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NOTE

from:	Presidency
to:	Working Party on Pharmaceuticals and Medical Devices
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:	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 proposal for Chapter V*

Delegations will find in the Annex a Presidency draft text for Chapter V of the proposal on medical devices, submitted for their agreement.

The changes proposed to the Commission proposal should also be applicable to the corresponding articles of the proposal on *in vitro* medical devices.

Text Conventions:

Additions to the Commission proposals are indicated in ***bold italics***.

Deletions to the Commission proposal are indicated with ~~strikethrough~~.

Proposal on medical devices

Chapter V
Classification and conformity assessment
Section 1 – Classification

Article 41
Classification of medical devices

1. Devices shall be divided into classes I, IIa, IIb and III, taking into account their intended purpose and inherent risks. Classification shall be carried out in accordance with the classification criteria set out in Annex VII.

2. Any dispute between the manufacturer and the notified body concerned, arising from the application of the classification criteria, shall be referred for a decision to the competent authority of the Member State where the manufacturer has his registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State where the authorised representative referred to in the last indent of point (b) of Section 3.2. of Annex VIII has his registered place of business. ~~At least 14 days prior to any decision,~~ ***T***he competent authority shall notify the MDCG and the Commission of its ~~envisaged~~ decision.

3. ~~The Commission may,~~ ***a A***t the request of a Member State or on its own initiative~~, by means of implementing acts, decide~~ ***and after consulting the MDCG, the Commission may decide, by means of implementing acts,*** on the ***following:***

a) application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view to determining their classification.

b) that a device, or category or group of devices, should, by way of derogation from the classification criteria set out in Annex VII, be classified in another class;

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

4. In the light of technical ***and scientific*** progress and any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 61 to 75, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 ~~as regards the following:~~

~~a) deciding, that a device, or category or group of devices, should, by way of derogation from the classification criteria set out in Annex VII, be classified in another class;~~

~~b)~~ amending or ~~supplementing~~ ***updating*** the classification criteria set out in Annex VII.

Section 2 – Conformity assessment

Article 42
Conformity assessment procedures

1. Prior to placing a device on the market ***or its putting into service***, manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to XI.

2. Manufacturers of devices classified as class III, other than custom-made or investigational devices, shall be subject to a conformity assessment based on full quality assurance and design dossier examination as specified in Annex VIII. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX coupled with a conformity assessment based on product conformity verification as specified in Annex X.

In the case of devices referred to in the first subparagraph of Article 1(4), the notified body shall follow the consultation procedure as specified in Section 6.1 of Chapter II of Annex VIII or Section 6 of Annex IX, as applicable.

In the case of devices that are covered by this Regulation in accordance with point (e) of Article 1(2), the notified body shall follow the consultation procedure as specified in Section 6.2 of Chapter II of Annex VIII or Section 6 of Annex IX, as applicable.

3. Manufacturers of devices classified as class IIb, other than custom-made or investigational devices, shall be subject to a conformity assessment based on full quality assurance as specified in Annex VIII, except for its Chapter II, with assessment of the design documentation within the technical documentation on a representative basis. ***By way of derogation, the design dossier examination as specified in Chapter II of Annex VIII shall be applicable for Class IIb implantable devices.*** Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX coupled with a conformity assessment based on product conformity verification as specified in Annex X.

4. Manufacturers of devices classified as class IIa, other than custom-made or investigational devices, shall be subject to a conformity assessment based on full quality assurance as specified in Annex VIII, except for its Chapter II, with assessment of the design documentation within the technical documentation on a representative basis. Alternatively, the manufacturer may choose to draw up the technical documentation set out in Annex II coupled with a conformity assessment based on product conformity verification as specified in Section 7 of Part A or Section 8 of Part B of Annex X.

5. Manufacturers of devices classified as class I, other than custom-made or investigational devices, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 17 after drawing up the technical documentation set out in Annex II. If the devices are placed on the market in sterile condition or have a measuring function, the manufacturer shall apply the procedures set out in Annex VIII, except for its Chapter II, or in Part A of Annex X. However, ***the*** involvement of the notified body shall be limited:
   a) in the case of devices placed on the market in sterile condition, to the aspects of manufacture concerned with securing and maintaining sterile conditions,
   b) in the case of devices with a measuring function, to the aspects of manufacture concerned with the conformity of the devices with the metrological requirements.

6. ~~Manufacturers may choose to apply a conformity assessment procedure applicable to devices of a higher class than the device in question.~~

7. Manufacturers of custom-made***, other than implantable*** devices shall follow the procedure set out in Annex XI and draw up the statement set out in that Annex before placing the device on the market.
Manufacturers of custom-made implantable devices shall be subject to the conformity assessment procedure based on full quality assurance as specified in Annex VIII, except for its Chapter II, with assessment of the design documentation within the technical documentation on a representative basis.

7a Furthermore, for devices intended for use by lay users, the manufacturer shall comply with the requirements laid down in Section 2 of Annex IX

8. The Member State in which the notified body is established may determine that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 6 shall be available in an official Union language. Otherwise they shall be available in an official Union language acceptable to the notified body.

9. Investigational devices shall be subject to the requirements set out in Articles 50 to 60.

10. The Commission may, by means of implementing acts, specify the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies for any of the following aspects:
– the frequency and the sampling basis of the assessment of the design documentation within the technical documentation on a representative basis as set out in Sections 3.3(c) and 4.5 of Annex VIII in the case of devices of classes IIa and IIb, and in Section 7.2 of Part A of Annex X in the case of devices of class IIa;

– the minimum frequency of unannounced factory inspections and sample checks to be conducted by notified bodies in accordance with Section 4.4 of Annex VIII, taking into account the risk-class and the type of device;

– the physical, laboratory or other tests to be carried out by notified bodies in the context of sample checks, design dossier examination and type examination in accordance with Sections 4.4 and 5.3 of Annex VIII, Section 3 of Annex IX and Section 5 of Part B of Annex X.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

11. In the light of technical ***and scientific*** progress and any information which becomes available in the course of the designation or monitoring of notified bodies set out in Articles 28 to 40, or of the vigilance and market surveillance activities described in Articles 61 to 75, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or ~~supplement~~ ***updat***ing the conformity assessment procedures set out in Annexes VIII to XI.

Article 43
Involvement of notified bodies

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned. An application may not be lodged in parallel with ~~more than~~***other*** ~~one~~ notified body for the same conformity assessment activity.

2. The notified body concerned shall inform the other notified bodies ***notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned*** of any manufacturer who withdraws his application prior to the notified body's decision regarding the conformity assessment. ***Manufacturers shall also declare whether they have withdrawn an application with another notified body prior to the decision of that notified body.***

3. The notified body may require any information or data from the manufacturer which is necessary in order to properly conduct the chosen conformity assessment procedure.

4. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical ***and scientific*** competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.

Article 44
Notification prior to placing on the market

1. Notified bodies shall inform the Commission of applications for conformity assessments for devices classified as class III, except applications to ~~supplement or~~ renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 19.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 26. In its notification, the notified body shall indicate the estimated date by which the conformity assessment is expected to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the MDCG.

2. The Commission shall be empowered to adopt implementing acts in accordance with Article 88(3) to extend the scope of devices which should be notified before placing on market as referred to in Article 44 (1).

Article 44a
Opinion prior to issuing a certificate

1. Subject to the following sub-paragraph, the opinion of the MDCG shall be consulted prior to issuing the conformity assessment certificate for the following devices:

- *Implantable or active therapeutic devices intended to be used in direct contact with the heart, the central circulatory system or the central nervous system;*
- *Spinal disc replacement implants, implantable devices that come into contact with the spinal column and hip, knee or shoulder total and partial joint replacements, except ancillary components ;*
- *Aesthetic implantable or invasive devices.*

The MDCG need not be consulted prior to granting the conformity assessment certificate opinion for the devices referred to in the previous sub-paragraph for which common specifications referred to in Article 7 have been adopted for the clinical evaluation and the post-market clinical follow-up.

2. Upon receipt of an application for conformity assessment concerning a device mentioned in paragraph 1, the notified body shall transmit to the Commission the following documents:

(a) The clinical evaluation report as referred to in Annex XIII(A), including the results of clinical investigations as referred to in Annex XIV;
(b) The post market clinical follow-up plan referred to in Annex XIII (B);
(c) The draft summary of safety and clinical performance referred to in Article 26;
(d) The draft instructions for use referred to in Section 19.3;
(e) The estimated date by which the conformity assessment is due to be completed by the notified body;

The Commission shall immediately transmit these documents to the MDCG.

3. ***As soon as available, the notified body shall transmit a summary of the preliminary conformity assessment prior to issuing a certificate to the Commission for submission to the MDCG.***

The MDCG ***shall have a period of 30 days from receipt of*** ~~may submit comments on~~ the summary of the preliminary conformity assessment ~~at the latest 60 days after submission of this summary.~~***, within which to give its opinion.***

Within ***this period of 30 days*** ~~that period and at the latest 30 days after submission~~, the MDCG may request ~~the submission of~~ additional information that ~~for~~ ***on*** scientifically valid grounds***, to analyse*** ~~are necessary for the analysis of~~ the notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for ***delivering its opinion*** ~~comments referred to in the first sentence of this subparagraph~~ shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for ~~the submission of comments~~ ***delivering its opinion***.

4. The MDCG opinion may rely on an assessment by an experts' panel referred to in Article 78.

5. The notified body shall issue the certificate only after a positive opinion from the MDCG has been given.

A positive opinion from the MDCG may be subject to modifications of the instructions for use, of the summary of safety and clinical performance or of the post-market clinical follow-up plan, or to communication to the MDCG of the summary of post-market clinical data.
In case of negative opinion, the notified body shall not deliver the certificate.

The notified body shall endeavour to take the utmost account of the opinion of the MDCG.

If the MDCG has not delivered an opinion within the period laid down in paragraph 3, the opinion shall be considered to be positive.

6. ~~The Commission shall make a summary of the comments submitted in accordance with paragraph 3 and the outcome of the conformity assessment procedure accessible to the public.~~ ***The Commission shall publish MDCG opinions given in accordance with paragraph 3 by means of the electronic system referred to in Article 45.*** It shall not disclose any personal data or information of commercially confidential nature.

7. The Commission shall set up the technical infrastructure for the data-exchange by electronic means between notified bodies and the MDCG for the purposes of this Article.

8. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the summary of the preliminary conformity assessment in accordance with paragraph~~s~~ 3 ~~and 4~~. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

9. ~~Where deemed necessary for the protection of patient safety and public health, the~~ ***The*** Commission may determine, by means of implementing acts, specific categories or groups of devices other than devices referred to in paragraph 1 ***to which the procedure referred to in paragraphs 2 to 7*** ~~other than devices of class III, to which paragraphs 1 to 4~~ shall apply during a predefined period of time. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

   Measures ***taken*** pursuant to this paragraph ***shall*** ~~may~~ be justified ~~only~~ by one or more of the following criteria:

   (a) ***technological novelty or new medical purpose, which can have a significant clinical or public health impact*** ~~the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof~~;
   (b) adverse change in the risk-benefit profile of a specific category or group of devices;
   (c) increased rate of serious incidents reported in accordance with Article 61 regarding a specific category or group of devices;
   (d) significant discrepancies in the conformity assessments carried out by different notified bodies on substantially similar devices;
   (e) public health concerns regarding a specific category or group of devices or the technology on which they are based.

Article 45
Certificates

1. The certificates issued by the notified bodies in accordance with Annexes VIII, IX and X shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates is set out in Annex XII.

2. The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.

3. Where a notified body finds that requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.

4. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information on certificates issued by notified bodies. The notified body shall enter into this electronic system information regarding certificates issued, including amendments and supplements, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. This information shall be accessible to the public.

5. In the light of technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the minimum content of the certificates set out in Annex XII.

Article 46
Voluntary change of notified body

1. In cases where a manufacturer terminates his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the modalities of the change of notified body shall be clearly defined in an agreement between the manufacturer, the outgoing notified body and the incoming notified body. This agreement shall address at least the following aspects:

   a) the date of invalidity of certificates issued by the outgoing notified body;
   b) the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material;
   c) the transfer of documents, including confidentiality aspects and property rights;

   ca) the date of transfer after which products would be assigned to the new notified body.

   d) the date as of which the incoming notified body assumes full responsibility for the conformity assessment tasks.

2. On their date of invalidity, the outgoing notified body shall withdraw the certificates it has issued for the device concerned.

Article 47
Derogation from the conformity assessment procedures

1. By way of derogation from Article 42, any competent authority may authorise, on duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific device for which the procedures referred to in Article 42 have not been carried out and use of which is in the interest of public health or patient ~~safety~~ ***health if the effectiveness and safety of that device can be presumed according to the current state of scientific knowledge.***

2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.

3. Upon request by a Member State and where this is in the interest of public health or patient ~~safety~~ ***health if the effectiveness and safety of that device can be presumed according to the current state of scientific knowledge*** in more than one Member State, the Commission may, by means of implementing acts, extend for a determined period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 88(4).

Article 48
Certificate of free sale

1. For the purpose of export and upon request by a manufacturer, the ***competent authority of the*** Member State in which the manufacturer has its registered place of business shall issue a certificate of free sale declaring that the manufacturer is properly established and that the device in question bearing the CE-marking in accordance with this Regulation may be ~~legally~~ marketed in the Union. The certificate of free sale shall be valid for the period indicated on it ~~which shall not exceed five years and shall not exceed the validity of the certificate referred to in Article 45 issued for the device in question~~.

2. The Commission may, by means of implementing acts, establish a model for certificates of free sale taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(2).