Question for written answer E-005044/2021
to the Commission
Rule 138
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Subject: Medical Devices Regulation (Regulation (EU) 2017/745)

Companies involved in the manufacture of medical devices have quality management systems and notified bodies carry out regular EC certification processes. The Regulation stipulates that the company placing the item on the market must have all stages of the work by companies upstream of the process certified again by its notified body, irrespective of the certification process already successfully completed by the latter. This leads to structures, and costs and bureaucracy, being duplicated.

This Regulation has created barriers to market entry. The process to approve both new products and improved existing ones is slow and costly, and with overall costs difficult to estimate, there is very little planning certainty, meaning less innovation. Increased costs have caused 35 % of medical device manufacturers to leave the market. There is a danger that the medical device market will gradually become an oligopoly. This will lead to a lower level of innovation, higher prices and poorer health for our citizens.

Functionality and safety are tested during certification. Registration of medical devices was already mandatory before the introduction of the Regulation, and traceability at every step in the manufacturing process was ensured. Nevertheless, there have been calls for years now for renewed certification for tried and tested existing products.

1. What resources is the Commission making available for manufacturers and notified bodies concerned to cover the increased costs?

2. How, in the Commission’s opinion, should the downwards slide in healthcare for EU citizens, and in particular smaller patient populations, be offset?

3. What arrangements is the Commission planning to ensure that existing products that are demonstrably safe and efficient are not subjected to further unnecessary certification?