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Subject:	Preparation of the **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** *- Progress report*

Delegations will find in the Annex a report on the progress achieved regarding the examination of the proposals on medical devices and on *in vitro* diagnostic medical devices that will be submitted by the Presidency to the Council (EPSCO) at its meeting of 9 and 10 December 2013.

ANNEX

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

PROGRESS REPORT BY THE PRESIDENCY

INTRODUCTION

The Commission proposals

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
   - 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],

   on the basis of Article 114 and of point c) of Article 168(4) of the Treaty on the Functioning of the European Union. The ordinary legislative procedure is applicable.

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

2. The proposals aim 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,

   – the smooth functioning of the internal market, as well as EU competitiveness and a suitable environment for innovation in the field of medical devices.

Consultations

3. The European Economic and Social Committee was consulted in accordance with Article 114(1) and point c) of Article 168(4) and issued its opinion on 14 February 2013[6].

   The Committee of the Regions was also consulted on 15 October 2012 but did not deliver any opinion given the low impact of the measures proposed on the local or regional authorities.

4. In accordance with Protocol No 2 annexed to the Treaties, the Member States' national parliaments were consulted on the compliance of the proposed provisions with the principle of subsidiarity. Although some comments were made on the proposals, the national parliaments did not express any veto[7].

5. The European Data Protection Supervisor was consulted by the Commission and issued an opinion on 8 February 2013[8].

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6 INT/665-666-667.
7 http://www.ipex.eu/.
8 Doc. 5590/13

European Parliament

6. In the European Parliament, the proposals were examined by the Committee on the Environment, Public Health and Food Safety. Mrs Dagmar ROTH-BEHRENDT (S&D, DE) was appointed Rapporteur for the proposal for a Regulation on medical devices and Mr Peter LIESE (EPP, DE) Rapporteur for the proposal for a Regulation on *in vitro* medical devices.

7. On 22 October 2013, the European Parliament voted on the reports and amendments submitted to the Plenary [9] and, postponing the vote on the first-reading Resolution, gave a mandate to the rapporteurs to start negotiations with the Council.

STATE OF PLAY IN THE COUNCIL

8. In general, the delegations welcomed the proposals. However, at this stage, they all have general scrutiny reservations on the entire proposed texts. Furthermore, the Danish and United Kingdom delegations have entered parliamentary scrutiny reservations.

9. The two proposals together are consisting of approximately 200 articles (20 Chapters) and 30 Annexes. The Working Party on Pharmaceuticals and Medical Devices (the Working Party) met 11 times during the Cyprus and Irish Presidencies. During those meetings, the following chapters have been examined:

- **Chapter I** of both Proposals – *Scope and definitions*;
- **Chapter IV** of both Proposals – *Notified Bodies*,
- **Chapter V** of both Proposals – *Classification and Conformity Assessment*,
- **Chapter VI** – *Clinical Evaluation & Clinical Investigation* (MD Proposal) and *Clinical Evidence* (IVD Proposal), and

[9] The amendments adopted by the EP Plenary can be found in 14936/13 and 14937/13.

- **Chapter VIII** of both Proposals - *Cooperation between Member States, Medical Device Coordination Group, EU Reference Laboratories*.

10. In parallel, informal technical expert meetings were organised by the Irish Presidency to discuss technical aspects, submit wording suggestions, and help to identify the political issues that should be discussed at the Working Party, concerning the following Annexes to the proposals:

    - **Annex VI** to both Proposals – *Minimum Requirements for Notified Bodies*;

    - **Annex VII** to both Proposals – *Classification Criteria*,

    - **Annexes XIII & XIV** to the Medical Devices Proposal – *Clinical Evaluation and Post-Market Clinical Follow-Up and Clinical Investigations*, and **Annexes XII & XIII** to the IVD Proposal – *Clinical Evidence and Post-Market Follow-Up and Interventional Clinical Performance Studies and other Clinical Performance Studies involving Risks for the Subjects of the Studies*.

    The results of those meetings were commented by delegations in writing and will be reflected in documents intended to be a basis for the work under the forthcoming Presidencies.

11. The Lithuanian Presidency planned six meetings of the Working Party , on 16 July, 18 September, 17 October, 19 November, 2 and 16 December. To date, it has undertaken the first examination of

    - **Chapter II** – *Making available of Devices, Obligations of Economic Operators, Reprocessing, CE Marking, Free Movement* – of both proposals, and

    - **Chapter III –** *Identification and Traceability of Devices, Registration of Devices and of Economic Operators, Summary of Safety and Clinical Performance, European Databank on Medical Devices* **–** of both proposals.

Chapter VII – *Vigilance and Market surveillance* – will be examined at the last Working Party meeting, on 16 December.

12. The Lithuanian Presidency also organised informal technical expert meetings on 16 and 18 October , 20, 21 and 22 November and on 3 December to deal with the technical aspects of:

- **Annex I** to both Proposals – *General Safety and Performance requirements*,
- **Annex VIII** to both Proposals – *Conformity Assessment Based on Full Quality Assurance and Design Examination*.

13. In relation, in particular, to **Chapters II** and **III** of both proposals, a number of main issues has emerged, including:

– whether and how to regulate at EU level devices that are manufactured by and intended to be exclusively used within one single health institution;

– to what extent medical devices offered by "means of information society services" should be specifically regulated by the proposed regulations or merely be subject to the general rules of Directives 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts[10] and 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services[11];

– the content of the obligations of the different economic operators: delegations consider that there is a need to ensure a proper delineation of responsibilities between different economic operators, in order, in particular, to avoid gaps or overlaps;

[10] OJ L 144, 4.6.1997, p. 19.
[11] OJ L 204, 21.7.1998, p. 37.

– the need for post-market surveillance and its modalities must be examined further and in greater depth;

– the requirements for a "qualified person" need to be reconsidered, with special attention being given to the application of these requirements in the case of small and medium-sized enterprises;

– EU legislation should determine which devices qualified as "single use" by the manufacturer could be reprocessed and under what conditions;

– a clear distinction must be made between the information to be contained on an implant card, intended to be permanently worn by the patient, a patient information leaflet and other documents that may accompany a device;

– should ethical considerations, regarding, for instance, the need for consultation before performing genetic tests, be covered by the proposed regulations;

– how the *European Databank on Medical Devices* (EUDAMED) will work, be compatible with and be built on the current national systems, in a way that spares available resources.

Outlook

14. The files are large, complex and should 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 implementation of the new legal framework.

The Lithuanian Presidency nearly concluded the first reading-through of the enacting part of the texts.
Furthermore, with the agreement of the upcoming Presidency, the Lithuanian Presidency's team is prepared to finish the work it has started on the Annexes during the next semester.