Brussels, 27 September 2026

Joint Statement on electronic instructions for use for medical devices

European organizations representing patients, doctors, nurses, community and hospital pharmacists, hospitals and healthcare services, consumers, elderly, health insurance funds and not-for-profit health mutuals, and people with disabilities *(to be adapted according to the signatories)* call on EU legislators to ensure that paper instructions for use continue to accompany medical devices whenever such instructions are already required[1] Electronic Instructions for Use (eIFU) should complement, not replace, paper information.

The signatories do not oppose the use of electronic instructions for use in the limited circumstances already permitted by Commission Implementing Regulation (EU) 2021/2226, as amended, provided that manufacturers comply with the applicable safeguards, including the obligation to make paper instructions available on request. However, the revision of the Medical Devices Regulation (MDR) should not broadly extend the use of electronic-only instructions, particularly for devices that are not intended exclusively for professional use.

Digital tools can improve access to information by offering updates, larger fonts, audio or video support, multiple languages and accessible formats. However, where instructions for use are required, they are essential for safe use, correct handling and the prevention of avoidable harm.

Medical devices can be used in situations of stress, urgency or vulnerability, and in settings where professional support, internet access or digital tools may not be immediately available. Patients, carers and healthcare professionals may need immediate access to instructions on how to assemble, apply, calibrate, clean, store, troubleshooting or safely dispose of a device. Requiring users to scan a QR code, search a website or download a file can delay use by introducing unnecessary and burdensome steps in accessing essential information, thereby increasing the risk of errors and harm.

[1] Under the current rules, instructions for use are not required for every medical device. Annex I, Chapter III, Section 23.1(d) of Regulation (EU) 2017/745 provides that instructions for use may be omitted for class I and class IIa devices that can be used safely without them, unless otherwise required elsewhere in Section 23. Accordingly, references in this statement to instructions accompanying medical devices concern devices for which instructions for use are legally required.

Electronic-only instructions also risk deepening the digital divide, generating inequalities. Not every user has a suitable device, the necessary digital skills, internet access or the ability to read information on a screen at the exact moment of need. Some users may be disproportionately affected, particularly elders, people with disabilities, vulnerable patients, people with low digital literacy and those living in rural or low-connectivity areas. Furthermore, emergencies and other disruptions such as floods, power outages or cyber incidents might make electronic instructions inaccessible by disrupting internet connectivity, electricity supplies or device battery life.

Paper instructions provide an essential and reliable fallback during service disruptions, including power cuts, cyber incidents, hospital IT outages, lack of mobile coverage and website downtime.

Privacy must also be protected. Accessing electronic instructions may reveal sensitive information about a person's health condition, disability, treatment, pregnancy status or use of specific devices. Users should be able to access essential safety information without being tracked or enabling manufacturers, digital platforms, advertisers or other third parties to collect or infer health-related information about them. It is also important to ensure that eIFU provides approved information only and is not used to deliver promotional information. It should be published as open data, freely accessible for use and reuse. To ensure that eIFU remains a trusted and non-promotional source, patients should be directed to eIFU stored by independent and official sources, such as national competent authorities' websites. Where available, electronic instructions for use should also be accessible through EUDAMED.

Finally, responsibility for providing complete, approved and accessible instructions with the medical device must remain with manufacturers. Removing paper instructions would risk shifting the burden to patients, consumers, carers, pharmacists, nurses, hospitals and other healthcare professionals, who may be forced to search, download, print, explain or store information themselves, adding a deterring and avoidable burden to an already overstretched healthcare workforce. Moreover, some medical devices may be sold in supermarkets or through vending machines, where the printing of instructions for use is highly unlikely to occur.

Our call

The signatory organisations call on EU co-legislators to ensure that the revision of the medical devices legislation:

1. preserves patients' access to paper instructions for use provided by manufacturers, ensuring safe use by healthcare professionals and lay users and avoiding a transfer of responsibility to healthcare professionals;
2. prevents electronic instructions from becoming the only source of essential safety information;
3. ensures that accurate and up-to-date digital instructions remain complementary, accessible, non-promotional, privacy-protective and available in all required languages;
4. protects vulnerable users, people with disabilities, elders, and those affected by the digital divide, guaranteeing all patients equitable and appropriate access to information on the use and risks of the device.

Digitalisation should make health information safer, clearer and more accessible. It should not create new barriers, new risks or new responsibilities for the people who rely on medical devices every day.

*The **International Association of Mutual Benefit Societies (AIM)** is a global network for equitable health and social care, which serves as the international umbrella organisation for federations of health mutuals and statutory and complementary health insurance bodies. The work of our members is based on solidarity, not-for-profit work and democracy across Europe, Latin America, Africa, and the Middle East. We advocate for equal access to health and care, fair pricing of medicines, a digitalization that serves the insured, the integration of health in all policies and a stronger focus on prevention.*

*The **European Consumer Organisation (BEUC)** is the largest organisation promoting the general interests of Europe's consumers. Founded in 1962, it proudly represents more than 40 independent national consumer organisations from over 30 European countries.*

*The **Council of European Dentists (CED)** is a European not-for-profit association which represents over 350,000 dentists across Europe. The association was established in 1961 and is now composed of 32 national dental associations from 30 European countries.*

*The **Standing Committee of European Doctors (CPME)** represents national medical associations across Europe, covering more than 1.7 million doctors in 36 countries.*

*The **European Association of Hospital Pharmacists (EAHP)** represents and develops the hospital pharmacy profession across 37 European member countries to ensure the continuous improvement of care and outcomes for patients in the hospital setting. This is achieved through science, research, education, practice, and sharing best-practice and responsibility with other healthcare professionals.*

*The **European Federation of Nurses Associations (EFN)** is a European not-for profit association representing 36 national nurses associations and represents as such 3 million EU Nurses.*

*The **European Patients' Forum (EPF)** is an umbrella organisation of patient organisations across Europe and across disease-areas. Our 81 members include disease-specific patient groups active at EU level and national coalitions of patients.*

*The **European Hospital and Healthcare Federation (HOPE)** is a European organisation, representing 36 national public and private hospital and healthcare associations and hospital, health and social care services owners from the 27 Member States of the European Union, the United-Kingdom, Switzerland and the Republic of Serbia. HOPE mission is to promote improvements in the health of citizens, fostering efficiency, effectiveness and humanity in the organisation and operations of hospital and health services.*

*The **Pharmaceutical Group of the European Union (PGEU)** is the organisation representing community pharmacists in 33 European countries. In Europe over 500.000 pharmacists provide services throughout a network of more than 200.000 pharmacies.*