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Subject:	Preparation of the **Employment, Social Policy, Health and Consumers** Council meeting on 1 December 2014 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 1 December 2014;

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

BACKGROUND

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 and submitted them to the Council and to the European Parliament.

2. The legal basis for the two proposals is Article 114 and point c) of Article 168(4) of the Treaty on the Functioning of the European Union ("TFEU"). The ordinary legislative procedure is applicable. The proposal for a Regulation on medical devices[1] aims at replacing Council Directives 90/385/EEC on active implantable medical devices[2] and 93/42/EEC[3] on medical devices; and the proposal for a Regulation on *in vitro* diagnostic medical devices[4] aims at replacing Council Directive 98/79/EC of the European Parliament and the Council on *in vitro* diagnostic medical devices[5].

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

CONSULTATIONS

3. 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. None of the national parliaments objected to the proposals[6].

4 The European Data Protection Supervisor was consulted by the Commission and issued an opinion on 8 February 2013[7].

5 Invited by the Council, the European Economic and Social Committee issued its opinion on the Proposals on 14 February 2013[8]. The Committee of the Regions decided not to deliver any opinion given the low impact of the measures proposed on the local or regional authorities.

STATE OF PLAY IN THE EUROPEAN PARLIAMENT

6. On 2 April 2014, the European Parliament adopted its legislative resolutions[9] on the two proposals and thus concluded its first reading. Following the elections, the Committee on the Environment, Public Health and Food Security (ENVI) of the European Parliament on 5 November mandated the Rapporteurs to enter into negotiations with the Council aiming to reach an agreement on these proposals.

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6 http://www.ipex.eu/

7 Doc. 5590/13

8 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

9 The EP adopted its amendments to the two proposals already at the Plenary on 22 October 2013. They are set out in documents 14936/13 and 14937/13.

STATE OF PLAY IN THE COUNCIL

7. In general, delegations have welcomed the proposals for a revision of the European legislative framework on medical devices, the aims of which are 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 users 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.

8. It is noted, that the examination is on-going and that all delegations have general scrutiny reservations on all proposals discussed so far. It is further noted, that the Danish, Austrian, Polish and United Kingdom delegations have entered Parliamentary scrutiny reservations.

9. Based on the conclusions of the EPSCO meeting on 20 June 2014, the Italian Presidency set itself an ambitious goal, which was to conclude work before the end of its tenancy.

   To this aim, the Italian Presidency organised ten meetings, one extra meeting included, of the Working Party on Pharmaceuticals and Medical devices (hereinafter "the Working Party"), in addition two expert meetings were organized.

10. Building on the examination in the Working Party during the Cyprus, Irish, Lithuanian and Hellenic Presidencies[10], the work has during the Italian Presidency concentrated on discussing various compromise proposals for different issues.

    Every chapter and every annex of both proposal (20 chapters, 187 articles and 29 annexes) have been discussed at least one time (at the end of the Presidency all chapters and annexes will have been discussed two times each).

    The Presidency has circulated three questionnaires, and related synthesis, on chapters II, VI and VII (83 questions followed by 2300 answers).

[10] The progress was reported to the Council in documents 10360/13 + COR 1 of 7 June 2013, 16609/13 of 26 November 2013 and 10855/14 of 12 June 2014.

11. From the outcome of the meeting of the Permanent Representatives' Committee on 19 November 2014, concerning the "general approach", the Presidency has realized that there are still some open questions and decided to prepare a progress report.

The Presidency is satisfied to have contributed to the progress of the work and intends to compile complete texts for both proposals by the end of its tenancy, that could serve as reference texts for the incoming Presidency.

12. During the examination by Member State experts in the Working Party that has resulted in a large number of redrafts of individual provisions in the two proposals, mainly aiming to facilitate the implementation and improve the enforcement of the EU medical devices framework, a number of "political issues" have been identified. These include:
    - Aesthetic devices;
    - Ingested products;
    - Reprocessing of single-use devices;
    - the Unique Device Identification System ("UDI");
    - Mechanisms for surveillance and appointment of the Notified Bodies responsible for conformity assessment of Medical devices and *In vitro* diagnostic medical devices;
    - the Scrutiny mechanism for certain high risk devices;
    - Clinical investigations;
    - Post-Market Surveillance;
    - Tasks of the proposed Medical Device Coordination Group;
    - Role of expert panels and reference laboratories.

    On 19 November, the Permanent Representatives' Committee discussed three of these, namely Aesthetic devices, UDI and the Scrutiny mechanism.

Aesthetic devices

13. Aesthetic devices are certain devices that are similar to medical devices but used for aesthetic, not medical, purposes. Examples of such devices are coloured contact lenses used to change the appearance of a person, not to correct sight problems. In order to create a legal basis for improved protection of the health of persons using such devices, the Commission proposed to include some such devices, listed in Annex XV, in the scope of the proposed Regulation on Medical devices.

14. On 19 November, the Permanent Representatives Committee discussed this issue. It was noted that 15 delegations favoured inclusion of Aesthetic devices under the scope of the Medical device Regulation. Five delegations opposed this, mainly on the grounds that this would increased the financial and administrative burden on competent authorities.

15. The Presidency concludes that the Working Party should continue its work to find a solution that could find broad support, based on the Presidency compromise text set out in Annex A to document 15546/14.

Ingested products

16. The proposal for a Regulation on medical devices provides for inclusion of certain substances or combinations of substances intended to be ingested, inhaled or administered rectally or vaginally ("Ingested products") into the scope of the Regulation. It further provides that all these devices be classified as high risk devices ("Class III")..

17. Several delegations expressed concerns on the suitability of the proposal, especially in relation to the delimitation between medical devices and medicinal products. Some delegations did not consider appropriate to classify the products as medical device and others considered it inappropriate to classify all such products in the highest risk class. It was however generally recognised that such products could not fall outside the scope of both medicinal products and medical device legislation.

18. Following an expert meeting on 29 September 2014 at which main issues such as the inclusion of other routes of administration, classification and the consultation procedure with competent authorities for medicinal products were discussed, some delegations undertook to elaborate a compromise. The compromise text has been further improved taking into consideration comments and suggestions and the Presidency believes that it could find support from a qualified majority.

Reprocessing of single-use devices

19. During the examination of the proposal that was the basis for the 2007 revision of the medical device directives, it was recognised that the issue of reprocessing of single-use devices needed to be addressed[11]. In response, the Commission proposal provides rules for reprocessing of single-use devices to make them suitable for further use within the Union. This covers also, for example, reprocessing in a hospital of a device that is used again in the same hospital. While some Member States would wish to prohibit entirely the reprocessing of devices that are intended for single-use, others support largely harmonised rules regulating reprocessing. The Presidency believes that a compromise proposal that allows Member States to prohibit re-processing under national law but provides that if not prohibited re-processing should follow minimum harmonised rules could find support from a broad majority.

Unique Device Identification System

20. The Commission proposal contains a requirement that manufacturers fit their devices with a Unique Device Identification (UDI) which allows traceability (Article 24 of the Medical device Regulation and Article 22 of the *In vitro* diagnostic medical device Regulation).

[11] See Article 2(11) of Directive 2007/47/EC OJ L 247, 21.9.2007, p21. that inserts Article 12a into Directive 93/42/EEC. In accordance with Article 12a, the Commission submitted a report on the issue of reprocessing set out in Council document 13440/10.

21. The UDI System and its connection to the central European database, where in accordance with the proposed Regulations manufacturers, authorised representatives and importers must be registered as must the devices they place on the EU market, has been the subject of discussion at Working Party level. Important issues include the functionality of the system, and the nature and scope of requirements that can be fulfilled in a reasonable time in view of the available resources and the relation to a possible European Medical Devices Nomenclature System.

22. The UDI system and related issues were the subject of a discussion in the Permanent Representatives Committee on 19 November. This discussion shows that further work is needed at Working Party level. While ten delegations supported a system that is close to what was proposed by the Commission (*e.g.* use of implementing acts to lay down details concerning the application of the system), eight delegations preferred a simpler system, and wanted more details of this system to be regulated in the Regulations themselves. Some of the delegations favouring "the Commission approach" had sympathy for the European Medical Device Nomenclature System, which is an element of the proposal for a "simpler system". The Commission representative pointed out that the simpler system did not allow for traceability.

Notified bodies

23. Medical devices are placed on the market following a conformity assessment performed either by the manufacturer or for devices in higher risk classes by a Notified body. One of the most important aims of the current proposals is to strengthen the surveillance of notified bodies by competent authorities and the surveillance of manufacturers by notified bodies.

24. A central element to achieve this is to clarify and strengthen the requirements for the designation of notified bodies, and to strengthen the exchange of information between Member states in order to further harmonise the requirements on notified bodies, while maintaining the responsibility for notified bodies at national level and not move it to Union level.

25. The main subject of controversy is the level of detail laid down in the legislative provisions and, consequently, what had better be left for guidelines.

Scrutiny mechanism for certain high risk devices

26. Article 44 of the Commission proposal for a Regulation on medical devices (and Article 42 of the proposal for a Regulation on *in vitro* diagnostic medical devices) provides that the Medical Device Coordination Group, set up by the proposed Regulation on medical devices, may scrutinise the preliminary conformity assessment by a Notified body of devices in the highest risk class before a certificate of conformity is issued and the device can be placed on the market.

27. Almost all delegations hold that the scrutiny procedure as proposed by the Commission is not possible to apply. While many delegations argue that strengthened market surveillance and vigilance measures regarding devices on the market are more efficient than pre-market measures, and therefore believe that a scrutiny mechanism before devices are placed on the market is not necessary, some delegations would wish to include a "pre-market scrutiny mechanism" for implantable devices in the highest risk class "Class III devices".

28 A possible compromise was discussed by the Permanent Representatives Committee on 19 November. This discussion showed that some delegations are strongly opposed to competent authorities taking over some of the responsibility now carried by notified bodies. Other delegations insisted on increasing the possibilities for competent authorities to intervene in the conformity assessment already at the "pre-market" stage. The discussion indicated that it is possible to find a compromise, but that further discussion is needed on the requirements on and scope covered by a possible pre-market scrutiny system.

Clinical investigations

29. Medical devices need to be evaluated as regards their safety and efficacy. To this aim clinical investigations are needed. These investigations can be performed before a device is placed on the market or as "post-market follow-up" after the device is placed on the market. In both cases patients must be involved as subjects.

30. The current directive 93/42/EEC on medical devices contains some provisions on clinical investigations, but the Proposal for a Regulation on medical devices contains further provisions in order to align the system to that for Clinical trials of medicinal products[12] and to improve comparability of data from different clinical investigations. In particular, the draft Regulation foresees clinical investigations that cover several Member States.

31. As the methodology for testing medical device is different and due to the variety of devices not as "standardised" as that for medicinal products and as for many types of medical devices the biggest problem is the availability, quality and reliability of data on their clinical performance, the Commission proposal does not include all provisions regarding *e.g.* subject recruitment that the Clinical trials regulation does.

32. The discussion of the Working Party is currently going in the direction of further aligning the provisions on ethical and methodological principles to those for clinical trials of medicinal product, which could be done either by applying provisions of the Clinical trials Regulation *mutatis mutandis* or by including them, appropriately adapted. in the Medical device Regulation.

33. As for *In vitro* diagnostic medical devices most studies aimed at obtaining evidence of their clinical performance, *e.g.* predictability and error frequencies, are observational, not interventional, but rules on clinical investigations are nevertheless necessary for the cases where patients are directly involved, as are provisions on personal data protection.

Post-Market Surveillance

34. The Presidency has proposed a compromise text for a new section of Chapter VII dedicated to Post-market surveillance, which defines obligations and responsibilities for the manufacturer. In particular, it contains the proposal to establish a separate annex regarding the Post-Market Surveillance (Annex IIa). This annex defines the requirements and procedures for the management of the fundamental documents of the Post-Market Surveillance: *Post-market surveillance plan* and *Periodic safety update reports*.

[12] Regulation (EU) No 536/2014.

Tasks of the proposed Medical Device Coordination Group

35. The Member States will be responsible for implementation of the proposed Regulations. In order to facilitate a harmonised interpretation and practice an expert committee (the Medical Device Coordination Group or MDCG) will be established. It shall consist of members appointed by the Member States due to their role and experience in the field of medical devices and chaired by the Commission. The MDCG and its subgroups should also allow to build a forum for discussions with stakeholders.

36. The discussions of the tasks of the MDCG is closely related to many of the other issues still subject to discussion, not least its rule in a possible pre-market scrutiny mechanism and in relation to expert panels.

37. A central question is the legal status of the opinions from MDCG, where most delegations hold that this cannot be of a binding nature, which would make it a decision-making body.

Role of expert panels and reference laboratories

38. The Commission proposal lays down a possibility for appointment of European reference laboratories for medical devices and *in vitro* diagnostic medical devices. While most delegations agree that there is a need for such laboratories for *in vitro* diagnostic medical devices in order to compare predicting powers of tests, few delegations see the same need as regards other medical devices. Instead, they favour the establishment of expert panels with competence for certain groups of devices. This issue must also be taken into account in a future compromise package.

CONCLUSION

The Permanent Representatives Committee is invited to take note of the Presidency's intention to forward this progress report to the Council (EPSCO) for its meeting on 1 December and to invite the Council to instruct the Council preparatory bodies to continue the work with the goal of establishing a Council position.