EUROMCONTACT
THE EUROPEAN ASSOCIATION OF THE
CONTACT LENS AND LENS CARE INDUSTRY

Comments on the draft Commission implementing regulation amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the instructions for use may be provided in electronic form

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EuromContact **welcomes the draft Implementing Regulation** aimed at expanding the scope of electronic instructions for use (eIFU) for medical devices. However, we **regret that the revision remains limited to medical devices intended exclusively for healthcare professionals** and remains to exclude:

- the products listed in Annex XVI of the MDR, even those to be used exclusively by healthcare professionals;
- medical devices and accessories for lay use, such as contact lenses and lens care products.

The revision of the eIFU scope is rooted in the broader EU objectives of digital transformation, competitiveness, sustainability and reduction of unnecessary regulatory burden. Therefore, **we urge the Medical Device Coordination Group (MDCG) to continue its work under "*Work Package 4: Electronic Instructions for Use*"** of the MDCG New Technologies Subgroup in its 2024-2025 work program. As part of this agreed Work Package, we **call for the collection of necessary evidence by the end of 2025 to support a future expansion of eIFU regulation to include some or all medical devices used by lay users.**

The strong and growing support for eIFU expansion to lay users highlights the **need to sustain this momentum and ensure timely regulatory progress** :

- In the 2024 EU Commission's survey on eIFU, **90% of the 7 300 healthcare professionals surveyed agreed that eIFU could be provided for additional medical devices intended for lay users**. They emphasized benefits such as a patient-centered approach, patient safety, compliance, and autonomy.
- European associations of optometrists and ophthalmologists, including **ECOO and ECLSO, support the transition towards eIFU for contact lenses and lens care products** due to benefits such as improved accessibility, ease of use, real-time updates, and user-friendly interfaces.
- A survey conducted in 2023 by OpinionWay for EuromContact among 1,008 contact lens wearers in the European Union found that **85% of respondents preferred eIFU for their contact lenses and lens care products**.
- The 2024 European Patients' Forum (EPF) survey on the implementation of the EU MDR calls for comprehensive, easy-to-understand information to patients about the devices they use and considers that as digital information becomes increasingly prevalent, **increased availability of eIFU for patients is helpful**, as long as paper-based instructions remain accessible to avoid inequalities in information access.

While under the MDR, **eIFU is already permitted for patients using software** as a medical device, with no reported safety concerns, we see that global regulatory trends, technological advancements and

sustainability considerations are leading to further develop information in digital format to ensure that patients have safe, effective, and user-friendly access to essential medical device information.

The European Medicines Agency (EMA) and EU national competent authorities recently concluded a one-year pilot project on electronic product information (ePI) for human medicines. The final report, published in December 2024, concludes that the network should **progress towards ePI implementation**.

As far as medical devices are concerned, **other jurisdictions are exploring the expansion of eIFU for lay users**. For example, the Australian Therapeutic Goods Administration (TGA) published the outcome of its public consultation in August 2024, which indicated support to allowing eIFU to be provided for a greater range of medical devices used by both professionals and consumers. In the Asia-Pacific region, 45% of current eIFU regulations already cover both professional and home-use devices, including in South Korea, Thailand, Vietnam, and India.

While we fully acknowledge the progress made with the forthcoming adoption of this draft implementing regulation, **the strong support from healthcare professionals, patients, and the global momentum toward broader eIFU adoption make it essential for the MDCG to continue its work in parallel in 2025, further exploring the inclusion of lay users.**