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.

CPME response to the European Commission Survey on Electronic Instructions For Use (eIFUs) for medical devices

On 12 September 2024, the CPME Board adopted the 'CPME response to the European Commission Survey on Electronic Instructions For Use (eIFUs) for medical devices' (CPME 2024/116).

Contribution ID: 1752d62b-58fe-45a0-a9c5-b0084488768f
Date: 12/09/2024 14:05:03

Survey on Electronic Instructions For Use (eIFUs) for medical devices

Fields marked with * are mandatory.

The European Commission is currently considering allowing the use of Electronic Instructions for Use for **all professional use devices** (i.e. devices that are used by healthcare professionals).
Healthcare professionals and or other persons working in or employed by a healthcare institution in the European Union are kindly requested to contribute to this survey. Your feedback will be essential to support the decision-making process of EU medical device regulators.
The time required to fill this survey is estimated to take **less than 5 minutes**.

Please read the **attached document** for important information **ahead** of filling this survey.
This survey is available **in all EU languages.** Choose your preferred language at the top of this screen.

This survey started on 1 August 2024 and will close on 11 October 2024.

---

* 1. What is your role?
- a. Physician/Surgeon

- b. Nursing staff
- c. Technician/Operator
- d. Emergency Room medical staff
- e. Central service sterile department processor
- f. Pharmacist
- g. Midwives
- h. Procurement staff
- i. Administrative staff
- j. Other

* Please provide the name of your institution. If private, please indicate 'private':

Standing Committee of European Doctors (CPME)

* 2. What EU Member State are you based in professionally, i.e. where do you work?

- AT - Austria
- (•) BE - Belgium
- BG - Bulgaria
- HR - Croatia
- CY - Cyprus
- CZ - Czechia
- DK - Denmark
- EE - Estonia
- FI - Finland
- FR - France
- DE - Germany
- EL - Greece
- HU - Hungary
- IE - Ireland
- IT - Italy
- LV - Latvia
- LT - Lithuania
- LU - Luxembourg
- MT - Malta
- NL - Netherlands
- PL - Poland

- PT - Portugal
- RO - Romania
- SK - Slovak Republic
- SI - Slovenia
- ES - Spain
- SE - Sweden

3. How **often** do you typically consult medical device instructions for use (IFU)?
   - a. Daily
   - b. Weekly
   - c. Monthly
   - d. Less than once a month
   - e. I don't consult IFU unless it's a new medical device.

*4. Do you **have** internet access where you work?
   - Yes
   - No

Is the internet access **public**?
   - Yes
   - No

5. When you **currently** consult instructions for use (IFU) do you consult a paper version or an electronic version?
   - Paper
   - Electronic
   - Both, depending on the situation (e.g. medical emergency)
   - Other

6. Would you prefer using **electronic** instructions for use (eIFU) if available to you?
   - Yes
   - No

7. Why do you prefer **paper** instructions for use (IFU)? (check all that apply)
   - a. This question does not apply to me as I use electronic IFU and/or would prefer to use electronic IFU.
   - b. I am not well trained/experienced to use the electronic format.

- [ ] c. Our Standard Operating Procedures (SOPs) require that we use paper IFUs.
- [ ] d. The internet connection of my workplace is unstable/not dependable.
- [ ] e. I don't have internet connection at work.
- [ ] f. I don't always have a device at hand to view the electronic IFU.
- [ ] g. I have concerns for data privacy when online.
- [ ] h. Electronic IFU are not always available in my language online.
- [x] i. Paper IFU is physically available with the product.
- [x] j. Other.

Other

> Paper instructions are valuable in case of electricity blackout, or if there is not a robust digital infrastructure in place or in emergencies.

8. Why do you use or would prefer to use **electronic** instructions for use (eIFU)? (check all that apply)

- [ ] a. Easier to store and access.
- [ ] b. Easier to search/navigate.
- [ ] c. Easier to find the latest version.
- [ ] d. They can be consulted anywhere e. They are available in multiple languages.
- [ ] e. Our SOPs require that we consult the electronic version.
- [ ] g. Hygienic reasons.
- [ ] h. Waste reduction.
- [ ] i. I would not prefer them – this question does not apply to me.
- [ ] j. They are available in multiple languages.
- [x] k. Other.

Other:

> Electronic product information could be good for healthcare professionals, since it would be easier and quicker 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.

9. What do you do with **paper** instructions for use (IFU) after you read them?

- (•) a. Store them & go back and consult them.
- ( ) b. Store them but rarely go back and consult them.

- c. Dispose of them after I have read them and familiarized myself with a new device.
- d. I don’t use paper IFU, only electronic IFUs.
- e. Other.

10. If you **prefer paper** instructions for use (IFU), **how often** do you need to receive them?

- a. Every time the medical devices is delivered, for all medical devices.
- b. Only the first (few) time(s) when using a new device.
- c. It depends on the type of device, for some a paper IFU is not/seldom required.

11. Are there **national provisions** requiring your institution **to store** instructions for use (IFU) and/or make them accessible at all times?

- a. Yes.
- b. No.
- c. I don't know.

12. **Beyond professional use devices**, would you agree that electronic instructions for use could be provided (instead of paper) for **other medical devices intended for lay users** (patients)? For example, devices where a healthcare professional trains the lay user to use the device (contact lenses, etc.)?

- a. Yes, it should be expanded to all medical devices.
- b. Yes, but limited to devices where a healthcare professional trains the lay user.
- c. No.

Please explain your thoughts on the matter.

While digitalization 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.

More specific remarks to the electronic product information 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 to a general part of the company website, rendering difficult to understand which leaflet is the correct one for the patients' case.

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.

13. Any other feedback you would like to share?

Two studies from 2023 (https://pubmed.ncbi.nlm.nih.gov/37132168/ and https://publications.jrc.ec.europa.eu/repository/handle/JRC134602), found a low level of alcohol beverages' consumers that scan the QR code. Also, according to Eurostat, in 2021, 54% of people in the EU aged 16 to 74 had at least basic overall digital skills (https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20220330-1).
This evidence supports our position on how important it is having both paper and digital information available for medical devices, especially the ones intended for lay users (patients).

Useful links

Medical Device Regulation (MDR) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20230320)

Electronic instructions for use (eIFU) Regulation (https://eur-lex.europa.eu/eli/reg_impl/2021/2226/oj)

Background Documents

Explanatory note on survey

Contact

Contact Form