Priority question for written answer P-002378/2021
to the Commission
Rule 138
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Subject: Regulation (EU) 2017/745 of the European Parliament and of the Council

The Commission and the Member States are working on the adoption of secondary legislation and guidelines for the implementation of Regulation (EU) 2017/745.

One of the most important aspects for businesses, and the subject of discussion, would appear to be the revision of the definition of 'pharmacological' in the MEDDEV 2. 1/3 rev 3 guidance, a definition which distinguishes between medical devices and medicinal products. If this were to be confirmed, medical devices would be liable to be included in the definition of medicinal product and would therefore be subject to Directive 2001/83/EC and no longer to Regulation (EU) 2017/745.

Moreover, in the context of the main innovation in the text and the MEDDEV 2.4/1 rev. 9 guidance on the classification of MDs, it would appear that no account is being taken of the provisions of the Regulation (Rule 21) regarding the possibility of having substance-based medical devices which are systemically absorbed and have a type of action that is different to that of pharmacology.

In view of this:

1. How does the Commission intend to protect a sector such as that of substance-based medical devices, which is a major sector in Italy with regard to employment and has invested significant amounts of resources in research and innovation?

2. Does it not agree that these changes alter the provisions adopted by Parliament at the negotiating stage, rendering them null and void?