EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Overview of the screening criteria for the clinical evaluation consultation report (CECP)

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Clinical Evaluation Consultation Procedure (CECP)

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

Consider the legal requirements

Type of device

- For class III implantable e.g. pacemakers, joint replacement devices, breast implants
- For class IIb active intended to administer/ remove medicinal product e.g. infusion pumps, ventilators

Consider exemptions

No Expert Panel if:

- Renewal of certification under MDR
- Same manufacturer/intended purpose and modification does not affect B/R
- CS available for the clinical evaluation of that type of

Phase I: Screening Panel

Decide on 3 criteria:

1. Novel AND major clinical / health impact
2. Valid health concerns due to adverse change of B/R profile of the group of devices
3. **Significant increase of serious incidents**

Phase II: Thematic Panel

Provide an Opinion

- Opinion publicly available on EC website
- NB need to give it due consideration

Notified body | **Expert Panel**

Clinical Evaluation Consultation Procedure (CECP)

- **All Class III implantable devices**
- **10 Opinions delivered in total**
  - 8 based on criterion 1 (clinical/health impact related to novelty aspects)
  - 2 based on criterion 2 (valid health concerns for a specific group/category of devices)

Thematic area	Number of opinions	Type of device
Circulatory system	5	- Transcatheter pulmonary valve - Transcatheter aortic valve - Transcatheter tricuspid valve replacement - Bioabsorbable stent (paediatric use) - Extravascular ICD
Orthopaedics, traumatology, rehabilitation , rheumatology	2	- Hip prosthesis - Shoulder prosthesis **-> criterion 2**
General and plastic surgery and dentistry	2	- Bone filler - Resorbable hernia surgical mesh **-> criterion 2**
Neurology	1	- Implantable neurostimulator
Total	**10**	