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NOTE

from:	General Secretariat of the Council
to:	Permanent Representatives Committee (Part 1) / 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 20 and 21 June 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 progress report prepared by the Presidency with a view to the meeting of the Council (EPSCO) on 20 and 21 June 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

PRESIDENCY PROGRESS REPORT

INTRODUCTION

1. On 26 September 2012, the Commission adopted its Proposals for a Regulation on medical devices and a Regulation on *in vitro* diagnostic medical devices ("IVD") and submitted them to the Council and to the European Parliament.

2. The Proposals for Regulations on medical devices and *in vitro* diagnostic medical devices revise the European legislative framework on medical devices to ensure the highest level of protection for European patients, consumers and healthcare professionals, to ensure that safe, effective and innovative medical devices can be placed on the market efficiently and made available to patients in a timely manner, and to ensure that the EU is competitive and maintains a suitable environment for innovation in the field of medical devices.

3. In the European Parliament, the Proposals are being examined by the Committee on the Environment, Public Health and Food Safety (ENVI). Mrs. Dagmar Roth-Behrendt (S&D, DE) has been appointed Rapporteur for the Medical Devices Proposal and Mr. Peter Liese (EPP, DE) has been appointed Rapporteur for the IVD Proposal. The ENVI Committee is expected to vote on its Reports on the Medical Devices and IVD Proposals on 10 July 2013.

4. The European Economic and Social Committee issued its opinion on the Proposals on 14 February 2013[1]. The Committee of the Regions has also been invited to give its opinion.

STATE OF PLAY

5. In general, delegations have welcomed the Proposals. However, at this stage all delegations have general scrutiny reservations on the entire Proposals and the Danish, Austrian, Polish and United Kingdom delegations have entered Parliamentary scrutiny reservations.

6. The Working Party on Pharmaceuticals and Medical Devices met on four occasions during the Cyprus Presidency to examine the two Proposals. Under the Irish Presidency, the Working Party met on a further seven occasions (on 17 January, 21 February, 7 March, 10 April, 3 and 31 May and on 18 June 2013) to continue the examination of the two Proposals, which, combined, consist of approximately. 200 articles and almost 30 technical annexes.

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[1] Opinion available in document INT/665-666-667 - CES2185-2012_00_00_TRA_AC - 2012/0266 (COD) and 2012/0267 (COD) of 14 February 2013.

7. Following on from the work of the Cyprus Presidency, the Working Party has, during the Irish Presidency, substantially progressed the first examination of the following Chapters of the two Medical Devices Proposals in parallel:
   - **Chapters IV** of both Proposals – *Notified Bodies*,
   - **Chapters V** of both Proposals – *Classification and Conformity Assessment*,
   - **Chapters VI** – *Clinical Evaluation & Clinical Investigation* (MD Proposal) and *Clinical Evidence* (IVD Proposal), and
   - **Chapters VIII** of both Proposals - *Cooperation between Member States, Medical Device Coordination Group, EU Reference Laboratories*.

8. In addition, seven technical expert meetings have been held (on 13 March, 16, 17, 21 and 22 May, 6 and 7 June) to examine the text, discuss technical clarifications and help identify political issues in the following Annexes to the Proposals, for further examination by the Working Party:
   - **Annexes VI** of both Proposals – *Minimum Requirements for Notified Bodies*
   - **Annexes VII** of both Proposals – *Classification*,
   - **Annexes XIII & XIV** of the Medical Devices Proposal – *Clinical Evaluation and Post-Market Clinical Follow-Up* and *Clinical Investigations*, and
   - **Annexes XII & XIII** of the IVD Proposal – *Clinical Evidence and Post-Market Follow-Up* and *Clinical Interventional Clinical Performance Studies and other Clinical Performance Studies involving risks for the subjects of the Studies*.

9. In the examination of the Proposals, to date, a number of issues have emerged, including:

- On the initiative of some delegations, the Working Party discussed, firstly, the feasibility of *splitting* the Medical Devices Proposals in order to prioritise certain new provisions for swifter agreement and, secondly, the possibility of *changing the legal form* of the Proposals from Regulations to Directives. A majority of delegations, however, preferred to continue the examination of the Proposals as a cohesive legislative framework, without splitting and without changing their legal form.
- The Working Party has had a series of discussions on *the "scrutiny mechanism"* (as provided for in Article 44 of the MD Proposal and Article 42 of the IVD Proposal). At present, delegations have expressed different views on the scrutiny mechanism: some delegations consider that it should be deleted; other delegations can accept the scrutiny mechanism as set out in the Proposals; while further delegations consider that it should be applied systematically and that the outcomes of the scrutiny mechanism should be binding.
- Regarding *oversight of notified bodies*, the Working Party has discussed provisions to strengthen criteria for designating the scope of competence of notified bodies, appropriate standards for notified bodies and joint assessments of notified bodies. The division of responsibilities between Member States and the Commission in designating a notified body remains to be clarified.
- With regard to the IVD Proposal, many delegations have welcomed the *alignment of the classification system* for *in vitro* diagnostic medical devices to the GHTF[2] classification principles.

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[2] Global Harmonisation Taskforce, *Principles of in vitro Diagnostic (IVD) Medical Devices Classification.*

- Regarding Chapter VI on the authorisation of *clinical investigations* (and clinical performance studies and other studies in the case of IVDs), many delegations have expressed the opinion that the time-limits for authorisation of clinical investigations are too short, expressed concerns regarding the provision for "tacit approval" of clinical investigations if time-limits are not complied with, and have drawn attention to the absence of an explicit reference to the role of ethics committees in the evaluation of applications for clinical investigations of medical devices.

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