Question for written answer E-003215/2023
to the Commission
Rule 138
Lukas Mandl (PPE)

Subject: Excessive regulations for medical products

The COVID-19 pandemic highlighted the importance of ensuring a universal supply of medical products. Given the intense global competition, in particular from China, it is even more important for the Union to have a strong and autonomous medical industry to ensure supply for its citizens. Commission President Ursula von der Leyen repeatedly stressed the importance of strategic autonomy in her State of the Union address. However, instead of supporting producers and distributors, Regulation (EU) 2017/745 (the Medical Devices Regulation) creates further bureaucratic obstacles that make it difficult for small and medium-sized enterprises in particular to operate in the Union.

1. On what grounds are even product samples and promotional items (such as plasters) deemed to be subject to the obligation for designations and instructions for use to be in the official EU language required by the respective Member States, as laid down in Article 10(11) of Regulation (EU) 2017/745?

2. What steps does the Commission intend to take to reduce the bureaucratic burden on medical device producers and distributors?

3. What does the Commission intend to do to promote the medical industry in the Union and thus safeguard security of supply in the Union?

Submitted: 30.10.2023