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New pilot programme to support orphan medical devices

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Free advice and guidance available for manufacturers and notified bodies

News Human

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EMA has launched a pilot programme for expert panels to support the development and assessment of orphan medical devices in the European Union (EU). The pilot programme offers free advice from the medical device expert panels to selected manufacturers and notified bodies on the orphan device status and the data needed for their clinical evaluation. While the pilot programme is currently scheduled to run until the end of 2025, the aim is to establish a long-term process for orphan device support.

Orphan devices are medical devices which are intended to be used for diseases or conditions affecting only a small number of individuals each year (not more than 12,000 individuals in the EU per year). Often they are used to treat or diagnose rare diseases or conditions for which no or insufficient alternative diagnostic or therapeutic options exist, thereby fulfilling an unmet medical need.

Manufacturers can consult the expert panels at different stages of the development of the clinical strategy for their device, while notified bodies can request advice at specific moments of the ongoing conformity assessment of the device. As part of the pilot programme, EMA will prioritise certain types of orphan medical devices, such as devices for treating a medical condition that is life-threatening or that could cause permanent impairment of a body function, devices intended for children, and novel devices with potential major clinical benefit.

In June 2024, the European Commission announced new guidance on the clinical evaluation of orphan medical devices issued by the Medical Device Coordination Group, which is composed of representatives of all EU Member States. This guidance provides the criteria to determine when a medical device should be regarded as an orphan device under the EU Medical Devices Regulation and aims to guide manufacturers and notified bodies when applying the clinical evidence requirements.

This pilot programme is part of EMA's regulatory support for the expert panels on medical devices, following the introduction of new legislation in the EU. Since 1 March 2022, the Agency supports the medical device expert panels

that provide opinions and views to notified bodies on the scientific assessment of clinical and performance evaluations of certain high-risk medical devices and in vitro diagnostic medical devices.

Early advice to manufacturers, particularly to small and medium-sized enterprises, is a key tool to foster innovation and accessibility to safer and effective devices that address patients' needs. The orphan device pilot will run in parallel to the scientific advice pilot to manufacturers which already prioritised advice to manufacturers on the clinical development strategy and clinical investigations of devices addressing unmet needs.

Related content

Medical devices

Information session on the pilot for expert panels' advice for orphan medical devices

External content

European Commission: Press release on the new guidance on the clinical evaluation of orphan medical devices published

Medical Device Coordination Group: Guidance on the clinical evaluation of orphan medical devices published

Medical Device Coordination Group Working Groups

EU Medical Devices Regulation

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