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NOTE

from:	General Secretariat
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
No. prev. doc.:	7315/14 PHARM 23 SAN 117 MI 236 COMPET 156 CODEC 654
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 VIII*

State of play and future procedure

1. On 10 and 16 April, the Working Party on Pharmaceuticals and Medical devices met to discuss Chapter VIII of the two proposals.

2. The basis used for the discussion was the Presidency compromise text set out in document 7315/14, which in turn was based on written and oral interventions by delegations during the CY, IE and LT Presidencies.

3. The Presidency took note of reactions to its proposals and has developed the attached texts based on the requests for changes by delegations on 10 and 16 April. Annex A sets out a new draft of Chapter VIII of the proposed Regulation on Medical devices and Annex B sets out a corresponding new draft for the proposed Regulation on *in vitro* diagnostic medical devices.

4. Both Annexes contain footnotes that reflect delegations' comments and suggestions.

5. The discussions on the attached texts began at the Working Party meeting on 13 May. In this revised document, a few footnotes have been corrected based on what was said on 13 May. The discussion will continue on 22 May. Following that meeting the texts will be updated. In that process footnotes that have resulted in Presidency proposals will be deleted if the corresponding Presidency proposals receive broad support. Delegations are also invited to withdraw any footnotes that are not essential for the continued examination.

General comments based on the examination of Chapters VIII of the two proposals

6. It was noted in response to many questions from delegations that the Medical Device Coordination Group is an advisory body, not a decision-making institution.

7. It is noted that all delegations have a general scrutiny reserve on the attached text.

Text Conventions:

8. New text, added to the Commission proposal by the Presidency and examined by the Working Party on 10 and 16 April is indicated in ***bold italics***.

9. Deletions by the Presidency of text in the Commission proposal that were examined by the Working Party on 10 and 16 April are indicated with ~~strikethrough~~.

10. New text, added by the Presidency based on the examination of the proposals by the Working Party on 10 and 16 April is indicated in ***bold italics underline***.

11. Deletions by the Presidency of text in the Commission proposal based on the examination of the proposals by the Working Party on 10 and 16 April and 13 May are indicated with ~~strikethrough and underlined~~ or ***~~bold italics strikethrough underline~~*** depending on whether it is a deletion in the original Commission proposal or of a previous Presidency proposal.

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

Chapter VIII

Cooperation between Member States, Medical Device Coordination Group, EU reference laboratories, device registers

Article 76

Competent authorities

1. The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation.[1] The Member States shall communicate ***the names and contact details of*** the competent authorities ***responsible for the implementation of this Regulation*** to the Commission which shall publish a list of competent authorities.[2]

2.[3] ~~***By way of derogation from paragraph 1,*** For ***for*** the implementation of Articles 50 to 60, the Member States may designate a national contact point other than a national ***competent*** authority. In this case, references to a competent authority in this Regulation shall be understood as including the national contact point.~~ [4]

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1 BG, DK, IE: Delete "*resources, equipment and knowledge*". Cion: This text is based on Regulation (EC) No 765/2008, compare *e.g.* Article 16(3).

2 DE: The requirement in the last sentence is impossible - DE has 80 competent authorities. AT, PT: Authority list needed *e.g.* for market surveillance.

3 DE, PT, UK: Delete this paragraph - there is no reference to "*national contact point*" elsewhere in the text. ES: Reservation. AT: Contact point needs powers so the paragraph is problematic. Need for contact point for clinical investigations. Cion: Similar provision in Clinical trials regulation

4 FR: Reservation on deletion of this paragraph.

Article 77

Cooperation

1. The competent authorities of the Member States shall cooperate with each other and with the Commission and exchange ~~with each other~~ the information necessary to enable this Regulation to be applied uniformly.[5]

2. Member States ***shall with the support of*** ~~and~~ the Commission ~~shall~~ participate***, where appropriate,*** in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.[6]

Article 78[7] [8] [9] [10]

Medical Device Coordination Group[11] [12] [13]

1. ***With a view to facilitating the uniform application***[14] ***of this Regulation*** ~~***by the Member States***~~[15]***, a*** ~~A~~ Medical Device Coordination Group (MDCG) is hereby established.

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5 DE, AT: The following text based on part of Article 20a in Directive 93/42/EC is missing: "*The Commission shall provide for the organisation of an exchange of experience between the competent authorities* ~~*responsible for market surveillance*~~ *in order to coordinate the uniform application of this Directive.*" Compare Pcy proposal in Article 79.

6 DE, AT: Important that all Member States can participate - therefore Cion should support MS.

7 IT, PT: Stress importance of co-ordination in order to achieve further harmonisation in implementation of EU medical device legislation.

8 SE: Reservation on Article 78.

9 CZ: Linkage to Article 80 - role of MDCG needs further clarification.

10 HR: Positive to this article as redrafted by Pcy.

11 DK, DE, FR; AT: Important to handle conflict of interests. Clear reference to article 82 needed.

12 CY, LT: questions the establishment of new structures. Resources are scarce.

13 LT, NL: Support for establishing MDCG.

14 DE: What is the meaning of this addition?

15 UK: Uniform application by Notified Bodies is also important. Cion: Important to add.

2.[16] Each Member State shall appoint, for a three-year term which may be renewed, one member and one alternate providing expertise in the field of this Regulation, and one member and one alternate providing expertise in the field of Regulation (EU) No […/…] [on *in vitro* diagnostic medical devices]. A Member State may choose to appoint only one member and one alternate providing expertise in both fields.

The members of the MDCG shall be chosen for their competence and experience in the field of medical devices and *in vitro* diagnostic medical devices. They shall represent competent authorities of the Member States ***and convey the expertise gained in MDCG back***[17] ***to those authorities***[18]. The names and affiliation of members shall be made public by the Commission. ***The members may be accompanied by experts.***[19]

The alternates shall represent and vote for the members in their absence.

3. The MDCG shall meet at regular intervals and, where the situation requires, ***up***on ~~a~~ request from the Commission or a Member State. The meetings shall be attended either by the members appointed for their role and expertise in the field of this Regulation, or by the members appointed for their expertise in the field of Regulation (EU) No […/…] [on *in vitro* diagnostic medical devices], or by the members appointed for both Regulations***, or their alternates***, as appropriate.[20]

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16 DE: The MDCG should have one representative of each Member State.
17 DE, LT: What is the meaning of this addition? Cion: Also against.
18 UK: Delete the added words.
19 UK: Delete the added words.
20 DE, IE: The MDCG should be one group - this should be reflected in the text. Technical work on specific subjects could be done in sub-groups.

4.[21] The MDCG shall use its best endeavours to reach consensus ***when adopting its opinions***. If such consensus cannot be reached, the MDCG shall ~~decide~~ ***adopt an opinion***[22] ***consisting of the position of*** ~~by~~ the majority[23] of ***the Member States*** ~~its members~~. Members with diverging positions may request that their positions and the grounds on which they are based ~~are~~ ***be*** recorded[24] in the MDCG's ~~position~~ ***opinion***.

4a. The MDCG opinions shall be forwarded for information to the Committee on Medical Devices referred to in Article 88.[25] [26]

5. The MDCG shall be chaired by a representative of the Commission[27] ***together with a representative of a Member State***. The ~~chair~~ ***Commission representative*** shall not take part in votes of the MDCG.

6. The MDCG may invite, on a case-by-case basis, experts and other third parties to attend meetings or provide written contributions.

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21 Pcy: The changes to the text of this paragraph are inspired by that of Article 5(1) of Regulation (EC) No 1901/2006 (on paediatric medicines).

22 SE: What is meant by adopting opinions? DE, HU: Similar question - what is legal status of MDCG? BE, IT, SE: Advisory body - no decision-making power. SE: Support for switch to "*adopt an opinion*". UK: Against reference to "opinion" - the role of this group is not that of EMA committees. Pcy: Changes based on pharmaceuticals legislation.

23 DE, ES, CY, AT, PT: Prefer qualified majority. Also quorum is needed.

24 DE: The divergent positions shall be attached to the opinion.

25 IE, ES, IT, AT, PT: MDCG should have the right to provide input to the decision-making on implementing and delegated acts.

26 DE, SE, UK: This provision is not meaningful in view of the role of MDCG. IT: Similar views. Cion: Opposed to introduction of this paragraph.

27 DE: Rotating Presidency possible. BE, DE, AT: Member State and Commission should co-chair.

7. The MDCG may[28] ***for consultation purposes***[29] establish ~~***and utilise***~~ standing or temporary sub-groups[30]. Where appropriate, organisations representing the interests of the medical device industry, healthcare professionals, laboratories, patients and consumers at Union level shall be invited in such sub-groups in the capacity of observers[31].

The MDCG may also establish Device Panels referred to in Article 80a. [32]

~~***7a.***~~[33] ~~***In particular, the MDCG may establish and utilise device panels***~~[34] ~~***(DP) for certain tasks. Device panels shall be composed of representatives of leading***~~[35] ~~***European scientific societies***~~[36] ~~***in the field, including representatives of relevant device register institutions***~~[37] ~~***[, and be organized by the Joint Research Centre***~~[38] ~~***on behalf of the Commission]. DP Members shall be appointed on the basis of scientific competence. The MDCG shall***~~[39] ~~***establish DPs for specific medical areas as well as a general clinical DP which shall deal with devices not covered by the DPs for specific medical areas.***~~ [40]

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28 DE, AT: Replace "*may*" by "*shall*". Existing groups should be used.

29 UK: Delete the added words.

30 IE, IT: Roles of subgroups must be clarified.

31 DK, FR: The role could be wider than just participation as observers.

32 UK: Delete the added words.

33 Based on the discussion on this paragraph, Pcy proposes Article 80a.

34 BE, DK; FR, IT, AT, PT, UK: Support for general idea. DE: Device Panels is useful concept but should be established by Cion, not MDCG. Avoid parallel structures with similar tasks. AT: Concept important in order to secure access to necessary scientific, clinical and technical expertise because development of medical device technology is rapid. AT, UK: Replace reference laboratories with device panels for medical devices. HR: against this paragraph - it is repetition of paragraphs 6 and 7. PL, SE: Device Panels not needed - use existing structures. NL: Against creation of additional structures but for medical devices the concept of Device Panels might be more appropriate than that of reference laboratories. Cion: Most tasks discussed for device panels could be handled by subgroups. No need for additional structure.

35 DK: How to define "*leading*"?

36 DE, FR, PT: Not sure that reference to "*scientific societies*" is needed. Suggest that there could be other sources for recruitment. IE; IT: Clinical expertise important. AT: The organisations mentioned are important but broader recruitment possible.

37 DK: What exactly is a "*device register institution*"? Suggest "*expertise on registers*" instead.

38 AT: Coordinating role by JRC important. BE, ES: Further clarification of JRC role needed.

39 DK: Replace "*shall*" with "*may*".

40 FR Replace this paragraph by:
"*7a. In particular, the MDCG may establish medical device experts panels (DP). Device panels shall be organized by the Joint Research Centre on the behalf of the Commission. DP Members shall be chosen for their scientific competence and medical experience. DP members shall be appointed by the Commission on the basis of Competent Authorities proposals and after consulting with the MDCG.*"

8.[41] The MDCG shall***, on the basis of a draft drawn up by the Commission***[42]**,** establish its rules of procedure which shall, in particular, lay down procedures for the following:

– the adoption of opinions or recommendations or other positions by the MDCG, including in cases of urgency;

– the delegation of tasks to reporting and co-reporting members;

[43]

– the functioning of sub-groups ***and Device Panels***[44].

– ***the appointment of the chair person representing Member States***

~~The rules of procedure shall enter into force after receiving a favourable opinion from the Commission.~~

Article 79

Support by the Commission

The Commission shall support the functioning of the cooperation between national competent authorities***. It shall, in particular, provide for the organisation of exchanges of experience between the competent authorities ~~responsible for market surveillance~~***[45] and provide [46] technical, scientific, ***~~financial~~***[47] [48] and logistic support to the MDCG and its sub-groups ***and Device Panels***[49]. It shall organise the meetings of the MDCG and its sub-groups ***and Device Panels***, participate in those meetings and ensure the appropriate follow-up.

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41 DE, IT, AT: Support for changes.

42 FR: Reservation on rules being drawn up by Cion.

43 FR: Add: the following point
"– *the implementation of Article 82 regarding conflict of interests;*". (DS 1229/14)
HR: Support.

44 FR: Add: "*, including the designation of the DP members*". (DS 1229/14)

45 IE, UK: Delete the added words. HR: Support for addition.

46 DE: Add "*administrative*".

47 Cion: Objects to adding "*financial*".

48 Pcy: Deleted following the discussion in the WP. Keeping "financial" here would limit the financial support to the MDCG tasks, which was not the intention behind the addition.

49 AT: Support for these changes. HR: Opposed to establishment of Device Panels.

Article 80

Tasks of the MDCG[50]

The MDCG shall have the following tasks:

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV; [51] [52] [53]

(b) ***to adopt opinions***[54] ***to be provided to notified bodies as part of the*** ~~to contribute to the scrutiny of certain~~ conformity assessments ~~pursuant to~~ ***for devices listed in*** Article 44***a(1)***[55] [56];

(c) to contribute to the development of[57] guidance aimed at ensuring effective and harmonised implementation[58] of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of [59] the clinical[60] evaluation ***and investigations***[61] by manufacturers and the assessment by notified bodies;

(ca) to continuously monitor the technical progress and assess whether the essential requirements on safety and performance provided in this Regulation and Regulation (EU) No […/…] [on in vitro diagnostic medical devices] are appropriate to ensure safety and performance of medical devices and identify the need to amend Annex I;[62] [63]

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50 CY, SE: Questions whether it is possible for the MDCG to take on all the tasks listed here. NL, UK: This article requires more discussion in order for the tasks to be sufficiently clear.

51 AT: Important provision.

52 IE, IT: Add coordination tasks here.

53 UK: Is this really a MDCG task?

54 DE: Unclear what this means, in particular in relation to MDCG role regarding guidelines.

55 CZ, DK, IE, IT, LT, NL, AT, PL, SK, SE, UK: Scrutiny reserve until discussion on Article 44a finalised.

56 DE: Replace points (b) to (f) with an aim to strengthen market surveillance (DS 1483/13).

57 DE, NL, AT, SK: Replace "*contribute to the development of*" with "*develop*".

58 AT: add "*including classification*".

59 PT: Add "*post-market surveillance,*".

60 SE: Need for coordination of clinical data.

61 Cion: "*investigation*" is part of evaluation - so this addition is not necessary.

62 DK: This task had better be allocated to the Commission due to the need for resources. NL, SE: Heavy task.

63 FR, IT, AT: Add reference to Annex VII (on classification).

(cb) to contribute to the development of medical devices standards and of Common ~~(Technical)~~ Specifications[64] [65] [66]***;***

(d) to assist the competent authorities of the Member States in their coordination activities in the fields of ***classification***[67] ***of medical devices,*** clinical investigations, vigilance and market surveillance ***including the development and maintenance of a framework for a European market surveillance program with the objective of efficiency and harmonisation of market surveillance in the European Union, in accordance with Article 67***[68] [69];

(e) to provide advice ~~***and assist the Commission***~~, ***either on its own initiative***[70] ***or*** at ~~its~~ request ***of the Commission***, in ~~its~~ ***the*** assessment of any issue related to the implementation of this Regulation; [71]

(f) to contribute to harmonised administrative practice with regard to medical devices in the Member States.

[72]

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64 FR, AT: CTS should be main task, standards less important for MDCG.

65 SE: Heavy task.

66 DK, NL: Support for this point.

67 ES, IT, NL, AT, PT, UK: Add "*and qualification*". PL: Opposed to this addition. ES: Give MDCG a role in the decision on the regulatory status of products (Article 3). Cion: Article 3 is on implementing acts, so there is already a committee assisting the Commission in those decisions.

68 DK, LT, PL, SE: Scrutiny reserve until discussion on Article 67 finalised.

69 IE, IT, SK: This point must be further elaborated.

70 SE: Questions if this is legally possible.

71 DK, FR: Support for the changes to this point.

72 UK: Add "*contribute to the development of EUDAMED*".

Article 80a
Device Panels[73]

Device Panels shall be composed of representatives of ~~leading~~ European scientific societies or other experts on scientific, clinical or technical issues ~~in the field~~ appointed by the MDCG on the basis of scientific competence, ~~including representatives of relevant device register institutions [, and be organized by the Joint Research Centre on behalf of the Commission]~~. ~~DP Members shall be appointed on the basis of scientific competence~~. The Device Panels ~~MDCG~~ shall be established ~~DPs~~ for specific medical areas. In addition, ~~as well as~~ a general clinical DP ~~which~~ shall be established to deal with devices not covered by the Device Panels for specific medical areas. The Commission shall facilitate contacts, at the appropriate level, between the Device Panels and relevant structures, such as the Joint Research Centre.

[73] Presidency redraft of former Article 78(7a) based on comments on 10 April. Compare footnotes on 78(7a). Changes to previous text indicated.

Article 81

European Union reference laboratories[74] [75] [76] [77]

1. For specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices, the Commission may designate, by means of implementing acts, one or more European Union reference laboratories, hereinafter referred to as 'EU reference laboratories', that satisfy the criteria set out in paragraph 3. The Commission shall only designate laboratories for which a Member State or the Commission's Joint Research Centre[78] have submitted an application for designation.

2. Within the scope of their designation, the EU reference laboratories[79] shall, where appropriate, have the following tasks[80]:
   (a) to provide scientific and technical assistance to the Commission, ***the MDCG***[81]**,** the Member States and notified bodies in relation to the implementation of this Regulation;
   (b) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices;

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74 CZ, DE, IE, ES, AT, PT, UK: Doubts whether reference laboratories are relevant for medical devices and on the costs therefore. Suggests using Device Panels instead. For IVD the concept is useful. BE: Similar ideas. UK: Could see role in verifying Common (Technical) Specifications. CZ, PT: Reference laboratories must be accredited. DE: There are no reference values for medical devices. Cion: While it is easier to imagine the tasks for IVD reference laboratories, the need for such reference laboratories also for medical devices *e.g.* as concerns the use of nanotechnology should not be underestimated.

75 DK, NL: Believes this could be a useful concept and notes that Cion will only appoint laboratories that fulfil the requirements laid down in this article. Sees need for clarification on financing of these laboratories. Cion: The laboratories will be financed through fees and through subsidies for development of methodology. Compare reference laboratories for foodstuffs.

76 NL: Could a portal helping to establish contact with expertise replace parts of the tasks of reference laboratories?

77 FR: Strong support for EU reference laboratories.

78 BE: What exactly is the role of the JRC here?

79 SE: Question regarding use of private-owned laboratories and their duties as regards confidentiality.

80 IT: The tasks are too broad.

81 SE: Delete this addition. Cion: The MDCG has no budget. Therefore it is not meaningful to add it here.

(c) to set up and manage a network of national reference laboratories ***after consulting with the national authorities***[82] and publish a list of the participating national reference laboratories and their respective tasks;

(d) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures and market surveillance;

(e) to collaborate with notified bodies in the development of best practices for the performance of conformity assessment procedures;

(f) to contribute to the development of standards at international level;

(g) to provide scientific opinions[83] in response to consultations by notified bodies in accordance with this Regulation ***and publish them by electronic means after consideration of national provisions on the respect of confidentiality*** [84]

3. EU reference laboratories shall satisfy the following criteria:

(a) to have ***adequate and*** appropriately qualified staff with adequate knowledge and experience in the field of the medical devices for which they are designated;

(b) to possess the necessary equipment and reference material to carry out the tasks assigned to them;

(c) to have the necessary knowledge of international standards and best practices;

(d) to have an appropriate administrative organisation and structure;

(e) to ensure that their staff observe the confidentiality of the information and data obtained in carrying out their tasks.

(f)[85] ***to act in the public interest and in an independent manner;***

(g) to ensure that their staff do not have financial or other interests in the in vitro diagnostic medical device industry which could affect their impartiality, declare any other direct and indirect interests they may have in the in vitro diagnostic medical device industry and update this declaration whenever a relevant change occurs.

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82 NL: Delete this addition. Cion: Same position.

83 UK: What exactly are scientific opinions?

84 DK: unclear what this addition means.

85 LT, NL, AT: Add the following points (Compare Article 78 IVD):
"*(f) to act in the public interest and in an independent manner;*
(g) to ensure that their staff do not have financial or other interests in the medical device industry which could affect their impartiality, declare any other direct and indirect interests they may have in the medical device industry and update this declaration whenever a relevant change occurs."

4. EU reference laboratories may be granted a Union financial contribution.

The Commission may adopt, by means of implementing acts, the modalities and the amount of the grant of a Union financial contribution to EU reference laboratories, taking into account the objectives of protection of health and safety, support of innovation and cost-effectiveness. ~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).~~

5. Where notified bodies or Member States[86] request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they may be required to pay fees to wholly or partially[87] cover the costs incurred by that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions.

6.[88] The Commission shall ***specify*** ~~be empowered to~~ ***by means of*** ~~adopt delegated~~ ***implementing*** acts in accordance with Article ***88***~~9 for the following purposes~~:

(a) ~~amending, or supplementing~~ ***detailed rules to facilitate the application*** ~~the tasks of EU reference laboratories referred to in~~ ***of*** paragraph 2 and ***detailed rules to ensure compliance with*** the criteria ~~to be satisfied by EU reference laboratories~~ referred to in paragraph 3***;***

(b) setting out the structure and the level of the fees referred to in paragraph 5 which may be levied by an EU Reference Laboratory for providing scientific opinions in response to consultations by notified bodies ***and Member States*** in accordance with this Regulation, taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness.

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86 DE, ES: The assistance for Member States should be free of charge.
87 DE: Delete "*wholly or partially*".
88 NL: Support for changes to this paragraph.

7. EU reference laboratories shall be subject to controls, including on-site visits and audits, by the Commission to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements for which they have been designated, the Commission, by means of implementing acts, shall take appropriate measures, including the ***restriction, suspension or*** withdrawal of the designation.

8. The implementing acts referred to in this article shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Article 82

Conflict of interests[89]

1. Members of the MDCG***, its sub-groups***[90]***, Device Panels*** and staff of the EU reference laboratories shall not have financial or other interests in the medical device industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. They shall declare any direct and indirect interests they may have in the medical device industry and update this declaration whenever a relevant change occurs. Upon request, the declaration of interests shall be accessible to the public. This Article shall not apply to the representatives of stakeholder organisations participating in the sub-groups of the MDCG.

2. Experts and other third parties invited by the MDCG on a case-by-case basis shall ~~be requested to~~ declare ~~their~~ ***any*** interests ***they may have*** in the issue in question.

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89 FR: A corresponding Article is needed in the IVD Regulation.

90 DE, NL; AT: Impossible, since industry is represented in sub-groups. FR, AT: Rules on how to limit conflicts of interest more appropriate in this case. Cion: Covered by last sentence in this paragraph.

Article 83

Device registers[91]

The Commission and the Member States shall take all appropriate measures to ~~encourage~~[92] ~~the~~ establish~~ment of~~ registers for specific types of devices to gather post-market experience related to the use of such devices. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices.[93]

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[91] ES: It should be made clear that Cion should finance device registers. AT: Device registers should be financed by manufacturers.

[92] SE, UK: Prefer original text. Not appropriate to regulate here who should create device registers and who should finance them. DE, AT: Similar views. Rules are needed to make registers compatible and facilitate joint data evaluation. Cion: Rules on compatibility important. Cion can not finance these registers.

[93] NL: Doubts on this article. How does it link to market surveillance and how does it link to EUDAMED? IT: Also has concerns about how meaningful this provision is. Made other suggestion (DS 1262/13).

ANNEX B

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on *in vitro* diagnostic medical devices

Chapter VIII

Cooperation between Member States, Medical Device Coordination Group, EU reference laboratories, device registers

Article 74

Competent authorities

1. The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate **the names and contact details of** the competent authorities **responsible for the implementation of this Regulation** to the Commission which shall publish a list of competent authorities.

2. **[*By way of derogation from paragraph 1,*** ~~For~~ ***for*** the implementation of Articles 48 to 58, the Member States may designate a national contact point other than a ~~national~~ ***competent*** authority. In this case, references to a competent authority in this Regulation shall be understood as including the national contact point.**]**

Article 75

Cooperation

1. The competent authorities of the Member States shall cooperate with each other and with the Commission and exchange with each other the information necessary to enable this Regulation to be applied uniformly.

2. Member States ***shall with the support of*** ~~**and**~~ the Commission ~~**shall**~~ participate***, where appropriate,*** in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.

Article 76

Medical Device Coordination Group

The Medical Device Coordination Group (MDCG) established in accordance with the conditions and modalities defined in Article 78 ***and 82***[94] of Regulation (EU) [Ref. of future Regulation on medical devices] shall carry out, with the support of the Commission as provided in Article 79 of that Regulation, the tasks assigned to it by this Regulation.

Article 77

Tasks of the MDCG

The MDCG shall have the following tasks:

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

(b) ***to adopt opinions to be provided to notified bodies as part of the*** ~~to contribute to the scrutiny of certain~~ conformity assessments ~~pursuant to~~ ***for devices listed in*** Article 42;

(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of the clinical ~~***evaluation***~~ ***investigations*** by manufacturers and the assessment by notified bodies;

(ca) to continuously monitor the technical progress and assess whether the essential requirements on safety and performance provided in this Regulation and Regulation (EU) No […/…] [on medical devices] are appropriate to ensure safety and performance of in vitro diagnostic medical devices and identify the need to amend Annex I;

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[94] Presidency proposal in response to FR request (see footnote on Article 82 in the MD Regulation).

(cb) to contribute to the development of in vitro diagnostic medical devices standards and of Common Specifications;

(d) to assist the competent authorities of the Member States in their coordination activities in the fields of ***classification of in vitro diagnostic medical devices,*** clinical performance studies, vigilance and market surveillance ***including the development and maintenance of a framework for a European market surveillance program with the objective of efficiency and harmonisation of market surveillance in the European Union, in accordance with Article XX[95]67***;

(e) to provide advice ~~***and assist the Commission***~~, ***either on its own initiative or*** at ~~its~~ request ***of the Commission***, in ~~its~~ ***the*** assessment of any issue related to the implementation of this Regulation;

(f) to contribute to harmonised administrative practice with regard to *in vitro* diagnostic medical devices in the Member States.

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95 The article corresponding to Article 67 of the medical device regulation.

Article 78[96] [97] [98]

European Union reference laboratories

1. For specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices, the Commission may designate, by means of implementing acts, one or more European Union reference laboratories, hereinafter referred to as 'EU reference laboratories', that satisfy the criteria set out in paragraph 3. The Commission shall only designate laboratories for which a Member State or the Commission's Joint Research Centre have submitted an application for designation.[99]

2. Within the scope of their designation, the EU reference laboratories shall, where appropriate, have the following tasks:

   (a) to verify compliance of class D devices with the applicable CTS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as provided for in the second subparagraph of Article 40(2) [100];

   (b) to carry out appropriate [101] tests on samples of manufactured class D devices or batches of class D devices, as provided for in the Section 5.7 of Annex VIII and in Section 5.1 of Annex X;

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[96] AT: The procedure for appointing EU reference laboratories must seek to find such laboratories covering all types of IVDs and avoid to "over-establish" laboratories for certain tasks.

[97] General support for creating EU reference laboratories for IVDs.

[98] DE: Need for clear rules for reference laboratories for IVDs. Results must be comparable and reliable. (See following footnotes on this article.)

[99] DE: (DS 1484/13) Replace this paragraph with:
"*1. For devices of class D a network of European Union reference laboratories shall be established. The Commission shall designate, by means of implementing acts, European Union reference laboratories as members of the network described in the first sentence, hereinafter referred to as 'EU reference laboratories', that satisfy the criteria set out in paragraph 3. The Commission shall only designate laboratories for which a Member State or the Commission's Joint Research Centre have submitted an application for designation.*"

[100] DE: replace: "*when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as provided for in the second subparagraph of Article 40(2).*" with ". *The laboratory evaluation according to Annex VIII and IX shall focus on the analytical and clinical sensitivity and specificity.*". (DS 1484/13)

[101] DE: Add: "*laboratory*". (DS 1484/13)

(c) to provide scientific and technical assistance to the Commission, ***the MDCG,*** the Member States and notified bodies[102] in relation to the implementation of this Regulation;

(d) to provide scientific advice regarding[103] the state of the art in relation to specific devices, or a category or group of devices;

(e) to set up and manage a network of national reference laboratories ***after consulting with the national authorities*** and publish a list of the participating national reference laboratories and their respective tasks; [104]

(f) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures [105] and market surveillance;

(g)[106] to collaborate with notified bodies in the development of best practices for the performance of conformity assessment procedures;

(h) to provide recommendations on suitable reference materials and reference measurement procedures of higher metrological order;

(i)[107] to contribute to the development of standards at international level;

(j)[108] to provide scientific opinions in response to consultations by notified bodies in accordance with this Regulation ***and publish them by electronic means after consideration of national provisions on the respect of confidentiality***.

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[102] DE: Delete: "*and notified bodies*". (DS 1484/13)

[103] DE: Replace: "*regarding*" with " *and technical assistance regarding the definition of* ". (DS 1484/13)

[104] DE: Replace this paragraph with: "*to contribute to a network of national reference laboratories in particular by developing common principles, best practices and participating in ring testings;*".(DS 1484/13)

[105] DE: Add: "*, for batch verification and*". (DS 1484/13)

[106] DE: Delete this point. (DS 1484/13)

[107] DE: Replace this point with: "*to contribute to the development of common technical specifications (CTS) as well as of international standards;* ". (DS 1484/13)

[108] DE: Replace this point with: "*to provide scientific opinions in response to consultations by the competent authorities of the Member States*.". (DS 1484/13)

3. EU reference laboratories shall satisfy the following criteria:

(a) to have ***adequate and*** appropriately qualified staff with adequate knowledge and experience in the field of the *in vitro* diagnostic medical devices for which they are designated; [109]

(b) to possess the necessary equipment and reference material to carry out the tasks assigned to them;

(c) to have the necessary knowledge of international standards[110] and best practices;

(d) to have an appropriate administrative organisation and structure;

(e) to ensure that their staff observe the confidentiality of the information and data obtained in carrying out their tasks;

(f) to act in the public interest and[111] in an independent manner;

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[109] DE: (DS 1484/13) Replace this point with:
"*(a) to have appropriately qualified staff with adequate knowledge and experience in the field of the in vitro diagnostic medical devices for which they are designated. Appropriate knowledge and experience shall be based on*
- *experience of assessing high-risk IVDs and of carrying out the relevant laboratory tests;*
- *in-depth knowledge of high-risk in-vitro diagnostic medical devices and relevant technologies;*
- *proven laboratory experience in one of the following areas: testing or calibration laboratory, supervisory authority or institution, national reference laboratory for class D devices, quality control of in-vitro diagnostic medical devices, development of reference materials for IVDs, calibration of diagnostic medical devices; laboratories or blood banks which experimentally assess and use high-risk IVDs or, where applicable, manufacture them in-house;*
- *knowledge and experience of product or batch testing, quality checks, design, manufacture and use of IVDs;*
- *knowledge of the health risks faced by patients, their partners and recipients of blood/organ/tissue donations/preparations associated with the use and, in particular, malfunctioning of high-risk IVDs;*
- *knowledge of this Regulation and of applicable laws, rules and guidelines, knowledge of the Common Technical Specifications (CTS), applicable harmonized standards, product-specific requirements and relevant guidance documents;*
- *participation in relevant external and internal quality assessment schemes organised by international or national organisations.*

[110] DE: Add "*, common technical specifications and*". (DS 1484/13)

[111] DE: Delete "*in the public interest and*". (DS 1484/13)

(g) to ensure that their staff do not have financial or other interests in the *in vitro* diagnostic medical device industry which could affect their impartiality, declare any other direct and indirect interests they may have in the *in vitro* diagnostic medical device industry and update this declaration whenever a relevant change occurs.

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4. EU reference laboratories may[113] be granted a Union financial contribution.

The Commission may adopt, by means of implementing acts, the modalities and the amount of the grant of a Union financial contribution to EU reference laboratories, taking into account the objectives of protection of health and safety, support of innovation and cost-effectiveness. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

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112 DE:(DS 1484/13) Add the following paragraph:

3a. The network of European Union reference laboratories shall satisfy the following criteria and the reference laboratories in the network should coordinate and harmonise their working methods as regards testing and assessment. This involves:

a) applying coordinated methods, procedures and processes;
b) agreeing on the use of same reference materials and common test samples and seroconversion panels;
c) establishing and common assessment and interpretation criteria
d) using common testing protocols and assessing the test results using standardised and coordinated evaluation methods;
e) using standardised and coordinated test reports;
f) developing, applying and maintaining a peer review system
g) organizing regular quality assessment tests (including mutual checks on the quality and comparability of test results).
h) agreeing on joint guidelines, instructions, procedural instructions or standard operational procedures (SOPs);
i) coordinating the introduction of testing methods for new technologies and according to new or amended CTS;
j) reassessing the state of the art on the basis of comparative test results or by further studies, as requested by the European Commission or a Member State"

113 DE: Replace "*may*" with "*shall*". (DS 1484/13)

5. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they may be required to pay fees to wholly or partially[114] cover the costs incurred by that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions.

6.[115] The Commission shall ***specify*** ~~be empowered to~~ ***by means of*** ~~adopt delegated~~ ***implementing*** acts in accordance with Article ***8***~~5 for the following purposes~~:

(a) ~~amending, or supplementing~~ ***detailed rules to facilitate the application*** ~~the tasks of EU reference laboratories referred to in~~ ***of*** paragraph 2 and ***details to ensure compliance with*** the criteria ~~to be satisfied by EU reference laboratories~~ referred to in paragraph 3***;***

(b) setting out the structure and the level of the fees referred to in paragraph 5 which may be levied by an EU reference laboratory for providing scientific opinions in response to consultations by notified bodies ***and Member States*** in accordance with this Regulation, taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness.

7. EU reference laboratories shall be subject to controls, including on-site visits and audits, by the Commission to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements for which they have been designated, the Commission, by means of implementing acts[116], shall take appropriate measures, including the ***restriction, suspension or*** withdrawal of the designation.

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[114] DE: Delete "*wholly or partially*". (DS 1484/13)
[115] DE: Delete this paragraph. (DS 1484/13)
[116] DE: Move "*by means of implementing acts*" to the end of the sentence. (DS 1484/13)

Article 79

Device registers

The Commission and the Member States shall take all appropriate measures to ~~encourage the~~ establish~~ment of~~ registers for specific types of devices to gather post-market experience related to the use of such devices. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices.

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