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Joint Statement Supporting the Expansion of the Use of eIFU in the Medical Devices Sector

Medical Device Regulation (MDR) requires manufacturers to provide detailed instructions for use (IFU) to guide proper and safe use of medical devices and products. Regulation (EU) 2021/2226 (eIFU Regulation) establishes the conditions under which instructions for use may be provided in electronic form only. Although the eIFU Regulation acknowledges that the provision of instructions for use in electronic form instead of in paper form can be beneficial, its scope is limited to specific categories of devices.

With the rapid evolution of technology and practices, the undersigned organizations believe that the eIFU Regulation no longer reflects the generally acknowledged state of the art and falls short of the needed legislation for a digital era. **We therefore propose a targeted update to the scope of the Regulation (EU) 2021/2226 to encourage a level playing field.**

Stakeholders have been asked to provide supportive data which would show that there is no safety concern to move from paper IFU to eIFU and that users feel comfortable using an electronic format. Several organizations conducted **data collection surveys among manufacturers, patients and healthcare professionals, from which clear messages emerged regarding the preference for an electronic format IFU:**

- Over 88% of healthcare professionals would prefer to have the electronic IFU 1;

- Over 90% of the hospital administrative staff/ hospital pharmacists would prefer to have eIFU for medical devices2;

- 85% of users prefer to have instructions for use of their contact lenses and lens care products in digital format3.

I addition, data collected showed that switching to eIFUs can save up to several thousand tons of paper per year, depending on the company:

- a complete switch to eIFUs could save an average of around 500 tons of paper per company per year. For larger companies, it can amount to over 6000 tons per year per company4.

- eliminating the IFU booklet would net a 60-fold reduction in the paper waste from the IOL packaging5.

The data collected calls for a rapid evolution of the eIFU Regulation and highlights the numerous and compelling advantages of eIFU over paper-based instructions:

- **Enhanced accessibility:** considering the high internet coverage6, electronic instructions can be accessed digitally and consulted anywhere, providing easier search and navigation and greater flexibility. • **Real-time updates:** eIFU allows for immediate updates and revisions, ensuring that users always have the latest information about the product they are using. This is crucial for patient safety and optimal device utilization.
- **User-friendly interfaces:** Electronic formats enable the incorporation of multimedia elements, such as videos and interactive features, enhancing the clarity and effectiveness of instructions.
- **Increased efficiency in MDR implementation:** electronic formats facilitate the inclusion of multiple languages and therefore contribute to reducing the risk of shortages of medical devices and improving the overall availability of these devices, especially in a multilingual context like the European Union.
- **Cost efficiency:** Over time, the implementation of eIFU can lead to cost savings for both manufacturers and healthcare institutions, as the need for printing, distribution, storage and waste management of paper IFU is significantly reduced.
- **Environmentally sustainable:** The transition to eIFU aligns with broader efforts to reduce paper usage, contributing to environmental sustainability and supporting the EU Green Deal.

The undersigned organizations therefore call on the Medical Device Coordination Group (MDCG) to consider as a priority in its 2024 work program the revision of Commission Implementing Regulation (EU) 2021/2226, with a view to expand the scope for specific product categories.

We are eager to engage in a constructive dialogue to provide further insights and collaborate on refining the regulatory framework to better align with the evolving needs and practices.

Source: COCIR

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