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NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	Challenges ahead in the medical device sector *- Information from the Danish and Spanish delegations*

Delegations will find in the Annex a note from the Danish and Spanish delegations on the above-mentioned subject to be raised under "Any Other Business" at the session of the Council (EPSCO) on 7 December 2018.

ANNEX

Challenges ahead in the medical device sector

Denmark and Spain welcome the new Regulations regarding medical devices and *in vitro* diagnostic medical devices. The recently adopted Regulations (EU) 745/2017[1] and 746/2017[2] establish a modernised and more robust EU legislative framework and contain important measures to increase patient safety. At this stage, it is of great importance that the Commission strongly supports the timely implementation process and prioritises *e.g.* the new database Eudamed, which will be key to improve both safety monitoring and ensuring traceability and the designation of Notified Bodies.

While the new Regulations do significantly raise the standards for ensuring patient safety, we need to reflect on the challenges that lie ahead.

With the rapid development of highly advanced and complex medical devices, *in vitro* diagnostic medical devices and technologies that challenge our understanding and definition of the products, we need to be proactive in making sure that innovative products are made available to European citizens with a high level of safety and without unnecessary delays.

Denmark and Spain favour that the safety issues have a due prominence in the implementation of the mentioned Regulations and would like to encourage the Commission to look into this area and to examine carefully if the Regulations address the challenges posed by new highly advanced and complex products.

Background

The new Regulations on Medical Devices establish a solid and transparent EU legislative framework to ensure better protection of public health and patient safety and a huge work is being

[1] OJ L 117, 5.5.2017, p. 1.
[2] OJ L 117, 5.5.2017, p. 176.

done at European level to get an effective implementation process. The development of advanced medical devices is rapid and shows promising results for patients, however, the new developments challenge our understanding of medical devices – examples could be borderline products regarding the definition of medicinal products and medical devices, including but not limited to the following:

- Active implanted medical devices that achieve a healing effect by controlled release of active pharmaceutical ingredients into the surrounding tissue (known as drug-eluting medical implants (*e.g.* drug-eluting vascular stents)),
- Combinations of medicinal products and software, such as sensor-enabled pills with companion software, and
- Bandages releasing pain-relieving medicinal products combined with measuring devices monitoring the healing.