EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4. Medical device expert panels' activities:

4.1. Update on the mandatory activities

4.2. State of play of the ongoing pilot on advice to medical device manufacturers

Industry Standing Group (ISG) meeting, 21 September 2023

Silvy da Rocha Dias (HoO), Miguel Antunes – Expert Panels and Groups Office

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State of play for CECPs and PECPs

CECP

- **68 files** submitted **- 87%** class III implantable devices and **13%** class IIb active ARMP devices:
  - **10 opinions** published

Expert panels' thematic areas	Number of files submitted
Circulatory system	23
Orthopaedics, traumatology, rehabilitation , rheumatology	15
Neurology	12
General and plastic surgery and dentistry	9
Respiratory system, anaesthesiology, intensive care	6 (all ARMP)
Endocrinology and diabetes	1
Gastroenterology and hepatology	1
Nephrology and urology	1
Total	**68**

PECP

- **18 files** submitted **(2 ongoing: HEV IgM and IgG IVDs):**
  - **16 views** published

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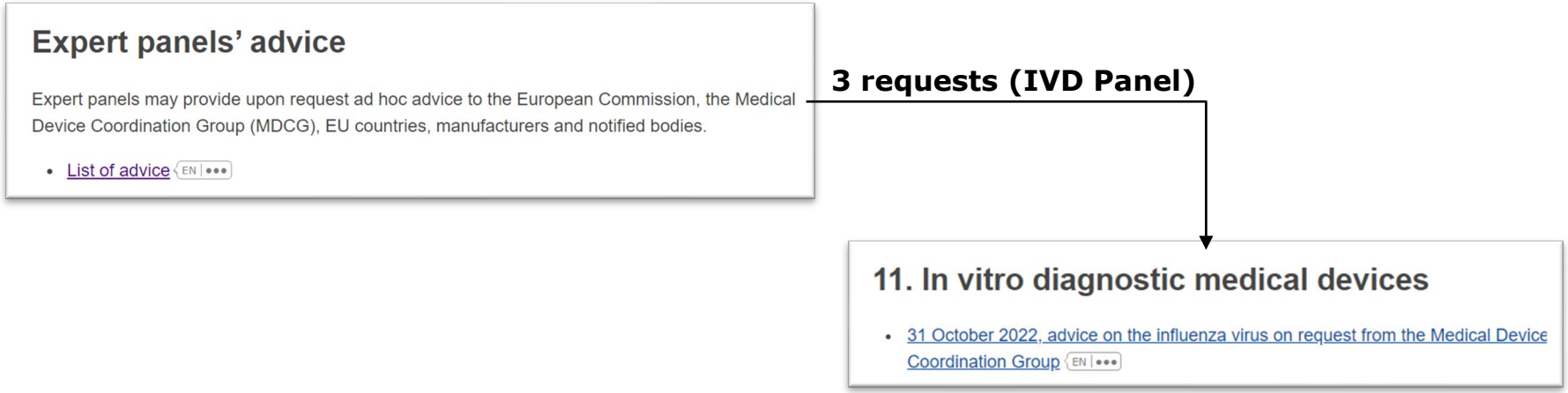
Advice to the MDCG and the Commission

https://health.ec.europa.eu/medical-devices-expert-panels/work-expert-panels_en



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Pilot on advice to Medical Devices' manufacturers

- **Selection criteria:**

  ✓ 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)

  ✓ 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**

- **Different clinical areas** and **types of devices** represented

State of play of the pilot on advice to MD manufacturers

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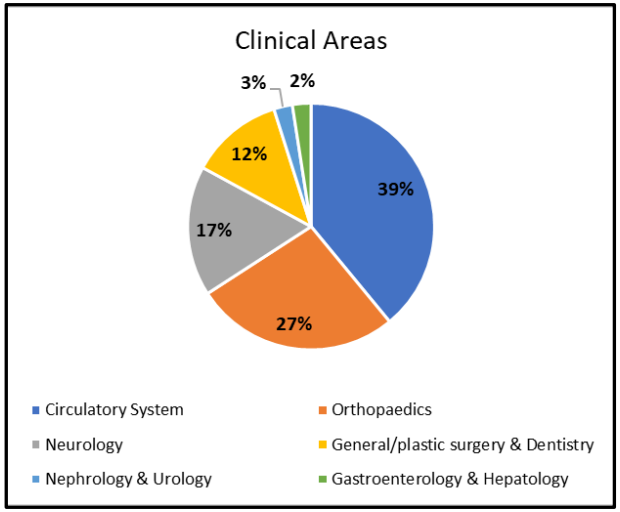
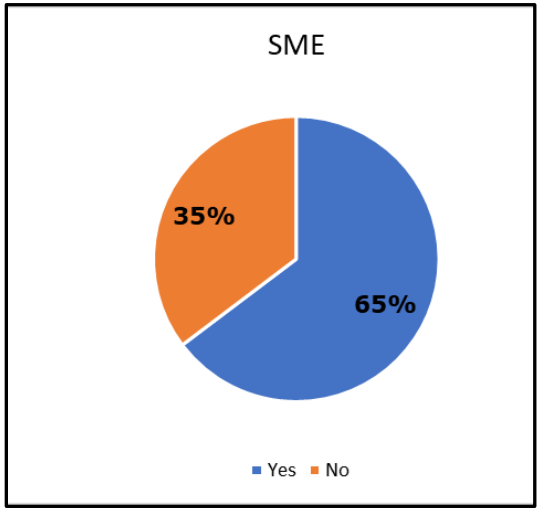
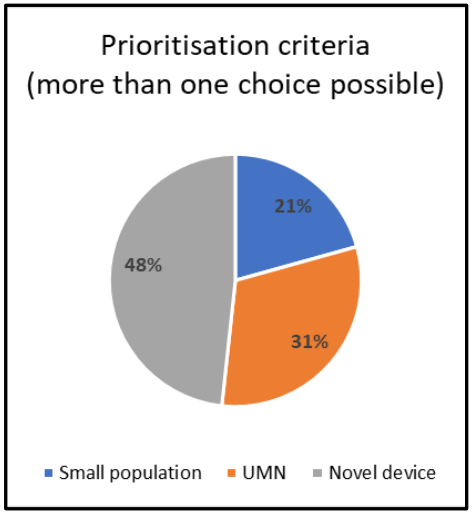
Pilot on advice to manufacturers: 41 letters of interest







Different phases of development of the device:
• FIH / pilot study
• Pivotal study
• Full clinical strategy (study designs for approval + PMCF plan)
• Advice on ongoing studies

Final messages

- **Very high interest from the developers** of high-risk medical devices in taking part on the pilot for advice
- **Developers' preparedness** for scientific advice was already identified as a key factor for a straightforward process: scientific officers will provide **more dedicated input to the applicants** throughout the process
- Both the mandatory scope and *ad hoc* advice are run in parallel, therefore **accurate forecasting** is needed for **predictability**

Any questions?

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