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Subject: **Employment, Social Policy, Health and Consumer Affairs** Council meeting on
19 and 20 June 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*
- *Policy debate*

Delegations will find attached a progress report (set out in Annex A) prepared by the Presidency
and intended to provide the background for a policy debate based on the questions set out in Annex
B at the meeting of the Council EPSCO on 20 June 2014.

This document also contains a text (set out in Annex C) proposed by the Presidency for Chapter IV
on Notified bodies and applicable to both proposals.

**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 AND CONTENTS

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 devices¹ aims at replacing Council Directives 90/385/EEC on active implantable medical devices² and 93/42/EEC³ on medical devices and the proposal for a Regulation on *in vitro* diagnostic medical devices⁴ aims at replacing Council Directive 98/79/EC of the European Parliament and the Council on *in vitro* diagnostic medical devices⁵.

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

3. The revision of the European legislative framework on medical devices aims to ensure:
- the highest level of protection for European patients, consumers and healthcare professionals;
 - that safe, effective and innovative medical devices can be placed on the market efficiently and made available to users in a timely manner;
 - and that the EU is competitive and maintains a suitable environment for innovation in the field of medical devices.

CONSULTATIONS

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. None of the national parliaments objected to the proposals⁶.
5. The European Data Protection Supervisor was consulted by the Commission and issued an opinion on 8 February 2013⁷.
6. The European Economic and Social Committee issued its opinion on the Proposals on 14 February 2013⁸. Invited by the Council, 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 COUNCIL

7. In general, delegations have welcomed the proposals. However, all delegations still have general scrutiny reservations on the entire proposals and the Danish, Austrian, Polish and United Kingdom delegations have entered Parliamentary scrutiny reservations.

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.

8. The Working Party on Pharmaceuticals and Medical Devices ("the Working Party") met four times during the Cyprus Presidency, seven times during the Irish Presidency and held six meetings during the Lithuanian Presidency to achieve a first read-through of all articles of the two Proposals. In addition, seven technical expert meetings were organised by the Irish Presidency and six technical expert meetings by the Lithuanian Presidency to examine Annexes I, VI, VII, VIII, IX, X, XI, XII, XIII and XIV of the Medical Device proposal and Annexes I, VI, VII, VIII; IX, X, XI, XII and XIII of the *In vitro* diagnostic medical devices proposal.⁹
9. On 10 December 2013, the Council held an exchange of views focusing on the supervision process by competent authorities and notified bodies and on reprocessing of "single-use" medical devices.¹⁰
10. Following on from the work of the previous Presidencies, the Hellenic Presidency has focused the discussions at the Working Party on changes to the text that could get broad support from delegations and thus constitute a basis for a future Council position at first reading. To this aim, the following Chapters of the two proposals have been examined:
- **Chapter I** – *Scope and Definitions*¹¹;
 - **Chapter II** – *Traceability, Registration and European databank*¹²;
 - **Chapter III** – *Obligations of economic operators and CE-marking*¹³;
 - **Chapter IV** – *Notified Bodies*¹⁴;
 - **Chapter V** – *Classification and Conformity Assessment*¹⁵;

⁹ The progress was reported to the Council in documents 10360/13 + COR 1 of 7 June 2013 and 16609/13 of 26 November 2013.

¹⁰ See doc. 16610/13.

¹¹ See doc. 8343/1/14 REV 1.

¹² See doc. 5458/14.

¹³ See doc. 5458/14.

¹⁴ See doc. 9773/14.

¹⁵ See doc. 6908/14.

- **Chapter VII** – *Vigilance and Market surveillance*¹⁶;
- **Chapter VIII** - *Cooperation between Member States, Medical Device Coordination Group, EU Reference Laboratories*¹⁷;
- **Chapters IX** – *Confidentiality, data protection, funding, penalties* and **X** – *Final provisions*¹⁸.

11. The Hellenic Presidency also intends to organise a discussion on **Chapter VI** – *Clinical Evaluation & Clinical Investigation* (MD Proposal) and *Clinical Evidence* (IVD Proposal), which means that the second examination of all Chapters will be almost completed.
12. In all, the Working Party will have met during 15 days in the period of the Hellenic Presidency for the examination of the two proposals.
13. At its meeting on 11 June 2014, the Permanent Representatives Committee (Part 1) instructed the Working Party to continue its work with the aim of preparing for a Council position to be established during the next Presidency.
14. During the second part of the Hellenic Presidency, efforts have concentrated on Chapters IV, VII and VIII, which contain many of the most important innovations compared to the current EU legislative framework for medical devices.

¹⁶ See doc. 10146/14.

¹⁷ See doc. 9094/1/14 REV 1.

¹⁸ See doc. 6804/14.

15. Chapter IV lays down rules for the designation, by a Member State, of a Notified body and the involvement of other Member States and the Commission in this process. It also contains provisions on the monitoring of Notified bodies by Competent Authorities and co-operation between those authorities.

As regards this chapter, most delegations support the general thrust of the changes proposed by the Presidency, which aim to clarify the procedures concerning designation of conformity assessment bodies as Notified bodies, and, in particular, to strengthen co-operation between Member States and mutual control of Notified bodies, *e.g.* through peer-review of National Competent Authorities and joint assessments of Notified bodies. Some delegations have however expressed concerns that the procedures could be too burdensome from an administrative and financial perspective.

16. Chapter VII deals with measures applicable once a medical device has been placed on the market, in particular reporting of incidents and market surveillance. It also lays down reinforced obligations to take corrective measures.

Most delegations support the introduction of provisions in Chapter VII requiring that, in addition to the surveillance activities for which competent authorities have the leading role, economic operators carry out post-market surveillance, *e.g.* by collecting and analysing data on the performance of medical devices, in particular on adverse reactions in which they are involved.

17. The most important provision of Chapter VIII establishes a Medical Device Coordination Group (MDCG) in order to facilitate co-operation between Member States Competent Authorities and in order to harmonise practises in the application of EU law on medical devices. This chapter furthermore lays down rules on EU reference laboratories for medical devices and *in vitro* diagnostic medical devices.

From the discussions on this chapter, it could be concluded that:

- = all delegations support the establishment of the MDCG;
- = most delegations support the idea to unify co-operation between Member States regarding medical devices and *in vitro* diagnostic medical devices by appointing one representative per Member State in the Medical Device Coordination Group (MDCG) rather than separate representatives for medical devices and *in vitro* diagnostic medical devices;
- = while many delegations want to allocate additional tasks to the MDCG compared to what the Commission proposed, other delegations are eager to limit its tasks, not only for economic reasons but also because of concerns regarding the capacity of the MDCG to fulfil all its tasks;
- = there is broad agreement that the establishment of a network of reference laboratories is important for the proper evaluation of *in vitro* diagnostic medical devices. As regards the evaluation of medical devices, however, many delegations have expressed an interest in either complementing the reference laboratories with device panels or replacing them entirely with device panels in order to provide relevant expertise input for regulatory measures. A few delegations have expressed doubts on the usefulness of new permanent structures.

NEXT STEPS

18. Almost all delegations deem it important to improve the current EU legislative framework for medical devices by adopting new Regulations based on the Commission proposals. Most delegations, while stressing the need for high-quality regulations that will stand the test of time, also underline the need to adopt the new legislation without unnecessary delay.

19. On 2 April 2014, the European Parliament adopted its legislative resolutions¹⁹ on the two proposals and thus concluded its first reading. Since the examination in the Working Party indicates that delegations wish to make changes to the proposals that do not concur with the European Parliament amendments on all points, interinstitutional negotiations will be needed in order to reach an agreement. Such negotiations could take place before the formal adoption of the Council position at first reading, in which case the European Parliament could approve the Council position without amendments in accordance with Article 294(7)(a) of the TFEU resulting in an "early second reading agreement". Should it not be possible to reach agreement before adoption of the Council position at first reading, the next step would be for the Council and the European Parliament to agree amendments to the Council position within the time limits following from Article 294, paragraphs 7 and 14 of the TFEU which could then be voted at plenary by the European Parliament in second reading. Thereafter the Council could approve the amendments in accordance with Article 294(8)(a) of the TFEU and the Regulations would be adopted following a second reading agreement.

¹⁹ 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.

CONCLUSION

The Council is invited:

- to take note of the progress report set out in Annex A,
 - to hold a policy debate at its forthcoming meeting on 20 June 2014, based on the three questions in Annex B, and
 - to instruct its preparatory bodies to continue the examination of the proposals with the aim of preparing a Council position to be established during the next Presidency.
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Questions for discussion

In light of the above, the Presidency suggests to hold a Council policy debate in order to provide answers to the following questions in order to steer the future examination by the Working Party:

1. *Does the text set out in Annex C constitute a good basis for the further discussion on the provisions regarding designation and monitoring of Notified bodies?²⁰*
 2. *Are specific provisions on post-market surveillance under the responsibility of economic operators a necessary element to secure an adequate level of protection of patients?*
 3. *Bearing in mind the aims of the proposed Regulations, and in view of the resources required, is it desirable to allocate further tasks to the MDCG other than those foreseen in the Commission proposal?*
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²⁰ Chapter IV of the proposals.

This Annex contains the text proposed by the Presidency for Chapter IV on Notified bodies and applicable to both proposals. The Article numbering refers to the proposal for a Regulation on Medical devices.

Text set out in ***bold italics*** and ***bold italics underline*** is new compared to what was proposed by the Commission. Deletions of text proposed by the Commission is set out in ~~striketrough~~ or in ~~striketrough and underlined~~.

Chapter IV

Notified bodies

Article 28

National authorities responsible for notified bodies

1. A Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out ~~third-party~~ conformity assessment tasks under this Regulation shall designate an authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors or subsidiaries of those bodies, hereinafter referred to as the ‘national authority responsible for notified bodies’.
2. The national authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interests with conformity assessment bodies.
3. ***The national authority responsible for notified bodies*** ‡ shall be organised so that each decision relating to ***designation or*** notification of a conformity assessment body is taken by personnel different from those who carried out the assessment of the conformity assessment body.

4. *The national authority responsible for notified bodies* shall not perform any activities that ~~conformity assessment notified~~ bodies perform ~~nor provide consultancy services~~ on a commercial or competitive basis.
5. The national authority responsible for notified bodies shall safeguard the confidentiality of the information it obtains. However, it shall exchange information on a notified body with other Member States and the Commission.
6. The national authority responsible for notified bodies shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Without prejudice to Article 33(3), ~~where a~~ *the* national authority is responsible for the designation of notified bodies in the field of products other than medical devices, *is separate from shall ensure that* the competent authority for medical devices, *it shall ensure that the authority responsible for medical devices is consulted* shall be consulted ~~on~~ *on* all aspects specifically related to medical devices ~~also where relevant in the designation of notified bodies for other fields of products than medical devices~~.

7. Member States shall provide the Commission and the other Member States with information on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any *relevant* changes *which have a significant impact on these tasks* ~~thereto~~. *The Commission shall make this information publicly available.*

8. **The national authority responsible for notified bodies shall actively participate in coordination and peer review assessments as described in Article 38.** ~~The national authority responsible for notified bodies shall be peer reviewed every second year. The peer review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. In the case referred to in the second subparagraph of paragraph 6, the competent authority for medical devices shall participate in the peer review.~~

~~The Member States shall draw up the annual plan for the peer review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission may participate in the review. The outcome of the peer review shall be communicated to all Member States and to the Commission and a summary of the outcome shall be made publicly available.~~

Article 29

Requirements relating to notified bodies

1. Notified bodies shall satisfy the organisational and general requirements and the quality management, **competence**, resource and process requirements that are necessary to fulfil their tasks for which they are designated in accordance with this Regulation. ~~Minimum~~ **The # Requirements** to be met by notified bodies are set out in Annex VI.

1a. Notified bodies shall make available and submit upon request, all relevant documentation, including the manufacturer's documentation to the national authority responsible for notified bodies to allow it to conduct its assessment, monitoring and surveillance activities.

2. *In order to ensure the uniform application of the requirements set out in Annex VI*, The Commission ~~shall be empowered to~~ *may* adopt ~~delegated~~ *implementing* acts in accordance with Article ~~889 (3)~~ *amending or supplementing the minimum requirements in Annex VI, in the light of technical and scientific progress and considering the minimum requirements needed for the assessment of specific devices, or categories or groups of devices.*

Article 30

Subsidiaries and subcontracting

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the relevant requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.
2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.
- ~~3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only with the agreement of the legal or natural person that applied for conformity assessment.~~
4. Notified bodies shall keep at the disposal of the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

5. *The annual assessment of notified bodies as provided for in Article 35(3) shall include verification of the compliance of subcontractors and subsidiaries of notified bodies with the relevant requirements set out in this Regulation Annex VI.*

The report on the assessment set out in Article 35(3) shall include the results of the audits conducted of the subcontractors and subsidiaries and the other documents referred to in Article 30(4) for all subcontractors and subsidiaries of notified bodies.

6. *When a notified body has a subsidiary or utilises a subcontractor in another Member State than the Member State where it is established and the competent authority for medical devices or the national authority responsible for notified bodies of a in any of the Member States concerned has reason to doubt that that subcontractor or subsidiary established in the territory of that Member State complies with the requirements set out in Annex VI, those authorities shall consult with the national authority responsible for the notified body and that competent authority may, if they do not agree on a satisfactory solution, request that the MDCG initiates the assessment process described in Article 32(3) and (4).*

Article 31

Application by a conformity assessment body for notification

1. A conformity assessment body shall submit an application for notification to the national authority responsible for notified bodies of the Member State in which it is established. The application shall be written in an official language or official languages specified by the Member State concerned.

2. The application shall specify the conformity assessment activities, ~~the conformity assessment~~ procedures and the ***types of*** devices for which the body ***applies to be notified*** ~~claims to be competent~~, supported by documentation proving compliance with all the requirements set out in Annex VI.

In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VI, ~~the relevant documentation may be submitted in form of~~ a valid certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008. ~~The conformity assessment body shall be presumed to be in conformity with the requirements covered by the certificate delivered by such accreditation body.~~ ***may be submitted in support of these requirements and shall be taken into consideration by the national authority responsible for the notified body during the assessment described in Article 32. However, the applicant shall make the full documentation to demonstrate conformity with these requirements available upon request.***

3. ~~After being designated, the notified body shall update the documentation referred to in paragraph 2 whenever relevant changes, in particular regarding personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in Annex VI, occur in order to enable the national authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VI.~~²¹

²¹ Pcy proposes to move this paragraph to become 35(0) since it is related to monitoring.

Article 32

Assessment of the application

1. The national authority responsible for notified bodies shall **within 30 days** check that the application referred to in Article 31 is complete and **may request the applicant to provide any missing information. At the latest 60 days after receiving a complete application, it shall** draw up a preliminary assessment report.

2. It shall submit the preliminary assessment report to the Commission which shall immediately transmit it to the Medical Device Coordination Group established by Article 78 ('MDCG'). ~~Upon request by the Commission, the~~ **The** report shall be submitted by the authority in **an the national official language or official languages specified by of the Member State concerned plus , and upon request by the Commission or the MDCG, in an additional** ~~up to three~~ official Union languages.

- 2a. Within 7 days of the submission the national authority responsible for notified bodies shall schedule an on-site assessment with the applicant body at least 84 days but not more than 104 days following submission to the MDCG. The national authority shall communicate this schedule to the MDCG.**

3. Within 14 days of the submission referred to in paragraph 2, the Commission shall designate a joint assessment team made up of at least ~~two~~ **three** experts chosen from a ~~the~~ list ~~of experts who are qualified in the assessment of conformity assessment bodies referred to in Article 32a and who do not have any conflict of interests who comply with Article 82 as regards with the applicant conformity assessment body.~~ The list shall be drawn up by the Commission in cooperation with the MDCG. **The first expert shall come from the Member State of the applying conformity assessment body and be appointed by the Commission. The second expert shall come from another Member State and be appointed by the Member State of the applying conformity assessment body.** At least ~~o~~ ~~One~~ of these **The third** experts shall be **appointed by** a representative of the Commission **and** ~~who~~ shall lead the joint assessment team. **The expert leading the team shall participate in the assessment of the applicant body and shall verify that the national authority responsible for notified bodies fulfils its obligations and effectively performs its designation and monitoring activities.**
- 3a. The joint assessment team shall be comprised of appropriate experts which reflect the conformity assessment activities and the types of devices which are subject to the application from the conformity assessment body or, in particular when this procedure is initiated in accordance with Article 37 to ensure that the specific concern can be appropriately assessed.**
- 3b. The national authority responsible for notified bodies shall provide the joint assessment team with all relevant documents necessary to support its preliminary assessment report to allow the joint assessment team to conduct a preliminary assessment of the compliance of the applicant with the requirements and obligations in Annex VI. The documents shall be available in the languages referred to in paragraph 2.**

3c. The national authority for notified bodies shall provide the joint assessment team with its initial plan for on-site assessment of the notified body. Following its assessment of the application the joint assessment team shall provide input into the on-site assessment plan.

If the joint assessment team, following an initial assessment, does not consider that the application is sufficient to allow an on-site assessment to proceed as provisionally scheduled it shall inform the national authority accordingly and provide its reasons within 30 days of the assignment of the team.

The authority shall decide whether to reject the application, to proceed with the on-site assessment in accordance with paragraph 4 or request the applicant to take action pursuant to paragraph 3d.

3d. The national authority responsible for notified bodies shall, based on the reasons provided by the joint assessment team or its own findings inform the applicant about measures arising from the assessment that shall be taken before the assessment can be continued. After taking those measures, the applicant shall submit an updated application, setting out in particular the measures taken. The assessment shall continue pursuant to paragraph 3b.

4. Within 90 days after designation assignment of the joint assessment team or, where applicable, of the updating of the application pursuant to paragraph 3d, the national authority responsible for notified bodies and the joint assessment team shall review the documentation submitted with the application in accordance with Article 31 and together plan and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process. Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 31(2), unless the national authority and joint assessment team following due consideration so decide ~~the Commission representative mentioned in Article 32(3) requests the on-site assessment.~~ The national authority responsible for notified bodies and the joint assessment team shall, verify that the applicant body has sufficient capacity to enable it to perform unannounced factory inspections as provided for in Section 4.4 of Annex VIII.

The on-site assessment of the applicant body shall be led by the national authority responsible for notified bodies.

- 4a. Findings regarding non-compliance of a body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team with a view to finding common agreement with respect to the assessment of the application.

The joint assessment team shall record non-compliances with Annex VI, observations on the performance of the national authority responsible for notified bodies and any opportunities for improvement in a report to be provided to the MDCG, the Commission and to the national authority responsible for notified bodies.

Divergent opinions shall be identified in the assessment report of the joint assessment team national authority responsible and shall be provided to the MDCG, the Commission and the national authority responsible for notified bodies.

5. The national authority responsible for notified bodies shall, ***following implementation of any measures arising from the assessment***, submit its assessment report and, ***if applicable, the*** its draft notification to the Commission, ~~which shall immediately transmit those documents to the MDCG and to the members of the joint assessment team. Upon request by the Commission, those documents shall be submitted by the authority in up to three official Union languages.~~
6. The joint assessment team shall provide its opinion regarding the assessment report ***prepared by the national authority responsible for notified bodies*** and, ***if applicable***, the draft notification within 21 days of receipt of those documents ~~and to~~ the Commission, ***which*** shall immediately submit this opinion to the MDCG. Within 21 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft notification which the relevant national authority shall duly take into consideration for its decision on the designation of the notified body.
7. The Commission may, by means of implementing acts, adopt measures setting out the modalities ***and associated documents*** for the application for notification referred to in Article 31 and the assessment of the application set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Article 32a

Nomination of experts for joint assessment of applications for notification

1. ***Member States shall nominate experts qualified in the assessment of conformity assessment bodies in the field of medical devices to participate in the joint assessment activities outlined in Article 32.***

2. **The Commission shall maintain a list of the experts nominated pursuant to paragraph 1, together with information on their specific competence and expertise.**

Article 33

Notification procedure

1. Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool developed and managed by the Commission.
2. Member States may notify only conformity assessment bodies which satisfy the **minimum** requirements set out in Annex VI **and for which the assessment pursuant to Article 32 was completed.**
3. ~~Where a~~ ***The*** national authority responsible for notified bodies ***shall not designate a notified body for any tasks related to medical devices unless*** ~~is responsible for designation of notified bodies in the field of products other than medical devices,~~ the competent authority for medical devices ~~shall~~ ***has*** ~~provided,~~ prior to the notification, a positive opinion on the notification **as regards conformity assessments related to medical devices** ~~and its scope.~~
4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities, the conformity assessment procedures and the type of devices which the notified body is authorised to assess.

- 4a.** The Commission shall within [three] years of the entry into force of this Regulation ~~may~~, by means of implementing acts, ~~set~~ draw up a list of codes and ~~the~~ corresponding types of devices to ~~define~~ describe the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the ~~advisory~~ examination procedure referred to in Article 88(~~2~~ 3).
5. The notification shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the opinion of the joint assessment team and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.
6. The notifying Member State shall provide the Commission and the other Member States with documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VI. It shall furthermore submit evidence of the availability of competent personnel for monitoring the notified body in accordance with Article 28(6).
7. ~~**The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within 28 days of a notification. The Commission and the other Member States may, within 28 days of the notification object to the notification on grounds relating to the designated with regard to the notified body**~~ Within 28 days of a notification, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the national authority responsible for notified bodies.

8. When a Member State or the Commission raises objections in accordance with paragraph 7, ~~the effect of the notification shall be suspended. In this case,~~ the Commission shall bring the matter before the MDCG within ~~150~~ days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within ~~4028~~ days after the matter has been brought before it. ~~If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion.~~²²

8a *Where the MDCG, after having been consulted in accordance with paragraph 8, raises an objection, the notifying Member State shall provide a written response to the MDCG's opinion within 28 days of its receipt. The response shall address the objections raised in the opinion, and set out the reasons why the notifying Member States intends to designate or not designate the conformity assessment body. including the steps the notifying Member State intends to take to resolve the objections.*

²² Pcy sentence deleted since it is covered by the new paragraph 8a.

9. Where no objection is raised in accordance with paragraph 7 or where the MDCG ~~or the Commission~~, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted ~~fully or partially~~, **or where the notifying Member State having responded in accordance with paragraph 8a, decides to designate the conformity assessment body** the Commission shall publish the notification accordingly.
- ~~**Where the MDCG, after having been consulted in accordance with paragraph 8, raises an objection, the notifying Member State shall provide a written response to the MDCG's opinion within 28 days of its receipt. The response shall address the objections raised in the opinion, including the steps the notifying Member State intends to take to resolve the objections.**~~
- ~~**At the same time When publishing the notification, the Commission shall ~~also~~ add the information relating to the notification of the notified body to the electronic system referred to in point (e) of Article 27(2). ~~This~~ That information shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the opinion of the joint assessment team and the recommendation of the MDCG mentioned in paragraph 5 of this Article. In addition, the Commission shall include details of the opinion and response referred to in paragraphs 8 and 8a of this Article on the electronic system where it shall be accessible to Member States and the Commission.**~~
- ~~**The data contained in the electronic system shall be accessible to Member States and the Commission.**~~
10. The notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the notified body.
- 11. The conformity assessment body-concerned may perform the activities of a notified body only after the notification has become valid in accordance with paragraph 10.**

Article 34

Identification number and list of notified bodies

1. The Commission shall assign an identification number to each notified body for which the notification ~~is accepted~~ ***becomes valid*** in accordance with Article 33**(10)**. It shall assign a single identification number even when the body is notified under several Union acts.
2. The Commission shall make the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the ***conformity assessment activities and the types of devices*** for which they have been notified, accessible to the public. The Commission shall ensure that the list is kept up to date.

Article 35

Surveillance, Monitoring and re-assessment of notified bodies

- 0.**²³ **After being designated, the notified body shall update the documentation referred to in Article 31(2) whenever relevant changes occur, in particular regarding personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in [Annex VI/this Regulation]²⁴, in order to enable the national authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VI.**

²³ This is former Article 31(3).

²⁴ To be aligned with the wording chosen elsewhere.

1. The national authority responsible for notified bodies shall **conduct surveillance and monitoring of regularly** continuously ~~monitor~~ the notified bodies **based on its territory** to ensure ongoing compliance with the requirements ***and the fulfilment of its obligations*** set out in **this Regulation Annex VI**. The notified bodies shall, on request, supply all relevant information and documents, required to enable the authority, **the Commission and other Member States** to verify compliance with those criteria.

Notified bodies shall, without delay, inform the national authority responsible for notified bodies of any ***relevant*** changes **referred to in paragraph 0**, ~~in particular regarding their personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment procedures relating to the devices for which they have been designated.~~

2. Notified bodies shall respond without delay to requests relating to conformity assessments they have carried out, submitted by their ~~or another Member State's authority or by the Commission~~ **and grant access to their premises upon request in accordance with paragraph 3e**. The national authority responsible for notified bodies of the Member State in which the body is established shall enforce requests submitted by authorities of any other Member State or by the Commission unless there is a legitimate reason for not doing so in which case both sides may consult the MDCG. **For this purpose the national authority responsible for notified bodies shall receive a copy of all such requests submitted to notified bodies based on their territory.** ~~The notified body or their national authority responsible for notified bodies may request that any information transmitted to the authorities of another Member State or to the Commission shall be treated confidential.~~

3. At least once a year, the national authority responsible for notified bodies shall assess whether each notified body *and the subsidiaries and subcontractors* under its responsibility still satisfies the requirements *and fulfil their obligations* set out in Annex VI. This assessment shall include an on-site visit to each notified body *and, if necessary, to its subsidiaries and subcontractors*. ~~For notified bodies performing quality system assessments, a witnessed audit of them performing an assessment at a manufacturer's facilities shall be included.~~

The national authority shall conduct its monitoring, surveillance and re-assessment activities in line with a reasoned plan to ensure that it can effectively conduct monitoring and surveillance of a notified body's continued compliance with the requirements of this Regulation. The authority shall submit its annual plan for surveillance, monitoring or re-assessment of notified bodies to the MDCG and to the Commission by the end of October each year.

3a. The national authority's monitoring of notified bodies shall include, at least once a year, witnessed audits of the notified body personnel, including subsidiaries and subcontractors when necessary, when conducting quality system assessments at a manufacturer's facility.

3b. The national authority, as part of its ongoing monitoring and surveillance of notified bodies shall assess an appropriate number of notified body reviews of manufacturers' clinical evaluations and technical document to verify the conclusions drawn by the manufacturer. The sample of files assessed shall be planned and representative of the types and risk of devices certified by the notified body. The sample chosen shall be appropriately justified and documented. These reviews shall be conducted both off site and on-site.

3c. The monitoring and surveillance of notified bodies conducted by the national authority responsible for notified bodies should be performed by appropriately competent and qualified personnel. The personnel may comprise both internal and external experts and should be representative of the range of devices for which the notified body is designated.

3d. The monitoring and surveillance of notified bodies conducted by national authorities shall consider data arising from market surveillance, vigilance and post-market surveillance systems to help guide its activities.

The authority shall provide for a systematic follow-up of complaints, vigilance reports and other information, including from other Member States, which may indicate non-fulfilment of the obligations by a notified body or its deviation from common or best practice.

In addition, effective mechanisms shall be in place to ensure the flow of information between the national authority responsible for notified bodies and the competent authority for medical devices. Particular emphasis shall be placed on the review of clinical data relevant to the device.

3e. The national authority responsible for notified bodies may in addition to surveillance or re-assessment on-site assessments conduct short-notice, unannounced or ‘for-cause’ assessments if needed to address a particular issue or to verify compliance.

3f. The national authority responsible for notified bodies shall document and record any findings regarding non-compliance of the notified body with the requirements set out in Annex VI and shall require necessary corrective and preventative actions by the notified body. The timely implementation and subsequent effectiveness of these actions shall be monitored by the national authority responsible for notified bodies.

3g. The national authority responsible for notified bodies may impose specific sanctions against a notified body based on its territory based on findings as referred to in paragraph 3f. The national authority shall be able to justify, upon request of the MDCG or the Commission, the reasons for imposing sanctions on the notified body rather than making any change to the notification as provided for in Article 36.

4. Three years after notification of a notified body, and again every third year thereafter, ~~the a re-~~assessment to determine whether the notified body still satisfies the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 32(3) and (4). ~~At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body or any of its subsidiaries or subcontractors with the requirements or the fulfilment of the obligations set out in Annex VI.~~
5. The Member States shall report to the Commission and to the other Member States, at least once a year, on their monitoring activities *regarding their notified bodies and, where applicable, subsidiaries and subcontractors.* **This report shall provide details of the outcome of the monitoring and surveillance activities, including details of the verification of technical and clinical reviews conducted by the authority.** This report **shall be treated as confidential by the MDCG and the Commission however it** shall contain a summary which shall be made publicly available.

Each year, the notified bodies shall send an annual activity report, containing the information mentioned in Annex VI point [to be decided], to the appropriate national competent authority responsible for notified bodies and the Commission. The Commission shall forward it to the MDCG.

Article 35a

Clinical assessments of certain notified bodies

1. In addition, as part of the surveillance activities set out in paragraphs 3 and 4 of Article 35 of this Regulation, national authorities responsible for notified bodies submit a plan to the MDCG for off-site assessment of a sample of reviews of clinical evaluations, submitted by manufacturers in support of class III and/or implantable medical devices, that is representative of the number and type of devices assessed by each notified body for which they are responsible.
2. The national authority responsible for notified bodies shall assess that the review by the notified body was conducted appropriately and verify the conclusions drawn by the notified body. The assessment conducted by the national authority shall utilise appropriate internal and, when necessary, external clinical expertise. These assessments shall be conducted utilising common technical specifications provided for in Article 7.
3. The national authority responsible for notified bodies shall, when conducting its assessment, consider data relevant from the surveillance systems described in chapter VII of this Regulation, the common technical specifications available and the state of the art.
4. The national authority responsible for notified bodies shall produce a report detailing the device, the clinical evidence, the review and conclusions of the notified body and its own conclusion on this assessment. This report shall be uploaded along with the notified body assessment to the European databank referred to in Article 27.
5. The MDCG will coordinate the joint clinical assessment of a sample of class III and/or implantable devices across the range of notified bodies informed by the sampling plan referred to in Article 35a(1).

- 6. The national authority responsible for notified bodies shall lead the assessment in conjunction with at least two clinical experts who have appropriate experience in assessing clinical evidence and of the type of devices in question.**
- 7. The MDCG shall draw up a list of clinical experts identified as either national authority experts or external clinical experts identified on the basis of their clinical speciality. The Commission may also contribute experts to the joint clinical assessment teams. The MDCG will implement a system to ensure impartiality and to manage potential conflicts of interest.**
- 8. The joint clinical assessment team will complete its assessment, in line with principles of paragraph 2 and 3 of this Article, within 30 days of all required documentation being provided to it. During this time it may seek clarification or ask questions to the notified body involved.**
- 9. The joint clinical assessment team shall prepare a report within 15 days of completing its assessment which shall be immediately provided to the MDCG.**
- 10. Where a joint clinical assessment report identifies deficiencies in a notified body's assessment of the clinical evaluation, the report shall include a recommendation to the MDCG on the remedial action that it judges appropriate with respect to the device in question.**
- 11. If the MDCG judges that these deficiencies are appropriately justified and evidenced, and depending on the type of nature of deficiencies concerned a remedial action will be implemented. This may include but will not be limited to, further enhanced assessment by a joint clinical assessment team on the reports submitted by the authority in accordance with Article 35a(3) and a joint clinical assessment on-site at the notified body in accordance with Article 37(3).**
- 12. The Commission in cooperation with the MDCG shall produce guidance to support the operation of clinical assessments.**

13. The MDCG may, based on performance in previous clinical assessments, the monitoring by the national authority and joint assessment teams, and inputs from the surveillance described in Chapter 7, recommend that the sampling shall cover a greater or lesser proportion of the clinical evaluations assessed by a notified body.

Article 36

Changes to notifications

1. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification ***by the national authority responsible for notified bodies. Where the change extends the scope of the notification, the procedures described in Articles 32(2) to (6) and 33 shall apply to the extension.*** ~~The procedures described in Article 32(2) to (6) and in Article 33 shall apply to changes where they entail an extension of the scope of the notification.~~ In all other cases, the Commission shall immediately publish the amended notification in the electronic notification tool referred to in Article 33(10).

1a. Where a notified body decides to cease its conformity assessment activities it shall inform the national authority responsible for notified bodies and the manufacturers concerned one year before ceasing its activities. The certificates may remain valid for a temporary period of six months after cessation of activities on condition that another notified body has confirmed in writing that it will assume responsibilities for these products and have completed assessment of the devices by the end of that time period. The national authority responsible for notified bodies shall also confirm that there is no question of certificates being unduly issued by the outgoing notified body.

2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations, the authority shall suspend, restrict, or fully or partially withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. A suspension shall not exceed a period of one year, renewable once for the same period. Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.

The national authority responsible for notified bodies shall immediately inform the Commission and the other Member States of any suspension, restriction or withdrawal of a notification.

2a. A restriction of a notification may constitute a reduction in the conformity assessment procedures, activities or the types of devices which a notified body can assess and certify.

3. In the event of restriction, suspension or withdrawal of a notification, the Member State shall take appropriate steps to ensure that the files of the notified body concerned are ~~either processed by another notified body or~~ kept available for the national authorities responsible for notified bodies and **national authorities responsible** for market surveillance at their request.

4. The national authority responsible for notified bodies shall assess whether the reasons which gave rise to the change to the notification have an impact on the certificates issued by the notified body and, within three months after having notified the *suspension, restriction, extension, change or withdrawal of* changes to the notification, shall submit a report on its findings to the Commission and the other Member States. ~~Where necessary to ensure the safety of devices on the market, that~~ **The national competent authority responsible for notified bodies** shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued. ~~If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.~~ **The authority shall enter into the electronic system mentioned in Article 45 paragraph 4 all certificates which it has suspended or withdrawn and inform the competent authority for medical devices of the Member State where the manufacturer concerned or his authorised representative has his registered place of business through this electronic system. Where necessary to avoid a potential risk to the health or safety of patients, users or others the authority responsible for the manufacturer of the device or his authorised representative shall take the appropriate measures.**
5. The certificates, other than those unduly issued, which were issued by the notified body for which the notification has been suspended, restricted or withdrawn shall remain valid in the following circumstances:

- (a) in the case of suspension of a notification: on condition that, **within one month of the suspension, that the national authority has confirmed that there is no safety issue, that no certificates relevant to the suspension will be issued, amended or re-issued and shall indicate whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued. If the notified body do not have the capability that national authority shall confirm that** within three months of the suspension, either the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate is established, or another notified body confirm in writing that it is assuming the functions of the notified body during the period of suspension.;
- (b) in the case of restriction or withdrawal of a notification: for a period of three months after the restriction or withdrawal. The competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate is established may extend the **provisional** validity of the certificates for further periods of three months, which altogether may not exceed twelve months, provided **that it has confirmed that there is no safety issue associated with the devices in question and that another notified body has confirmed in writing that it will assume responsibilities for these products and have completed assessment of the devices by the end of that time period.** ~~it is assuming the functions of the notified body during this period.~~

The authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately inform the Commission, the other Member States and the other notified bodies thereof.

Article 37

Challenge to the competence of notified bodies

1. The Commission, **in conjunction with the MDCG**, shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body of the requirements set out in Annex VI or the obligations to which it is subject. **It shall ensure that the concerned national competent authority responsible for notified bodies and the MDCG are informed and are given opportunity to investigate these concerns.** It may also commence such investigations on its own initiative.

2. The notifying Member State shall provide the Commission, on request, with all information regarding the notification of the notified body concerned.

2a. The Commission in conjunction with the MDCG may initiate the assessment process described in Article 32(3) and (4) when there is reasonable concern about the ongoing compliance of a notified body or a subsidiary or subcontractor of the notified body with the requirements set out in Annex VI. The reporting and outcome of this assessment process will follow the principles of Article 32(5) and 32(6) without necessarily the inclusion of a notification.

3. Where the Commission ascertains that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the notification if necessary.

Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the notification. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3). It shall notify the Member State concerned of its decision and update the database and list of notified bodies.

3a. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

Article 38

Peer review team assessment of national authorities responsible for notified bodies and Exchange of experience ~~between national authorities responsible for notified bodies~~

- 1. The national authority responsible for notified bodies shall be subject to peer review team assessment of their surveillance and monitoring activities, every three years.**
- 2. The peer review team assessments shall be conducted by a representative of the Commission together with up to two representatives from other Member States' national authorities responsible for notified bodies or national competent authorities for medical devices.**
- 3. The peer review team assessment shall be organised by the MDCG in conjunction with the national authority responsible for notified bodies.**
- 4. The peer review team shall participate in the assessment of a notified body for which the national authority is responsible during one of its planned on-site assessments as part of its surveillance activities.**

5. The peer review team upon conclusion of its assessment shall transmit to the national authority any observations with respect to compliance of the national authority with this Regulation and any suggestions for improvement. The national authority shall be given the opportunity to respond to these observations and to comment on the peer review team assessment report prior to its finalisation.
6. Within 45 days of the on-site assessment the Commission representative, together with the Member State representatives on the peer review team, shall produce an on-site assessment report which shall set out any observations with respect to compliance with this Regulation and opportunities for improvement.
7. The national authority shall respond to the observations in the peer review team assessment report within 60 days of it being made available, and if appropriate it shall put in place a plan to address these observations.
8. The peer review team assessment report and the national authority's comments and response to this report shall be made available to the Member States through the MDCG. A summary of this report shall be made publicly available.
9. Member States shall cooperate with the peer review team assessment process, providing all required documentation and technical support to the peer review team and allow access to premises and systems so that the peer review team assessment can be conducted effectively.
10. The Commission may, by means of implementing acts, adopt measures setting out the modalities and associated documents for peer review team assessment. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

11. The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the national authorities responsible for notified bodies under this Regulation.

~~**The national authority responsible for notified bodies shall be peer-reviewed every third year.**~~

~~**The Member States shall draw up the annual plan for the peer-review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission may participate in the review. The outcome of the peer-review shall be communicated to all Member States and to the Commission and a summary of the outcome shall be made publicly available.**~~

~~**The peer-review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. In the case referred to in the second subparagraph of paragraph 28(6), the competent authority for medical devices shall participate in the peer-review.**~~

13. **Detailed rules concerning peer review in Member States may be drawn up or amended in accordance with the examination procedure referred to in Article 88(3).**

Article 39

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of a coordination group of notified bodies in the field of medical devices, including *in vitro* diagnostic medical devices.

The bodies notified under this Regulation shall participate in the work of that group.

Article 40

Fees

1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies **and by the joint assessment teams** in accordance with this Regulation.

- ~~2. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 setting out the structure and the level of the fees referred to in paragraph 1, taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness. Particular attention shall be paid to the interests of notified bodies that submitted a valid certificate delivered by the national accreditation body as referred to in Article 31(2) and notified bodies that are small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.~~