

*The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.*

## Statement on medical devices – electronic instructions for use

The Standing Committee of European Doctors (CPME) welcomes the opportunity to provide input to the European Commission draft implementing regulation on medical devices – electronic instructions for use.

CPME already had the opportunity to provide input previously on a [response to the European Commission Survey on Electronic Instructions For Use \(eIFUs\) for medical devices](#).

While digitalisation offers opportunities to enhance information delivered to patients or healthcare professionals, we strongly believe that the electronic product information should never replace the paper version to medical devices intended for patients, but remain complementary.

CPME believes that electronic instructions for use could be helpful for healthcare professionals, since it would be easy and quick to find information in the electronic form. Nonetheless, paper instructions should be kept to be used in case of electricity blackout, or when there is not a robust digital infrastructure in place or in emergencies.

Considering the [Implementing regulation - 2021/2226](#), allowing electronic product information for certain medical devices intended for professional users, we stress that electronic product information should not be extended beyond what is foreseen in that Regulation.

We would also like to make more specific remarks to the electronic product information that should be taken into account:

- Any form of advertisement linked to the electronic versions must be prohibited. No push notifications should be installed in user's phone without his/her consent.
- No personal data should be collected or stored for the simple fact of consulting the electronic leaflet. Depending on how it is set up, the system could collect the Internet Protocol (IP) address of the user patient or healthcare professional or healthcare facility, use cookies or other surveillance tools to single out individuals, identifying their behaviour or habits, making a profile of users.
- The QR code or links can send the patient or healthcare professional to a wrong website, or be hacked. There needs to be sufficient oversight to avoid the risks arising from such technical problems.
- Electronic instructions for use imply a mobile phone or a computer; electricity or charged battery; access to the internet. If you are in the country side with poor or no internet connection, you will not be able to access the leaflet. It implies digital health literacy.