Question for written answer E-000535/2024
to the Commission
Rule 138
Kathleen Van Brempt (S&D)

Subject: Allowing electronic instructions for use for medical devices to be issued to patients

Essential information on using medical devices is provided in the form of instructions for use (IFUs). The requirements for IFUs are laid down in the EU Medical Device Regulation (Regulation (EU) 2017/745). The legislation currently requires that a printed IFU, in multiple languages, is provided to each patient with each device.

Electronic IFUs (eIFUs) also exist, and the rules for them are laid down in Implementing Regulation (EU) 2021/2226. Currently, eIFUs are only an option for devices intended for the exclusive use of professional users (Article 3(2)(a) of the Implementing Regulation).

Allowing eIFUs for patient use, if the patient so desires, enables patient choice and would align the EU's environmental agenda with the policies laid down in the Medical Device Regulation without risking patient safety.

Given the choice between printed IFUs and eIFUs, patients might prefer eIFUs as they can be updated, corrected and revised more easily and can include interactive features, such as hyperlinks, videos, zooming and text-to-speech.

eIFUs would also have a lower environmental impact and would reduce the cost to manufacturers of printing and distributing paper instructions.

1. Is the Commission considering or assessing eIFUs for patient use?

2. Is the Commission considering updating the Implementing Regulation accordingly, and if so, when will it do this?

Submitted:19.2.2024