Priority question for written answer P-003581/2022
to the Commission
Rule 138
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Subject: Single market for digital therapeutics

The EU regulates medical devices through Regulation (EU) 2017/745 (the Medical Devices Regulation (MDR)). This sets the rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices.

The MDR creates a single market for medical devices. Some Member States have established national legislation to further regulate a subset of medical devices, namely digital health applications. The aim has been to create a ‘fast track’ for those applications to become reimbursable. Germany has been the front runner with its Digital Healthcare Act and France is following suit. Other Member States are planning their own ‘fast tracks’. There is a real need for a clear model for digital health applications to find their way into the hands of patients, as national models are causing fragmentation in the EU single market.

1. Does the Commission have plans to tackle the fragmentation of the market for digital health applications or ‘apps on prescription’?

2. Would the Commission support the idea of setting up a joint action funded through the EU health programme to bring Member States together to find solutions to promote the harmonised use of digital health applications across the EU?

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