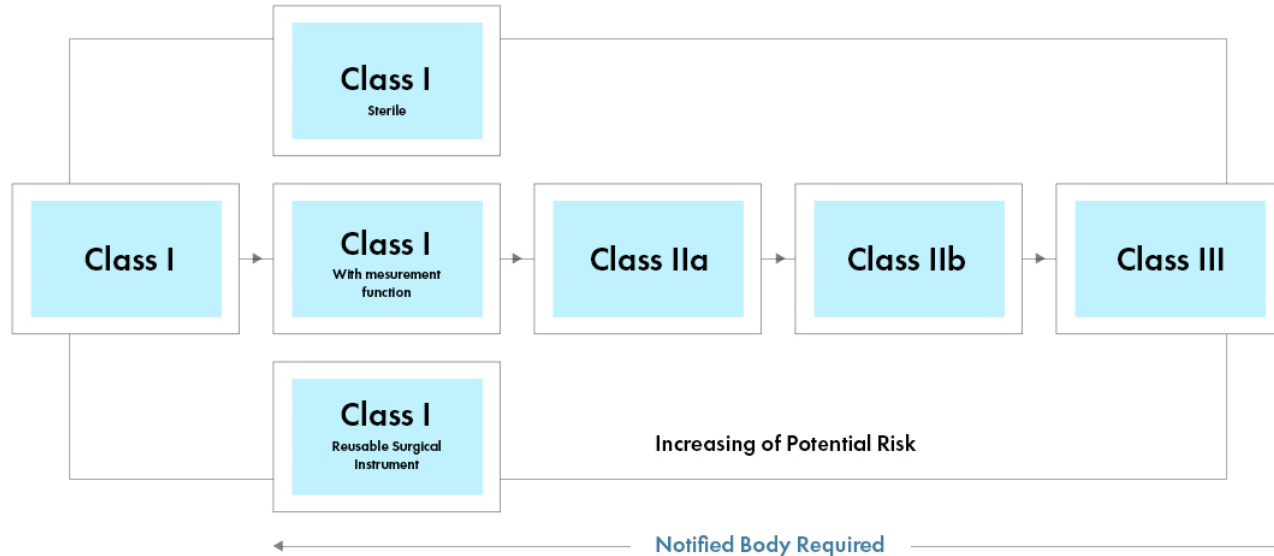
Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for specific medical purposes (...)

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Notified Bodies

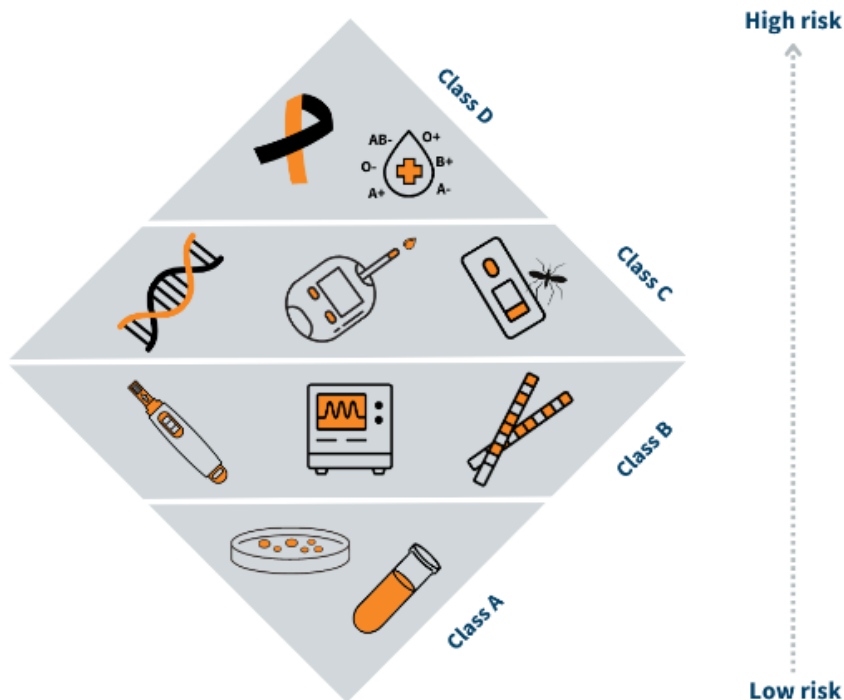


Organisations designated by EU Member States, either public or private, for assessing a device's compliance with EU legislation before it is placed on the market



Freyr. 2022

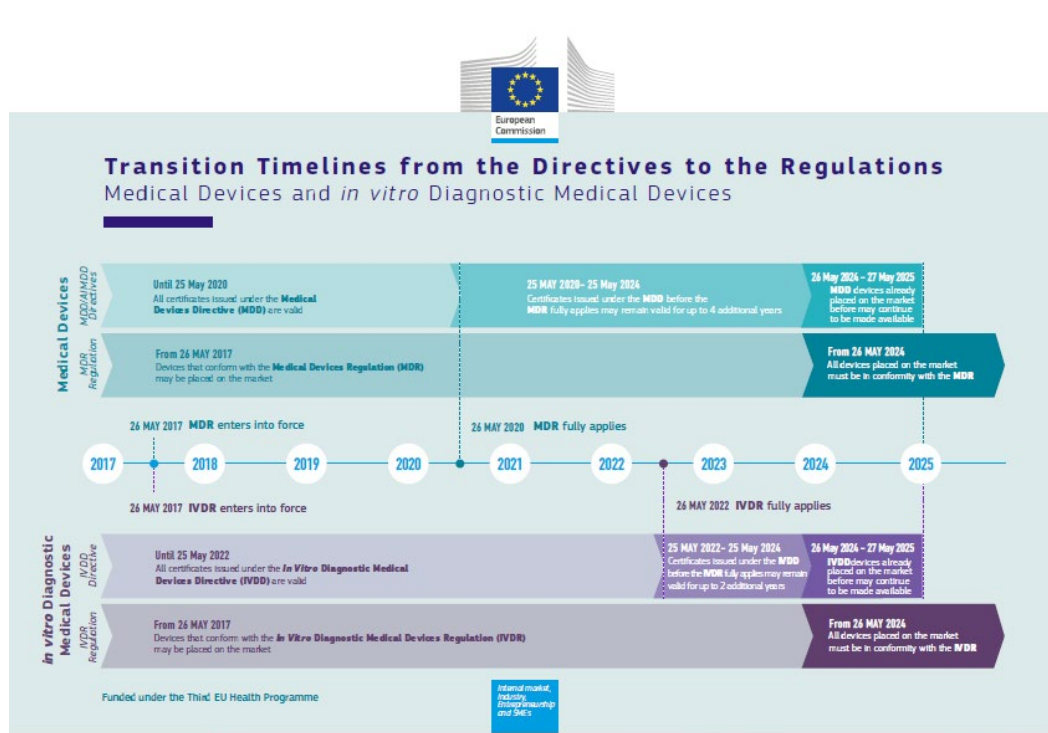
In vitro diagnostic medical devices



<https://laegemiddelstyrelsen.dk/en/devices/>

Any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, (...), intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on physiological or pathological process or state, congenital (...), predisposition to (...) condition or a disease, etc.

MDR and IVDR implementation



16 February 2023

The European Parliament adopted a position on the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices

Devices	Limit date
All other devices covered by a certificate	31/12/2028
Class III and IIb implantable	31/12/2027
class III implantable custom-made devices	26/05/2026



Expert Panels on medical devices: main activities



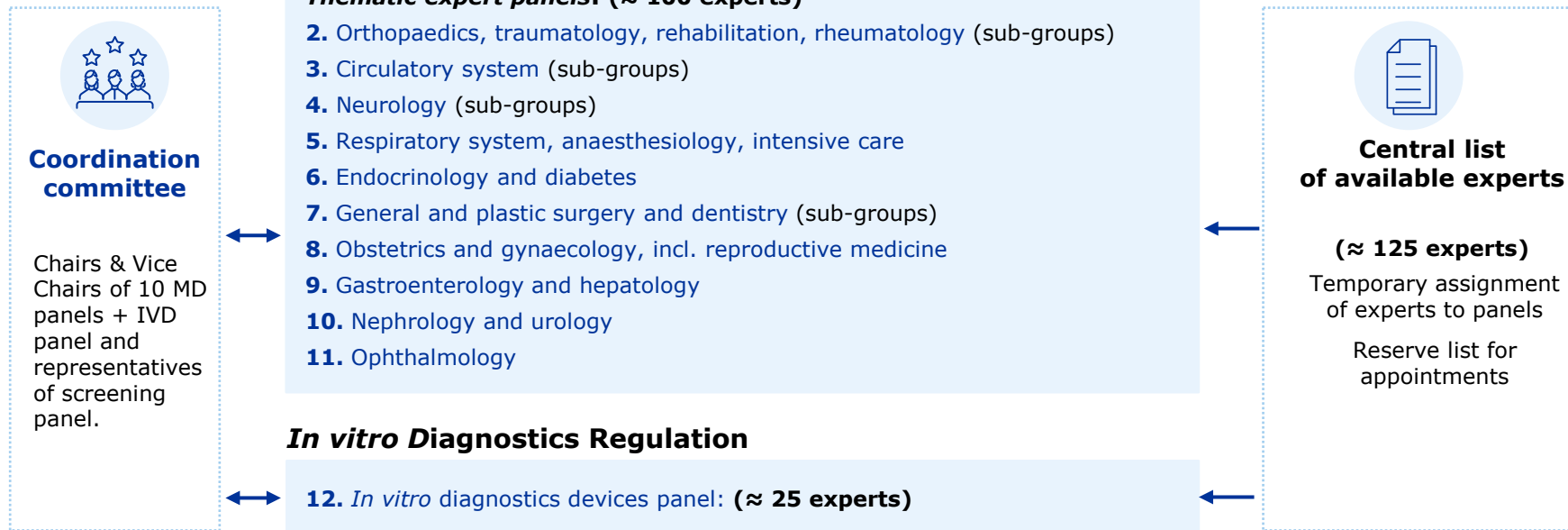
Expert Panels – What are they and who are the experts

- Created by the European Commission according to Articles 106 and 48(6) of the Medical Device Regulation (MDR) and the Regulation on *In Vitro* Medical Devices (IVDR) to support the **scientific assessment and advice** in the field of **medical devices** and ***in vitro* diagnostic medical devices**
- Panel members are **experts in their own field** appointed by the European Commission on the basis of their scientific, clinical and technical expertise following a **call for expression of interests**
- The **Secretariat** for the expert panels has been provided by the EMA (QA-EPG) since **1st March 2022** (before it was the Joint Research Center – JRC)



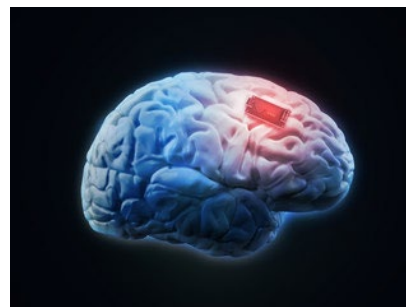
How are the Expert Panels organised

12 expert panels

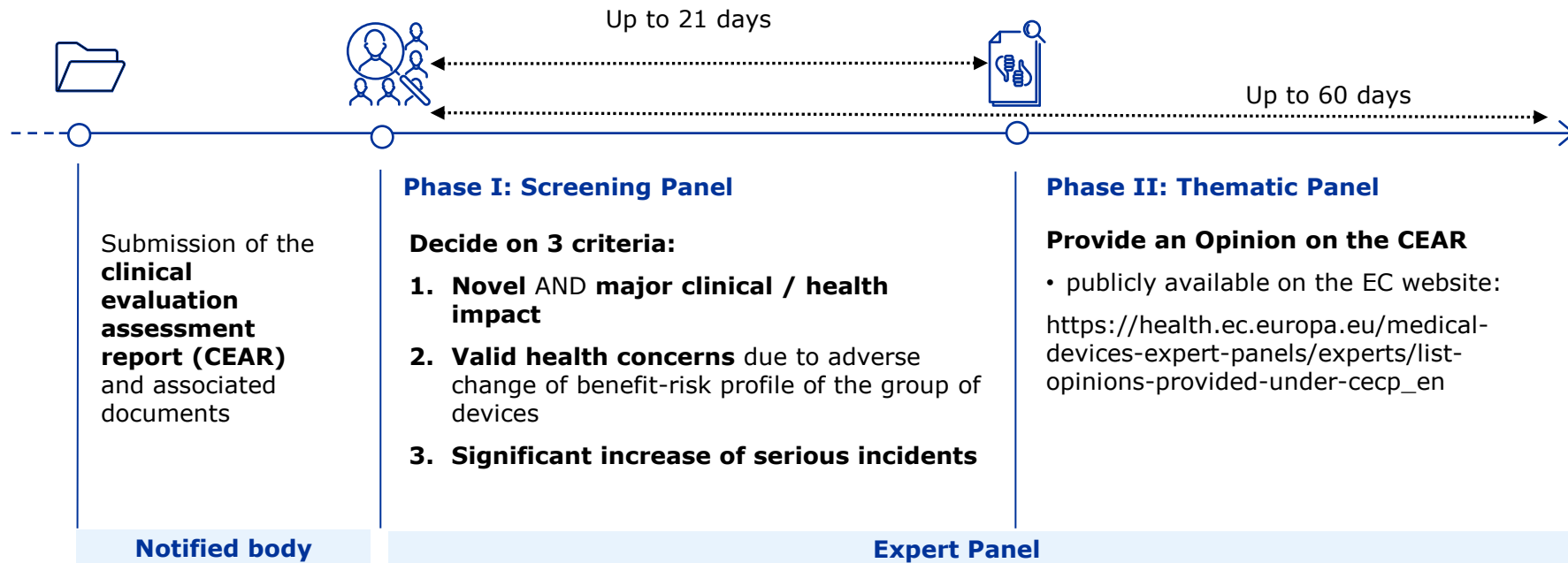


Clinical Evaluation Consultation Procedure (CECP)

- ✓ Class III implantable (e.g., pacemakers, ICDs, IPGs, breast implants, joint prosthesis)
- ✓ Class IIb active devices destined to administer and/or remove a medicinal product.



Clinical Evaluation Consultation Procedure (CECP)

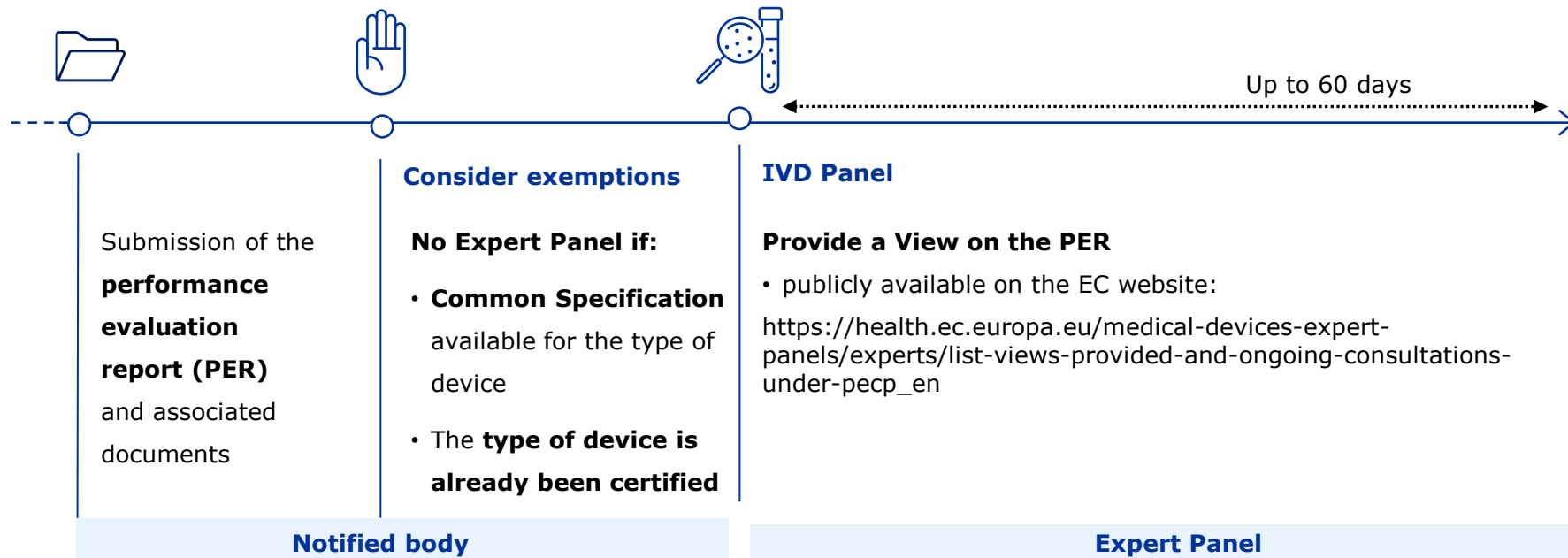


Performance Evaluation Consultation Procedure (PECP)

- ✓ Class D IVDs that detect a transmissible agent relevant for transfusional medicine or that causes a life-threatening disease with a potential high risk of propagation (e.g., SARS-CoV-2, HIV, HBV, HCV, *Treponema pallidum*)
- ✓ Class D IVDs for blood grouping in the systems AB0, Rhesus, Kell, Kidd and Duffy.



Performance Evaluation Consultation Procedure (PECP)





Expert Panels – advisory role (*ad hoc* activities)

- To the Medical Device Coordination Group (MDCG) and the European Commission concerning **safety and performance** of high-risk medical devices and *in vitro* diagnostics
- To contribute to the development and maintenance of appropriate **guidance** and **Common Specifications**
- To manufacturers on their **clinical development strategy and proposals for clinical investigations** for all **class III devices** and **class IIb active devices intended to administer and/or remove a medicinal product** (Art. 61(2))



Pilot on advice from the Expert Panels to manufacturers



Pilot Scientific Advice – Objective and selection of applications

- **Objective of the pilot:** to build an efficient process, adapted to the MedTech's specificities sector
- **10 SA procedures** will be taken for the pilot **(5+5)**
- In case the number of requests exceeds that number, a **selection process** will be applied:
 - ✓ Devices intended to benefit a relatively **small group of patients** in the treatment or diagnosis of a disease or condition (e.g. "orphan devices", devices for paediatric use only)
 - ✓ Devices for **unmet medical needs** i.e., medical conditions that are life threatening or cause permanent impairment of a body function AND for which current medical alternatives are insufficient or carry significant risks ("breakthrough device" - MEDDEV 2.7/1 rev.4, Appendix 8)
 - ✓ **Novel devices** with a possible **major clinical or health impact.**



European
Commission

European Health Union: Supporting the transition to the new medical device framework

Measures for a successful transition in the longer term



Pilot project on **scientific advice for clinical development strategies** for high-risk devices



Targeted **support for SMEs** through the Enterprise Europe Network



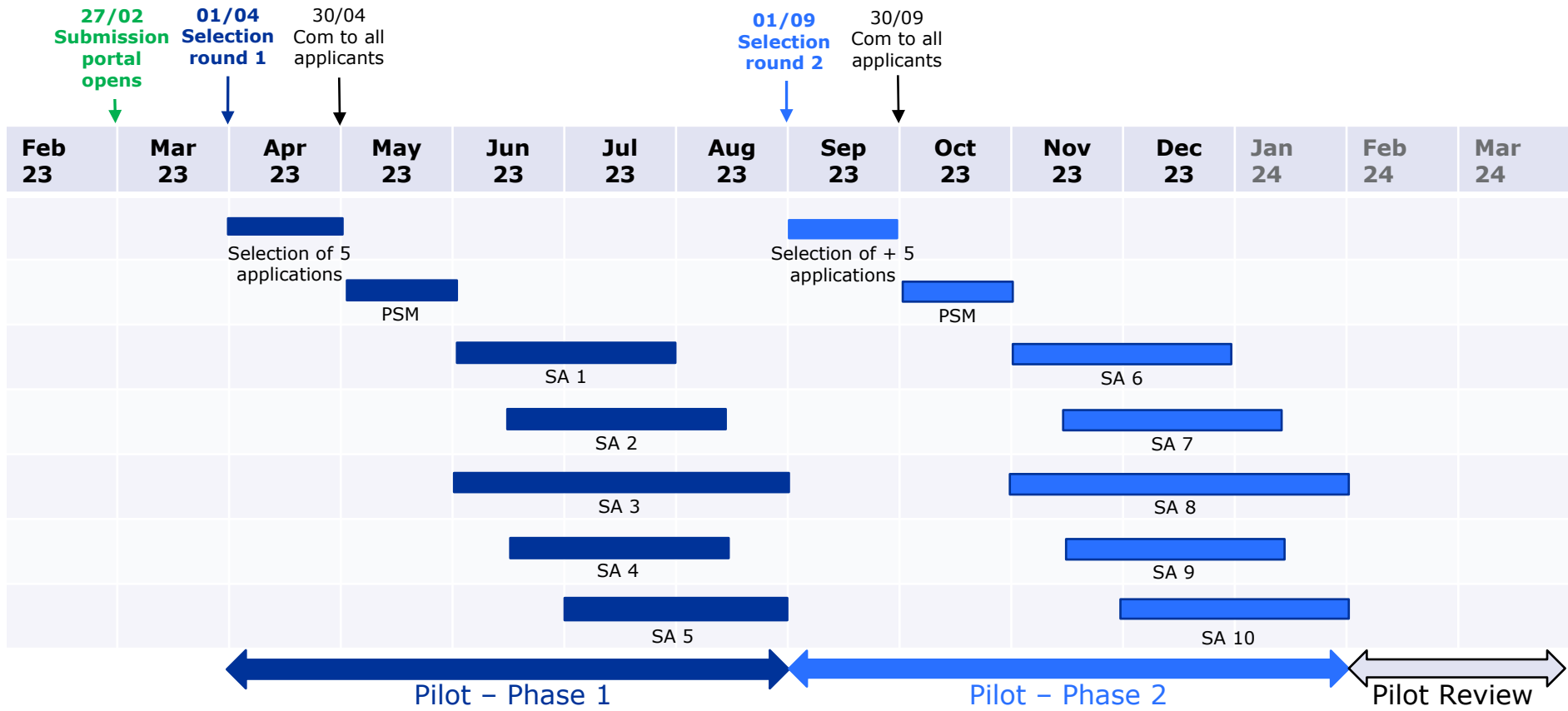
Tailored **solutions for orphan devices**

Orphan devices are crucial for treating relatively small group of patients, especially children.

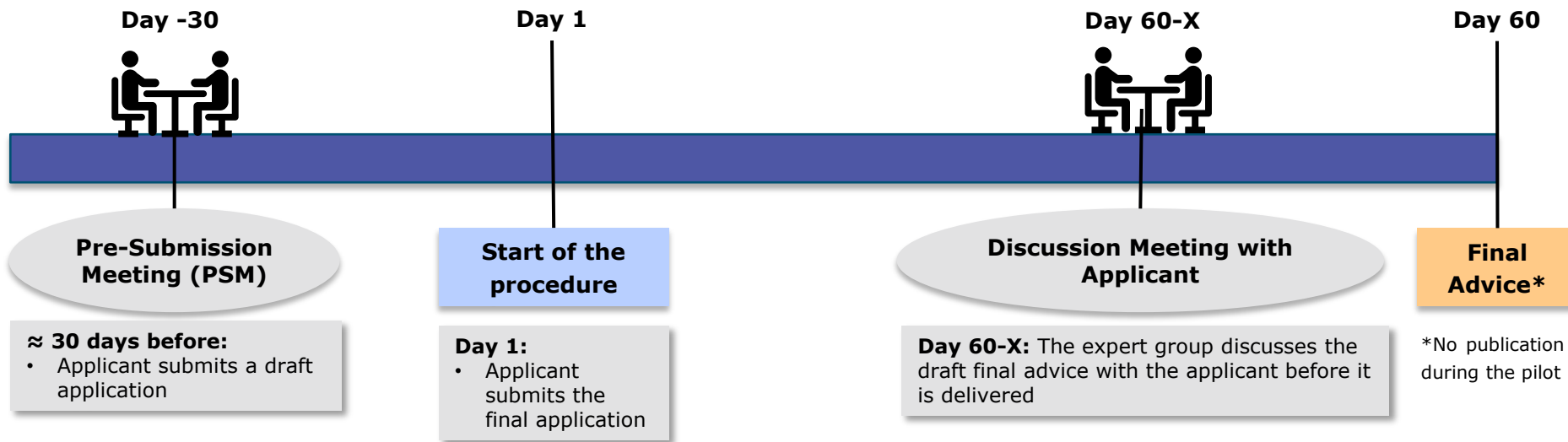
Small and Medium sized Enterprises (SMEs) represent around **95% of medical device manufacturers** in Europe.



Pilot Scientific Advice – Timeline (tentative)



Pilot Scientific Advice – Process Overview



- **No fees** for the applicants during the piloting phase
- The process **timeline may vary slightly**, depending on expert's availability and the nature of the request
- The consideration given to the proposals made in the advice needs to be documented in the manufacturer's **Clinical Evaluation Report (CER)**



Discussion on patients and HCP potential involvement in EP activities



Provision in the Medical Device Regulation (MDR) regarding patients and healthcare professionals' input in expert panels' procedures

MDR Art. 106 (4): *"Expert panels shall take into account relevant information provided by stakeholders including patients' organisations and healthcare professionals when preparing their scientific opinions."*

- EP => **250 medical experts** who are active practitioners and members of Academia and/or clinical and scientific Societies:
https://health.ec.europa.eu/medical-devices-expert-panels/experts/expert-panels_en
- EP => **25 IVD experts** (technology and infectious disease epidemiology) members of Academia and/or clinical and scientific Societies:
https://health.ec.europa.eu/medical-devices-expert-panels/experts/expert-panels_en
- EP => **50 technical experts** on all types of medical technology:
https://health.ec.europa.eu/document/download/e2da2cac-878d-4b1d-8274-2daa842a72ca_en?filename=md_expert-panels_central_list_available_experts_en.pdf



How to collect patients and healthcare professionals input

- Safety issues regarding individual devices or groups/categories of devices are captured and assessed by the **vigilance systems** set up at national level by the Member States
- Patients and HCP contribute actively to the system reporting on **incidents** associated with medical devices
- Manufacturers also play a very important role in these systems, collecting and analyzing incidents potentially associated with the use of their device
- Expert panel Secretariat to liaise with the **Post-market surveillance and vigilance (PMSV)** to collect relevant information for the consultation procedures
- **Specific groups/categories of devices** could be identified by the expert panels for input.



Any questions?

Further information: EU-OPERATIONS-EXPAMED@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Telephone +31 (0)88 781 6000

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