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Symplifying instructions for use of medical devices

Digitalisation of healthcare systems

Healthcare professionals will be able to receive instructions for use of medical devices in electronic format, rather than solely on paper, following a regulation of the European Commission presented at the end of June.

The regulation applies to all medical devices used by healthcare professionals within the EU. Professionals can still request paper versions if preferred. The adoption of electronic instructions for use is a part of the commission's broader initiative to modernise healthcare, support environmental sustainability, and alleviate financial and administrative pressures on device manufacturers. The measure was broadly supported in recent consultations of the European Commission with professionals and industry representatives.

The announcement is part of the commission's ongoing work to streamline and improve the EU's rules for medical devices. In the coming days, the commission will adopt a decision to establish an expert panel to provide scientific and clinical advice concerning devices intended for small patient populations, such as children or patients with a rare disease.

The commission is furthermore carrying out an evaluation of the regulatory framework, with a view to a revision of the legislation for medical devices and *in vitro* diagnostics, to reduce unnecessary burden and make the requirements more cost-efficient and proportionate. This will ensure a secure supply of safe devices for EU patients, while supporting innovation and boosting the competitiveness of the EU's medical devices sector. This evaluation and its follow-up actions will be presented in December, when commissioner Várhelyi will host a conference on medical devices in Brussels.

Source: EU Commission, Directorate-General for Health and Food Safety on 25 June 2025