EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA pilots scientific advice for certain high-risk medical devices

News 27/02/2023

EMA has launched a pilot to give scientific advice on the intended clinical development strategy and proposals for clinical investigation for certain high-risk medical devices (all class III devices and class IIb active devices intended to administer and/or remove medicinal product(s)). As of today, manufacturers can submit their letter of interest to be part of the pilot on scientific advice which will be provided by the medical device expert panels.

The expert panels will provide free advice to ten selected applicants on their clinical development strategy and/or proposals for clinical investigation. The pilot will last approximately one year and will help to establish an efficient scientific advice procedure. Scientific advice is a key tool to foster innovation and promotes faster patient access to safer and more effective devices.

The pilot will prioritise certain types of medical devices:

- devices that benefit a small group of patients in the treatment or diagnosis of a disease or condition, such as devices intended for the treatment of a rare condition, known as 'orphan devices', and devices for paediatric use;
- devices addressing 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;
- novel devices with a possible major clinical or health impact.

More information on the process and the selection criteria is available on EMA's website.

The first five applications will be selected in April. Small and medium-sized enterprises are strongly encouraged to submit their letters of interest.

Once the pilot has been completed, EMA will assess the process and the applicant's and experts' experience, and will hold a meeting with stakeholders to discuss potential improvements.

More on the medical device expert panels and scientific advice

The medical device expert panels provide opinions and views on the clinical assessment conducted by notified bodies in the context of the certification of certain high-risk medical

devices and in vitro medical device diagnostics.

EMA took over the coordination of the medical device expert panels on 1 March 2022 as part of its extended mandate on crisis preparedness and management of medicinal products and medical devices under Regulation (EU) 2022/123.

Related content

- Medical devices: High-risk medical devices
- Information session on the pilot for expert panels' scientific advice to manufacturers of high-risk medical devices (25/01/2023)

External links

- Regulation (EU) 2022/123

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