EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Overview of EMA activities in the area of medical devices

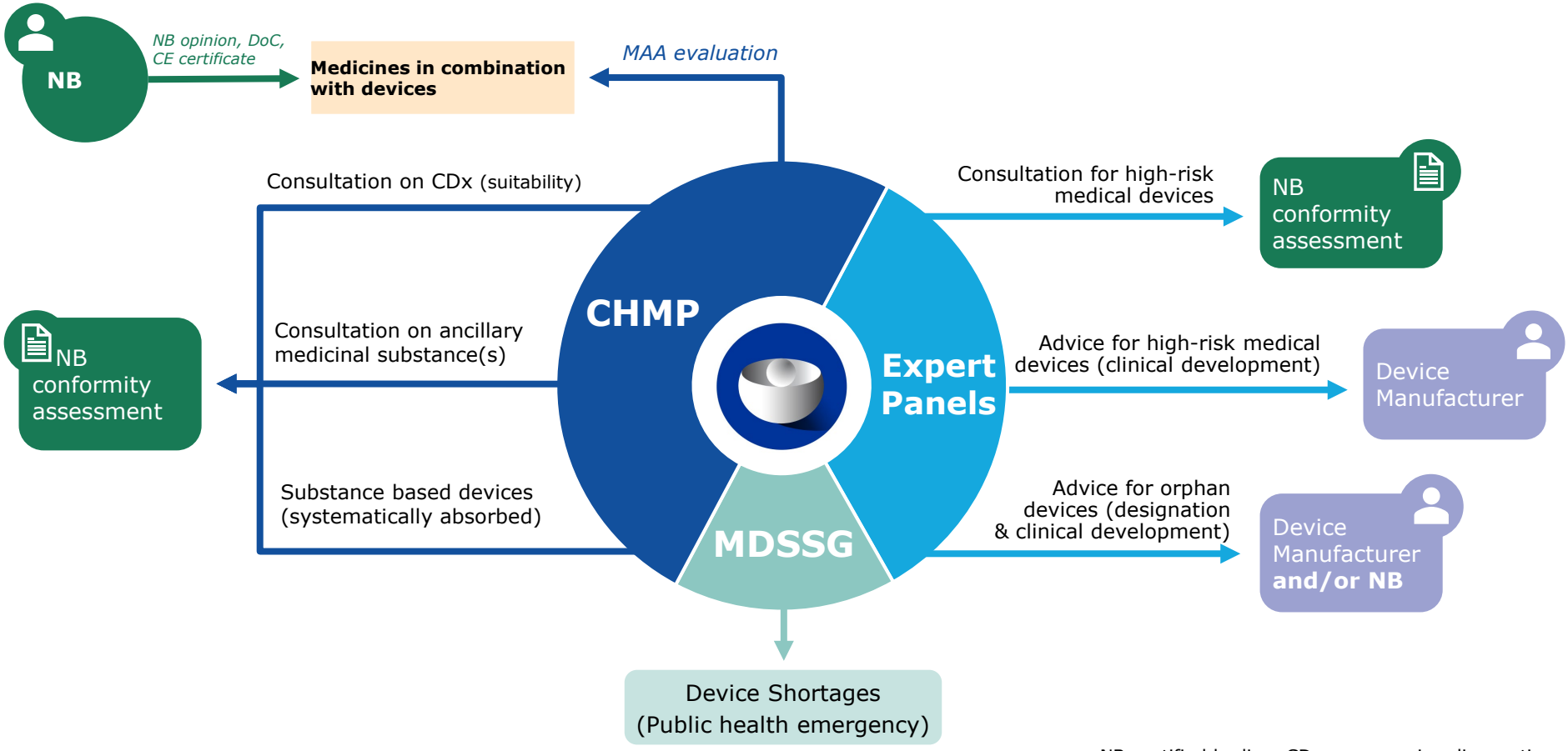
PCWP/HCPWP and all eligible organisations meeting

20 November 2024

Silvy da Rocha Dias
Head of Expert Panels and Groups Office

EMA roles and responsibilities for Medical Devices

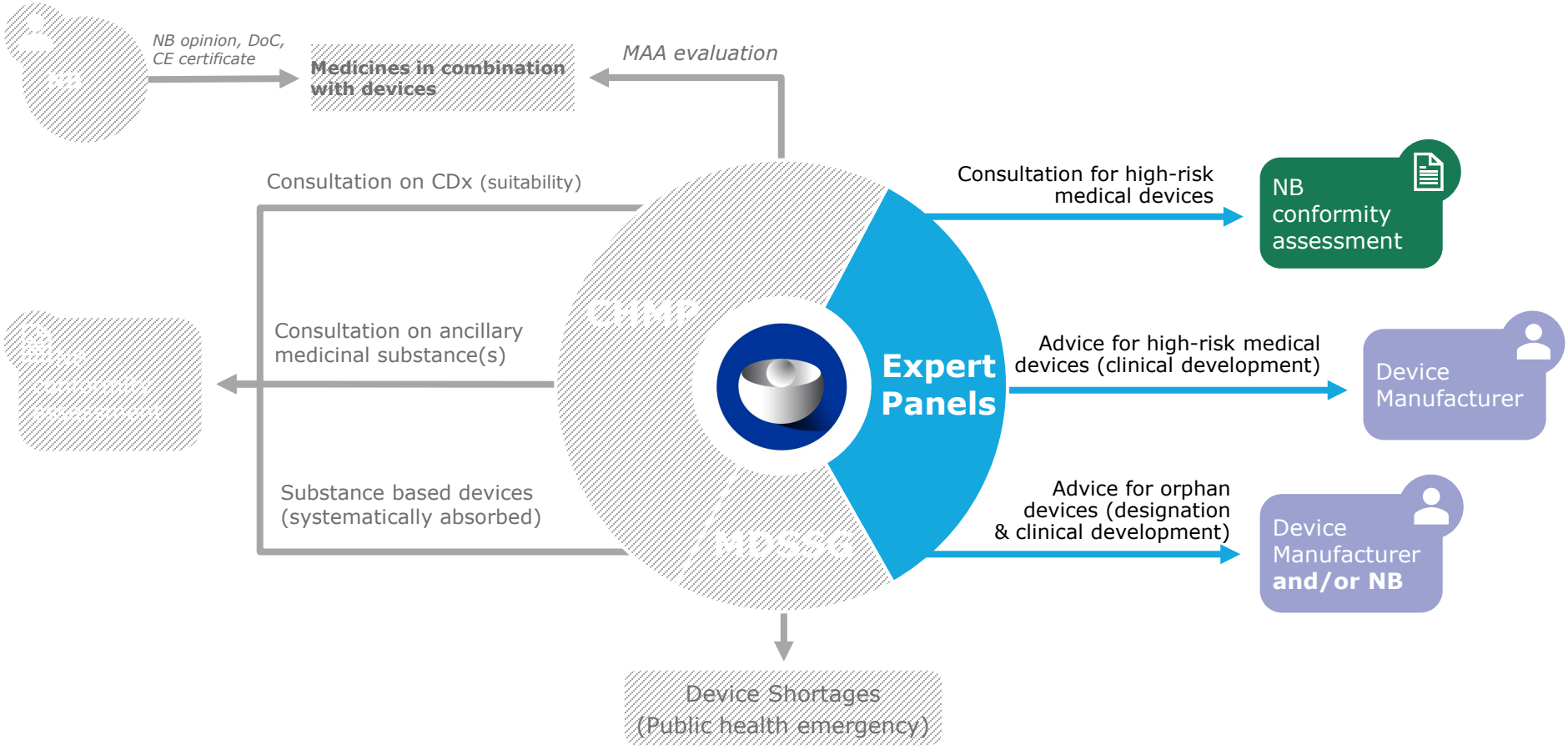
EUROPEAN MEDICINES AGENCY



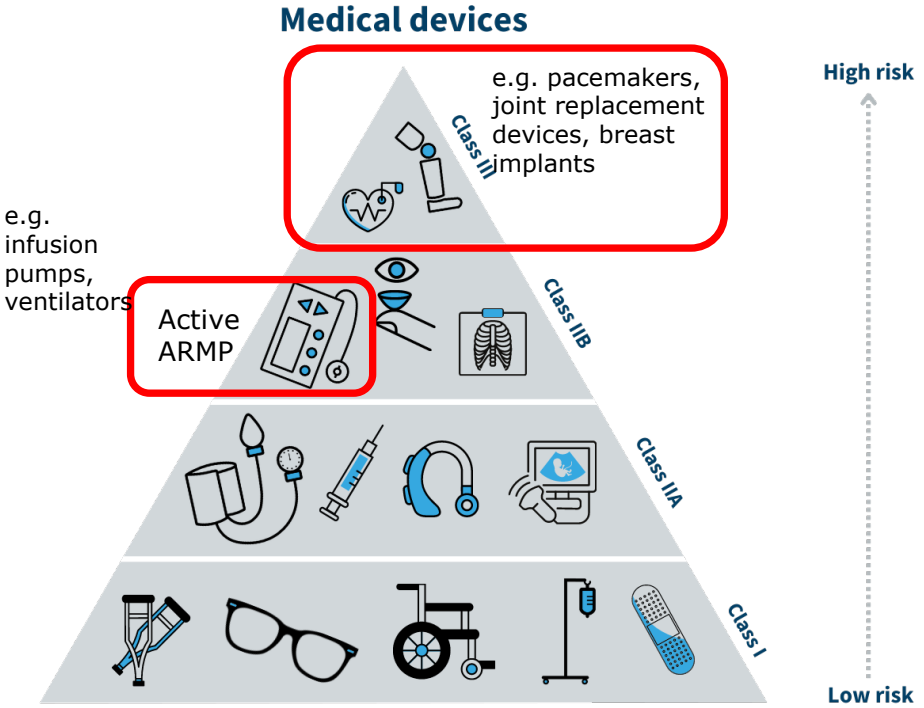
NB- notified bodies; CDx – companion diagnostics

EMA roles and responsibilities for Medical Devices

EUROPEAN MEDICINES AGENCY



`High-risk` Medical devices



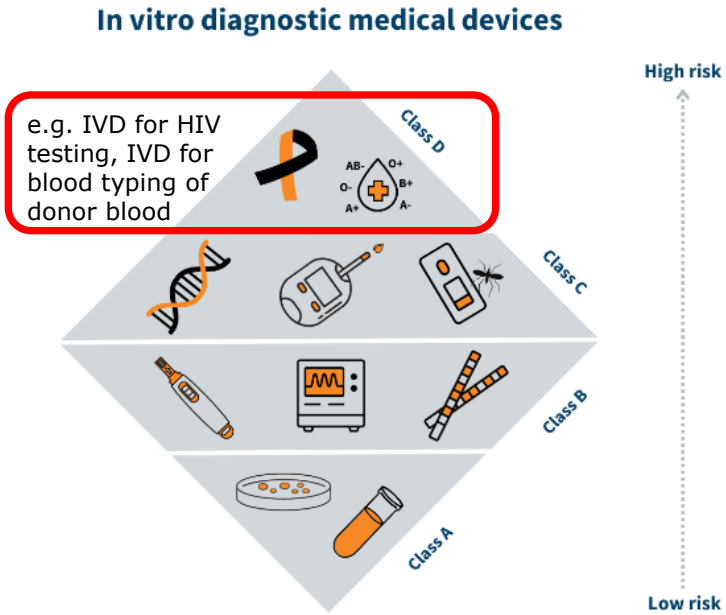
https://laegemiddelstyrelsen.dk/en/devices/

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.

Regulation (EU) 2017/745 – MDR

`High-risk` In vitro diagnostic (IVD) medical 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.

Regulation (EU) 2017/746 – IVDR

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

Medical device Expert Panels

Group of independent advisors set-up according to Articles 106 and 48(6) of the medical device Regulation (MDR) and the *in vitro* diagnostic devices Regulation (IVDR), respectively, to support the **scientific assessment and advice of medical devices** (including IVD)

EMA provides the administrative and technical **Secretariat support** since **1 March 2022**

Advisory role:

- Opinions and views to **notified bodies**
- To **manufacturers** on their clinical development strategy/proposals for clinical investigations
- To **EC and MDCG** on the safety and performance of any device

Expert Panels – structure of the panels

Coordination committee

Chairs & Vice Chairs of 11 thematic panels + representatives of screening panel.

1. Screening panel

Thematic expert panels

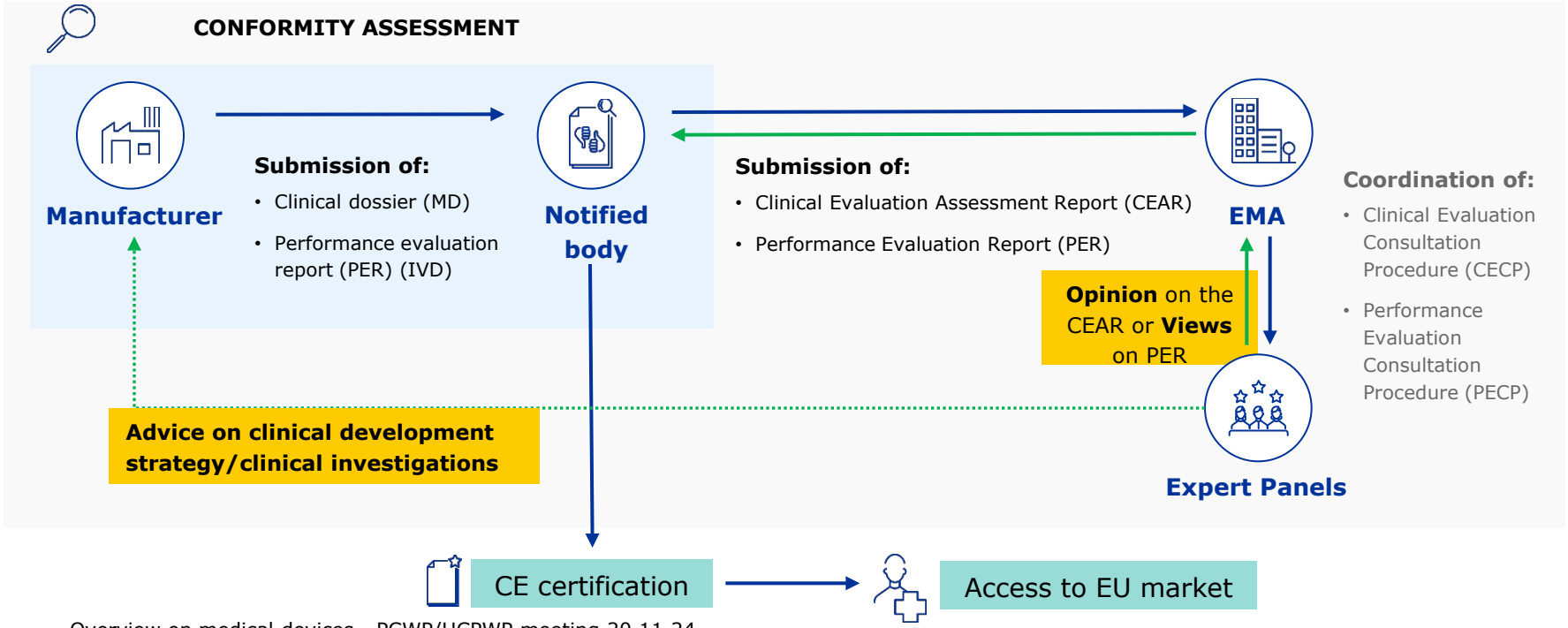
2. Orthopaedics, traumatology, rehabilitation, rheumatology (sub-groups)
3. Circulatory system (sub-groups)
4. Neurology (sub-groups)
5. Respiratory system, anaesthesiology, intensive care
6. Endocrinology and diabetes
7. General and plastic surgery and dentistry (sub-groups)
8. Obstetrics and gynaecology,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

Central list of available experts

Temporary assignment of experts to panels

Reserve list for appointments

Medical device Expert Panels in the regulatory framework



Overview on medical devices - PCWP/HCPWP meeting 20.11.24

Impact of published opinions

Medtech Insight
Informa Pharma Intelligence

Expert Panel Opinion Defers EU Market Entry For Tricuspid Valve Replacement System

26 Aug 2022 | NEWS

by Amanda Maxwell | @MedtechAmanda | amanda.maxwell@informa.com

Executive Summary

Once again, an EU expert panel has challenged the adequacy of a notified body review of the manufacturer's clinical evaluation report, clearly tightening up on high-risk device oversight.

The expert panel specializing in the circulatory system has evaluated a notified body clinical assessment of a completely new class III implantable device used in cardiology, a tricuspid valve replacement system and called for more studies.

The product has no CE marking. Indeed this is the first tricuspid replacement system where a company has applied for conformity assessment by a notified body as required for CE marking, the opinion states.

There are currently no other valve replacement options available on the market for this intended purpose.

The panel's subgroup on prosthetic heart valves and devices for heart valve repair has found that the notified body's assessment of the adequacy of the manufacturer's benefit-risk determination for this highly novel device is "not sufficiently thorough".

Medtech Insight
Informa Pharma Intelligence

How Expert Panel Deep Dive Reviews Are Challenging Clinical Data And Setting

28 Jul 2022 | NEWS

by Amanda Maxwell | @MedtechAmanda | amanda.maxwell@informa.com

Executive Summary

Latest opinion published by circulatory system expert panel review challenges part of notified body risk/benefit assessment.

After a hiatus of some five months, a new EU expert panel opinion has been published for a class III implantable medical device. This is only the fourth expert panel review published so far under the Medical Device Regulation, which fully applied from 26 May 2021.

The circulatory system expert panel has reviewed a transcatheter heart valve and published an expert decision and opinion in the context of the Clinical Evaluation Consultation Procedure (CECP), dated 27 May, for new indications for a transcatheter heart valve.

Transcatheter aortic valve implantation (TAVI), or transcatheter aortic valve replacement, is a minimally invasive heart procedure, conducted through the blood vessels, to replace a thickened aortic valve that

Expert Panel – Advice to the MDCG

6 requests received from MDCG: **5 advice reports** delivered (1 in progress)

Influenza virus: transmissibility and virulence of certain strains (for IVD classification purposes). Appropriateness & feasibility for development of Common Specifications for Class D IVDs targeting influenza virus

SARS-CoV-2 Neutralizing Antibody Assay: performance evaluation method

Monkeypox: transmissibility, virulence and disease characteristics

Indirect antiglobulin test used in transfusion medicine and determination of fetal-maternal blood grouping incompatibility

SARS-CoV-2 and respiratory infectious agents in general: transmissibility, virulence, consequences of false negative tests for detection of viruses *(in progress)*

Paclitaxel-eluting stents in peripheral arterial disease

Pilot on advice to medical device manufacturers

Period

Feb 2023 – end of 2024

Reopen 2025

Remit

Class III devices or IIb active devices to administer/remove medicines (MDR Art 61(2))

Area of advice

Clinical (clinical strategy and/or proposals for clinical investigations)

Fees

No fees during the pilot phase

Applicants

Manufacturers/authorised representatives established in the EEA

Procedures

3 rounds of applications to balance with the mandatory activities.

More information: EMA Web on medical devices and EU-operations-expamed

Advice to manufacturer process

1. **Exploratory meeting**
2. **Pre-submission meeting**
3. **Start of 60D procedure**
4. **Discussion with Applicant**
5. **Final advice letter**

At least 2 months prior to the start of every procedure:
- Meet with applicant to confirm admissibility/scope of advice
- High-level discussion on the procedure

Preliminary phase
- 1st Draft of briefing document submitted by applicant

Evaluation phase
- Kick off meeting
- Exchange between experts from the panel

Final recommendation phase
- Clarification of remaining issues
- Agreement on the final advice by the Expert Panel

Delivery of advice
- Final meeting of expert panels to adopt the final advice
- Advice sent to the manufacturer