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NOTE

from:	Presidency
to:	Permanent Representatives Committee (Part I) / Council
No. Cion prop.:	14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + COR 1 14499/12 PHARM 72 SAN 216 MI 598 COMPET 599 CODEC 2312 + COR 1
Subject:	**Employment, Social Policy, Health and Consumers** Council meeting on 9 and 10 December 2013 Proposal for a Regulation of the European Parliament and of the Council on **medical devices**, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 Proposal for a Regulation of the European Parliament and of the Council on ***in vitro* diagnostic medical devices** - *Exchange of views*

1. On 27 September 2012, the Commission submitted to the Council and to the European Parliament:

   – a proposal for a Regulation on medical devices[1], aiming at replacing Council Directives 90/385/EEC on active implantable medical devices[2], and 93/42/EEC[3] on medical devices; and

1 14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + COR 1.
2 OJ L 189, 20.7.1990, p. 17.
3 OJ L 169, 12.7.1993, p. 1.

– a proposal for a Regulation on in vitro diagnostic medical devices[4], aiming at replacing Council Directive 98/79/EC of the European Parliament and the Council on in vitro diagnostic medical devices[5],

aimed to revise the European legislative framework on medical devices, while ensuring:

– the highest level of protection of health and safety;
– that safe, effective and innovative medical devices can be placed on the market efficiently and made available to patients, consumers and healthcare professionals in a timely manner, and
– the smooth functioning of the internal market, as well as EU competitiveness and a suitable environment for innovation in the field of medical devices.

2. The Working Party on Pharmaceuticals and Medical Devices has been examining both proposals in depth since September 2012.
The files are large, complex and aim to introduce some changes in the system to assess the conformity of medical devices with the legal requirements, which have to be carefully evaluated before the adoption of the two Regulations.

3. A report on the progress achieved in the analysis of the proposed Regulations by the Working Party on Pharmaceuticals and Medical Devices under the Lithuanian Presidency can be found in document 16690/13.

4. In this context and in order to facilitate further work, the Presidency intends to invite the ministers to hold an exchange of views at the Council (EPSCO) session of 9 and 10 December 2013.

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4 14499/12 PHARM 72 SAN 216 MI 598 COMPET 599 CODEC 2312 + COR 1.
5 OJ L 331, 7.12.1998, p. 1.

ANNEX

I. Background

1. The existing regulatory framework has demonstrated its merits but has also shown its limits. The objective of the revision of the current medical devices regulatory framework is to further strengthen patient safety by overcoming certain flaws and gaps, like substantial divergences in the interpretation and application of the rules.

   "*A robust, transparent and sustainable regulatory framework should be put in place."*[6]. The aim of the revision is also to strengthen the regulatory framework for medical devices in order to ensure patient safety and dissuade fraud, while preserving the smooth functioning of the internal market, promoting innovation and ensuring the competitiveness of EU products.

   In view of the above-mentioned objectives, it should be pondered whether the regulatory system should focus mainly on measures in the pre-market stage, such as the scrutiny mechanism and certification by the designated notified bodies, or should also be based on more detailed and stronger post-market surveillance provisions.

2. Medical devices may, under certain conditions, be reprocessed.

   Moreover, mainly for safety reasons, manufacturers may classify medical devices as "single use". This classification might, however, be used with excessive prudence and result in an incentive to over-consumption. In that event, the adequate balance between patient safety and cost-saving should be found.

   In this context, it would be important to know if it would be possible to define the conditions under which some devices, namely those classified as "single-use", might be "reprocessed" and, in particular taking into account the subsidiarity principle, if it is appropriate to establish those conditions in the EU legislation.

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6 Explanatory memorandum, documents 14493/12 and 14499/12.

II. Questions for discussion

In light of the above, the Presidency suggests the following questions for Ministers:

1. *How can the medical devices supervision process[7] be improved in order to achieve the objectives of the proposed Regulations without increasing the administrative burden?*

2. *Subject to which requirements may a medical device, in particular a medical device classified by the manufacturer as "single use", be reprocessed without hampering patient safety?*

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[7] *Which could include elements of pre-market controls, such as scrutiny mechanism and certification by the notified bodies, and of post-marketing surveillance.*