Question for oral answer O-000043/2022
to the Commission
Rule 136
Angelika Niebler, **Peter Liese**
on behalf of the PPE Group

Subject: Revision of the Medical Devices Regulation – how to ensure the availability of medical devices

In 2017, the revision of the Medical Devices Regulation (MDR) entered into force. The Regulation was adopted to address deficiencies in the notified body system and provide better controls for medical devices in order to increase patient safety. For multiple reasons, the implementation creates a lot of problems which particularly affect niche products. Some medical devices, even if they are of excellent quality and have been used for a long time, may disappear from the market because companies are currently deciding to withdraw them because the bureaucratic and financial effort of recertification is too high. In practice, the MDR is leading to a decrease in the availability of medical devices across Europe. Consequently patient care in the EU is worsening instead of improving.

1. How does the Commission intend to ensure that medical devices remain available in hospitals in the EU so that patients in urgent need of them can survive and European medical device manufacturers can continue to innovate and produce them?

2. Is the Commission considering amending the MDR so that once a manufacturer has submitted an application for recertification of a medical device, the previous certificate remains valid until the notified body accepts or rejects the application?

3. Is the Commission considering amending the MDR in order to allow certifications of niche medical devices awarded under the old Medical Devices Directive to remain valid under the new MDR without recertification, and what specific measures is the Commission considering for niche products in the short-, medium-, and long-term?

Submitted: 10.10.2022

Lapses: 11.1.2023