Question for oral answer O-000085/2018
to the Commission
Rule 128
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on behalf of the Committee on the Environment, Public Health and Food Safety

Subject: Implementation of the Medical Devices and In-Vitro Diagnostic Medical Devices Regulations

The new Medical Devices (MD) and In-Vitro Diagnostic (IVD) Devices Regulations will strengthen EU patients' access to safe and effective medical devices and bolster the EU's reputation in medical innovation. On 25 May 2017, both regulations entered into force with a three and five-year transitional period respectively.

One year on, it is proving difficult to prepare all the necessary elements of the system and, in particular, to designate the necessary notified bodies (NBs) on time. In the interests of public health, efforts must be made to ensure there is no disruption to the supply of medical devices.

As of May 2018, out of 59 existing NBs only 20-30 have applied for re-designation, and the joint assessment of an NB designation process lasts approximately 18 months. The reduced number of NBs and the challenge of having all NBs ready by May 2020, could lead to certification capacity issues. Three separate Commission DGs have a role in the support and coordination of the regulatory system – DG GROW, DG SANTE and DG JRC. It is unclear how these DGs will work together. The new regulations require increased knowledge and expertise, particularly for NB assessors, leading to shortages of in-house and specialist expertise. An additional complication is added by the fact that UK NBs are responsible for certifying a significant number of medical devices. On the day of Brexit, all UK-based NBs may no longer be able to perform conformity assessments in line with EU legislation.

1. How will the Commission prevent any future disruption to the MD/IVD supply chain?

2. Can the Commission clarify what steps it is taking to ensure coordination between the three DGs? Are there sufficient staff resources to provide the necessary support to the new system?

3. What action has the Commission taken to ensure that all aspects of the regulations will be ready by the end of the transitional period, such as implementing and delegated acts, the Eudamed database and NB notification?

4. Has the Commission considered the impact of Brexit? Will CE certificates granted by UK NBs still be recognised after March 2019?

5. Do Member States have the resources required for the successful implementation and coordination of the regulatory system?

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