Council of the European Union

Brussels, 16 July 2015
(OR. en)

10683/15

LIMITE

PHARM 31
SAN 210
MI 469
COMPET 350
CODEC 1018

PUBLIC

Interinstitutional File:
2012/0267 (COD)

NOTE

From:	Presidency
To:	Working Party on Pharmaceuticals and Medical devices
No. prev. doc.:	9770/15 PHARM 27 SAN 177 MI 392 COMPET 305 CODEC 859 + ADD 1
No. Cion doc.:	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 ***in vitro*** **diagnostic medical devices**

Delegations will find in the Annex to this document a consolidated text for the preamble and the recitals of the proposed Regulation on *in vitro* diagnostic medical devices. This document, which has been prepared by the Luxembourg Presidency, is based on document WK 5/2015 and on written comments from delegations. The recitals should reflect the consolidated text of the regulation set out in document 9770/15 + ADD 1.

New text compared to the Commission proposal is written in ***bold italics***. Deletions are marked by ~~strikethrough~~. Presidency changes to the text that are presented for the first time are highlighted in grey.

ANNEX

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on *in vitro* diagnostic medical devices

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

~~Having regard to the opinion of~~ ***After consulting*** the Committee of the Regions[2],

~~After consulting the European Data Protection Supervisor,~~[3]

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices[4] constitutes the Union regulatory framework for *in vitro* diagnostic medical devices. However, a fundamental revision of that Directive is needed to establish a robust, transparent, predictable and sustainable regulatory framework for devices which ensures a high level of safety and health whilst supporting innovation.

---

1 OJ C […], […], p. […].

2 ~~OJ C […], […], p. […].~~ The Committee of the Regions decided to refrain from giving an opinion.

3 ~~OJ C […], […], p. […].~~ Replaced by Recital (66a).

4 OJ L 331, 7.12.1998, p.1

(2) This Regulation aims to ensure the ***smooth***[5] functioning of the internal market as regards *in vitro* diagnostic medical devices, taking as a base a high level of protection of health. At the same time, this Regulation sets high standards of quality and safety for devices to meet common safety concerns as regards those products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union, this Regulation harmonises the rules for the placing on the market and putting into service of *in vitro* diagnostic medical devices and their accessories on the Union market which may then benefit from the principle of free movement of goods. As regards Article 168(4)(c) of the Treaty on the Functioning of the European Union, this Regulation sets high standards of quality and safety for those devices by ensuring, among other things, that data generated in ~~clinical~~ performance studies is reliable and robust and that the safety of subjects participating in ~~clinical~~[6] performance studies is protected.

(3) Key elements of the existing regulatory approach, such as the supervision of notified bodies, risk classification, conformity assessment procedures, ~~clinical evidence~~ ***performance evaluation and performance studies***[7], vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding *in vitro* diagnostic medical devices should be introduced to improve health and safety.

(4) To the extent possible, guidance developed for *in vitro* diagnostic medical devices at international level, in particular in the context of the Global Harmonization Task Force (GHTF) and its follow-up initiative the International Medical Devices Regulators Forum, should be taken into account to promote the global convergence of regulations which contributes to a high level of safety worldwide and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification criteria, conformity assessment procedures and clinical evidence.

---

5 Standard wording.
6 "Clinical" deleted to correspond to the text in the Articles.
7 See title Chapter VII.

(5) There are specific features of *in vitro* diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the *in vitro* diagnostic medical device sector which require the adoption of a specific legislation, distinct from the legislation on other medical devices, whereas the horizontal aspects common to both sectors should be aligned.

~~(6) A Regulation is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for divergent transposition by Member States. Moreover, a Regulation ensures that legal requirements are implemented at the same time throughout the Union.~~[8]

(7) The scope of application of this Regulation should be clearly delimited from other legislation concerning products such as medical devices, general laboratory products and products for research use only.

(8) It should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. If necessary, the Commission may[9] decide ***on its own***, on a case-by-case basis, whether or not a product falls within the definition of an *in vitro* diagnostic medical device or of an accessory to an *in vitro* diagnostic medical device. ***Such action should be taken any time at a duly substantiated request of a Member State.***[10]

---

[8] This recital is, as written, not necessarily true.

[9] **WK 16/2015 DK** replace "*may*" with "*should after consulting the MDCG*".

[10] **Pcy** proposal for amendments based on **DE, FR** request for alignment with Art.3.

(9) To ensure the highest level of health protection, the rules governing *in vitro* diagnostic medical devices manufactured and used, including measurement and delivery of results, only within a single health institution should be clarified and strengthened.

(10) It should be clarified that software specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of an *in vitro* diagnostic medical device is qualified as an *in vitro* diagnostic medical device, while software for general purposes, even when used in a healthcare setting, or software intended for well-being applications is not qualified as an *in vitro* diagnostic medical device. ***The qualification of software, either as device or accessory, is independent of its location or type of interconnection between the software and a device.***[11]

(11) It should be made clear that all tests that provide information on the predisposition to a medical condition or a disease (e.g. genetic tests) and tests that provide information to predict treatment response or reactions, such as companion diagnostics, are *in vitro* diagnostic medical devices.

(11a) Companion diagnostics are essential to identify patients for eligibility of treatment with a specific medicinal therapy (e.g. molecule, dose, scheduling) through the determination of a biomarker, either qualitatively or quantitatively, which is specific for a population of responders, non-responders or persons which will develop an adverse response towards this specific therapy. Such biomarker may be present in healthy persons or may be present or induced in the patient due to a condition or pathology.[12]

---

[11] **BE** suggestion for an additional sentence on qualification of software.

[12] **Cion** sees need for changing the wording for recitals 11a and 11b on companion diagnostics.

(11b) It should be clarified that devices monitoring the response to treatment by the corresponding medicinal product are considered companion diagnostics where treatment adjustment to achieve improved safety or effectiveness is essential for the safe and effective use of a corresponding medicinal product, while devices that are used in treatment drug monitoring (TDM) to ensure that the drug concentration in the human body is within the therapeutic window of the drug are not considered companion diagnostics.

[13]

(12) Aspects addressed by Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC[14] ~~and aspects addressed by Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery and amending Directive 95/16/EC[15]~~ are an integral part of the general safety and performance requirements for *in vitro* diagnostic medical devices. Consequently, this Regulation should be considered a *lex specialis* in relation to those Directives.

[13] **DS 1261/15** A recital is needed to explain that the risk minimisation goal should be related to the state of the art. See Section 1aa in Annex I.

[14] OJ L 390, 31.12.2004, p. 24

[15] ~~OJ L 157, 9.6.2006, p. 24~~.

(13) This Regulation should include requirements regarding the design and manufacture of *in vitro* diagnostic medical devices emitting ionizing radiation without affecting the application of Council Directive ***2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom***[16] ~~96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation[17] nor of Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure and repealing Directive 84/466/Euratom[18]~~ which pursue**s** other objectives.[19]

~~(14) It should be made clear that the requirements of this Regulation also apply to the countries that have entered into international agreements with the Union which confer on that country the same status as a Member State for the purpose of application of this Regulation, as it is currently the case with the Agreement on the European Economic Area[20], the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment[21] and the Agreement of 12 September 1963 establishing an association between the European Economic Community and Turkey[22].[23]~~

---

16 ***OJ L 13, 17.1.2014, p. 1.***
17 ~~OJ L 159, 29.6.1996, p. 1.~~
18 ~~OJ L 180, 9.7.1997, p. 22.~~
19 Corresponds to the changes in Article 1(5).
20 OJ L 1, 3.1.1994, p. 3.
21 OJ L 114, 30.4.2002, p. 369.
22 OJ 217, 29.12.1964, p. 3687
23 Deleted since Article 1(7) is deleted.

(15) It should be made clear that *in vitro* diagnostic medical devices offered to persons in the Union by means of information society services within the meaning of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations[24] as well as devices used in the context of a commercial activity to provide a diagnostic or therapeutic service to persons within the Union must comply with the requirements of this Regulation at the latest[25] when the product is placed on the market or the service is provided in the Union.

(16) To recognise the important role of standardisation in the field of *in vitro* diagnostic medical devices, compliance with harmonised standards as defined in Regulation (EU) No [Ref. of future Regulation on European standardisation] on European standardisation[26] should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as quality and risk management.

(17) The definitions in the field of *in vitro* diagnostic medical devices~~, for example,~~ regarding ***the device itself, the making available of devices,*** economic operators, ***users and specific process, the conformity assessment,*** clinical evidence, ~~and~~ vigilance ***and market surveillance, standards and other technical specifications***, should be aligned with well-established practice at Union and international level in order to enhance legal certainty.[27]

---

[24] OJ L 204, 21.7.1998, p. 37, as amended by Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998, OJ L 217, 5.8.1998, p. 18.

[25] **HU, PT** delete "*at the latest*".

[26] OJ C […], […], p. […].

[27] **Pcy** proposal for amendments based on **DE, PT** request to provide more elements according to Art.2.

(18) The rules applicable to *in vitro* diagnostic medical devices should be aligned, where appropriate, with the New Legislative Framework for the Marketing of Products, which consists of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93[28] and Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC[29].

(19) The rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to *in vitro* diagnostic medical devices and their accessories covered by this Regulation which does not prevent Member States from choosing the competent authorities to carry out those tasks.

(20) It is appropriate to set out clearly the general obligations of the different economic operators, including importers and distributors, ***building on*** ~~as laid down in~~[30] the New Legislative Framework for the Marketing of Products, without prejudice to the specific obligations laid down in the different parts of this Regulation, to enhance understanding of the legal requirements and thus to improve regulatory compliance by the relevant operators.

---

28 OJ L 218, 13.8.2008, p.30.

29 OJ L 218, 13.8.2008, p. 82.

30 This change reflects the fact that the draft Regulation does not follow the NLF "model" provisions very closely.

(21) To ensure that *in vitro* diagnostic medical devices manufactured in series production continue to be in conformity with the requirements of this Regulation and that experience from the use of their *in vitro* diagnostic medical devices is taken into account for the production process, all manufacturers should have a quality management system and a post-market surveillance ~~plan~~ ***system***[31] in place which should be proportionate to the risk class and the type of the *in vitro* diagnostic medical device. ***In addition, in order to prevent and*** ~~***control***~~ ***mitigate***[32] ***risks or prevent incidents related to in vitro medical devices manufacturers should establish a system for risk management and a system for reporting incidents and field corrective actions.***[33]

(22) It should be ensured that supervision and control of the manufacture ***as well as post-market activities***[34] of *in vitro* diagnostic medical devices is carried out within the manufacturer's organisation by[35] a person ***responsible for regulatory compliance*** who fulfils minimum conditions of qualification.

---

31 See Article 8(6).
32 **UK** use "*mitigate*" instead of "*control*" ; **Cion** maintain the word "*prevention*".
33 See paragraphs 1a and 8a of Article 8.
34 See Art. 13(2) point (ca).
35 **HU** use "*under supervision of*" instead of "*by*".

(23) For manufacturers who are not established in the Union, the authorised representative plays a pivotal role in ensuring the compliance of the *in vitro* diagnostic medical devices produced by those manufacturers and in serving as their contact person established in the Union. The tasks of an authorised representative should be defined in a written mandate ~~with the manufacturer which for example may allow the authorised representative to lodge an application for a conformity assessment procedure, to report events under the vigilance system or to register devices placed on the Union market. The mandate should empower the authorised representative to duly fulfil certain defined tasks~~. Considering the role of authorised representatives, the minimum requirements to be met by them should be clearly defined, including the requirement of having available a person who fulfils minimum conditions of qualification which should be similar to those for a manufacturer's qualified person**.** ***Moreover, in view of the difficulty of enforcement of awards of compensation for damage as against manufacturers established outside the Union, it is appropriate to provide that authorised representatives be legally liable for defective devices in case of non-compliance with the obligations of the manufacturer***[36] ~~but, with a view to the authorised representative's tasks, could also be satisfied by a person with qualification in law~~.[37]

(24) To ensure legal certainty in respect of the obligations incumbent on economic operators, it is necessary to clarify when a distributor, importer or other person[38] is to be considered the manufacturer of an *in vitro* diagnostic medical device.

---

[36] **Pcy** proposal based on **DK** suggestion to introduce the wording of Art. 9(4a) into the text of this recital.

[37] **DK, DE, IE, PT** Align with Art.9.

[38] **DE** delete "*or other person*".

(25) Parallel trade in products already placed on the market is a lawful form of trade within the internal market on the basis of Article 34 of the Treaty on the Functioning of the European Union subject to the limitations set by the protection of health and safety and by the protection of intellectual property rights provided by Article 36 of the Treaty on the Functioning of the European Union. Application of this principle is, however, subject to different interpretations in the Member States. The conditions, in particular the requirements for relabelling and repackaging[39], should therefore be specified in this Regulation, taking into account the case-law of the European Court of Justice[40] in other relevant sectors and existing good practices in the field of *in vitro* diagnostic medical devices.

(26) *In vitro* diagnostic medical devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to their placing on the market or putting into service for reasons related to the requirements laid down in this Regulation.

(27) The traceability of *in vitro* diagnostic medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of *in vitro* diagnostic medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve purchase-policy and stock-management by ~~hospitals~~ ***health institutions***[41].

[39] **DE** clarify the meaning of "*requirements for relabelling and repackaging*".
[40] Judgment of the Court of 28 July 2011 in joined cases C-400/09 and C-207/10
[41] **HU** replace "*hospitals*" by "*health institutions*" for consistency with the basic act.

(27a) The UDI system should apply to all* in vitro *diagnostic medical devices placed on the market and be based on internationally recognised principles including definitions that are compatible with those used by major trade partners. In order for the European Unique Device Identification System to become functional in time for the application of this regulation detailed rules should be laid down in this Regulation and in Regulation [reference to the future Regulation on medical devices. [42]

(28) Transparency and better information are essential ***in the public interest, to protect public health*** [43] to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

(28a) To facilitate the functioning of the European Databank on medical devices (Eudamed) and the UDI database [44]***, a ~~unique~~ medical devices nomenclature should be available free of charge to economic operators and other ~~stakeholders~~ natural or legal persons obliged to use that nomenclature under this Regulation. Furthermore this nomenclature it ~~It~~ should be ~~available for free to manufacturers and~~ provided, to the maximum possible extent free of charge, also to other stakeholders such as health care institutions ~~legal or physical persons legally obliged to use the nomenclature~~.*** [45] [46]

---

[42] Recital explaining the degree of detail in *e.g.* Annex V, Part C.

[43] **DS 1331/15 IE** Addition based on **IE** suggestion.

[44] **Cion** replace by "*the device registration system based on UDI*" so that it is clear that the device registration and the UDI module are integrated.

[45] **DS 1294/15** Based on **Cion** suggestion. See article 21a.

[46] **Pcy** proposal for amendments based on **ES, AT, PT, FI** request for alignment with Art.21a.

(29) One key aspect is the creation of a central database that should integrate different electronic systems~~, with the UDI as an integral part of it,~~[47] to collate and process information regarding *in vitro* diagnostic medical devices on the market and the relevant economic operators, ***certain aspects of conformity assessment,***[48] certificates, interventional clinical performance studies and other ~~clinical~~[49] performance studies involving risks for the subjects of the studies, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) by further developing the databank set up by Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices[50].

[51]

---

47 **DE** delete "*with the UDI as an integral part of it*".

48 **Pcy** proposal for amendments based on **DE, FR** request to add reference to conformity assessment.

49 "*Clinical*" deleted to correspond to the text in the Articles.

50 OJ L 102, 23.4.2010, p. 45.

51 **DE** suggestion for new recital:
"*(30a) To avoid multiple reporting requirements the registration of economic operators in the electronic system on registration of economic operators is focused on the operator not on the device which is registered in the UDI database. Both modules should be clearly distinguished. Therefore the relevant economic operators should be required to submit only core data with regard to their role, contact details etc. to the electronic system on registration of economic operators. In addition they should be responsible for checking /verifying/scrutinising the relevant information submitted to other modules of EUDAMED.*"

(30) Eudamed's electronic systems regarding devices on the market, the relevant economic operators and certificates should enable the public to be adequately informed about devices on the Union market. The electronic system on ~~clinical~~[52] performance studies should serve as tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and, in this case, to report serious adverse events. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of their assessment by ~~national~~ competent authorities.[53] The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.

(31) In respect of data collated and processed through the electronic systems of Eudamed, Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[54] applies to the processing of personal data carried out in the Member States, under the supervision of the Member States competent authorities, in particular the public independent authorities designated by the Member States. Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data[55], applies to the processing of personal data carried out by the Commission within the framework of this Regulation, under the supervision of the European Data Protection Supervisor. In accordance with Article 2(d) of Regulation (EC) No 45/2001, the Commission should be designated as the controller of Eudamed and its electronic systems.

---

52 "*Clinical*" deleted to correspond to the text in the Articles.
53 **DE** review this sentence.
54 OJ L 281, 23.11.1995, p. 31.
55 OJ L 8, 12.1.2001, p. 1.

(32) For high-risk *in vitro* diagnostic medical devices, manufacturers should summarise the main safety and performance aspects of the device and the outcome of the ~~clinical~~ ***performance***[56] evaluation in a document that should be publicly available.[57]

(33) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.

58

~~**59**~~

~~**60**~~

(33a) The outcome of the notified body assessment of the manufacturer's technical documentation and performance evaluation documentation should be critically evaluated by the national authority responsible for notified bodies, as part of the risk based approach to the oversight and monitoring activities of the notified body. Such reviews may also require reference to manufacturer's documentation such as but not limited to the risk analysis documentation and the clinical evaluation report and supporting data.[61]

---

56 See Art. 24(1a) Point (e).

57 **PT** add in the beginning of the sentence the following text: "*In view of increasing the level of confidence in the regulatory system and promoting access to relevant information, in the context of a well informed decision and adequate use of medicinal devices by health professionals,*".

58 **7763/15 BE** Suggests adding a recital explaining the obligation on the national authority responsible for notified bodies to ensure the consultation of the national competent authority responsible for *in vitro* diagnostic medical devices on relevant aspects. **DE** in favour.

59 ~~**DS 1192/15 IE** Proposes clarifying the terminology of article 30(2) in the recital.~~

60 ~~**DS 1192/15 IE** Suggests outlining in a recital the technical and performance evaluation documentation referred to in article 33a. **DE** in favour.~~

61 **IE** suggestion for a new recital – rationale: In order to reflect the intention of article 33a, a new recital 33a is proposed to outline the need for critical evaluation of the NB assessment conducted as part of the national designating authority's oversight responsibilities/activities.

(34) The position of notified bodies vis-à-vis manufacturers should be strengthened, including their right and duty to carry out unannounced factory ~~inspections~~ ***audits*** and to conduct physical or laboratory tests on *in vitro* diagnostic medical devices to ensure continuous compliance by manufacturers after receipt of the original certification.

(34a) To increase transparency on the oversight of notified bodies by national authorities, the responsible authorities ~~shall~~ should publish information on their provisions ~~procedures~~ for designation and monitoring of notified bodies for* in vitro *diagnostic medical devices. In accordance with good administrative practice this information ~~will~~ should be kept up to date by the national authority in particular to reflect relevant, significant or substantive changes to the procedures.

(34b) In particular in[62] view of the responsibility of Member States for the organisation and delivery of health services and medical care, Member States may lay down additional requirements on notified bodies designated for conformity assessment of devices based on their territory as concerns issues that are not regulated in this Regulation. That possibility is without prejudice to more specific horizontal EU legislation on notified bodies and equal treatment of notified bodies.[63]

(35) For high risk *in vitro* diagnostic medical devices, authorities should be informed at an early stage about devices which are subject to conformity assessment and be given the right, on scientifically valid grounds, to scrutinise the preliminary assessment conducted by notified bodies, in particular regarding devices for which no common ~~technical~~ specifications exist, devices which are novel or for which a novel technology is being used, devices belonging to a category of devices with increased serious incident rates, or devices for which significant discrepancies in the conformity assessments by different notified bodies have been identified in respect of substantially similar devices. The process foreseen in this Regulation does not prevent a manufacturer from informing voluntarily a competent authority of his intention to file an application for conformity assessment for a high risk *in vitro* diagnostic medical device before submitting the application to the notified body.

---

62 **FI, UK** add "*in particular*".

63 Part of compromise in relation to the deletion of "Minimum" in the heading of Annex VI.

(36) To enhance patient safety and to take due account of technological progress, the risk classification system for *in vitro* diagnostic medical devices set out in Directive 98/79/EC should be fundamentally changed, in line with international practice, and the corresponding conformity assessment procedures should be accordingly adapted.

(37) It is necessary, in particular for the purpose of the conformity assessment procedures, to classify *in vitro* diagnostic medical devices into four risk classes and to establish a set of robust risk-based classification rules, in line with international practice.

(38) The conformity assessment procedure for class A *in vitro* diagnostic medical devices should be carried out, as a general rule, under the sole responsibility of the manufacturers, since such devices pose a low risk to patients. For *in vitro* diagnostic medical devices in classes B, C and D, the involvement of a notified body should be compulsory to the appropriate degree.

(39) The conformity assessment procedures should be further developed whilst the requirements for notified bodies as regards the performance of their assessments should be clearly specified to ensure a level playing field.

(39a) It is appropriate that certificates of free sale contain information that makes it possible to use the European databank on medical devices (Eudamed) in order to obtain information on the device and in particular whether it is on the market, no longer manufactured[64], withdrawn from the market or recalled and on any certificate on its conformity.[65]

(40) It is necessary to clarify the requirements regarding batch release verification for the highest risk *in vitro* diagnostic medical devices.

---

[64] **DE** delete "*no longer manufactured*" to align with Art. 46.

[65] Explanation of the changes to Article 46.

(41) European Union reference laboratories should be enabled to verify ***by laboratory testing the claimed performance and the***[66] compliance of such devices with the applicable common ~~technical~~ specifications, when such common ~~technical~~ specifications are available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent.

(42) To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements should be based on clinical evidence. It is necessary to clarify the requirements for such clinical evidence. As a general rule, clinical evidence should be sourced from ~~clinical~~[67] performance studies to be carried out under the responsibility of a sponsor who can be the manufacturer or another legal or natural person taking responsibility for the ~~clinical~~[68] performance study.

(43) The rules on ~~clinical~~[69] performance studies should be in line with major international guidance, such as the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for human subjects ***to facilitate for performance studies conducted in the Union are accepted elsewhere and to ensure that performance studies conducted outside the Union in accordance with international guidelines can be accepted within the Union.*** ~~and~~ ***In addition the rules should be in line with***[70] the most recent ~~(2008~~) version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects to ensure that ~~clinical~~[71] performance studies conducted in the Union are accepted elsewhere and that ~~clinical~~[72] performance studies conducted outside the Union in accordance with international guidelines can be accepted under this Regulation.

---

66 See Art. 40(2) second subparagraph.
67 "*Clinical*" deleted to correspond to the text in the Articles.
68 "*Clinical*" deleted to correspond to the text in the Articles.
69 "*Clinical*" deleted to correspond to the text in the Articles.
70 **Pcy** proposal for amendments based on **SE** request for alignment with Chapter VI.
71 "*Clinical*" deleted to correspond to the text in the Articles.
72 "*Clinical*" deleted to correspond to the text in the Articles.

(44) An electronic system should be set up at Union level to ensure that every interventional clinical performance studies and other ~~clinical~~[73] performance studies involving risks for the subjects of the studies are ~~registered~~ ***recorded and reported***[74] in a publicly accessible database. To protect the right to protection of personal data, recognised by Article 8 of the Charter of Fundamental Rights of the European Union, no personal data of subjects participating in a ~~clinical~~ performance studies should be recorded in the electronic system. To ensure synergies with the area of clinical trials on medicinal products, the electronic system on ~~clinical~~ performance studies on *in vitro* diagnostic medical devices should be interoperable with the EU database to be set up for clinical trials on medicinal products for human use.

(45) ***Where an*** ~~Sponsors of~~ interventional clinical performance studies ~~and~~ ***or an***other ~~clinical~~[75] performance studie~~s~~ involving risks for the subjects ***is*** to be conducted in more than one Member State***, Member States*** should ~~be given~~ ***have*** the possibility ***to allow the sponsor*** to submit a single application in order to reduce administrative burden.[76] In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety related aspects of the device for performance evaluation and of the scientific design of the clinical performance study to be conducted in several Member Stats, such single application should facilitate the ***voluntary*** coordination between the Member States under the direction of a coordinating Member State.[77] The coordinated assessment should not include the assessment of intrinsically national, local and ethical aspects of a clinical performance study, including informed consent. Each Member State should retain the ultimate responsibility for deciding whether the clinical performance study may be conducted on its territory. ***The Commission, collecting experiences of this voluntary coordination between Member states, should draw up a report and propose a review of the relevant provisions on a coordinated assessment procedure.***[78]

---

73 "*Clinical*" deleted to correspond to the text in the Articles.
74 **Pcy** proposal for amendments based on **DE** request for alignment with Article 48.
75 "*Clinical*" deleted to correspond to the text in the Articles.
76 **Pcy** proposal for amendments to better reflect provisions in Art. 49.
77 **DE** add a new sentence: "*Nevertheless, the sponsor and each concerned Member State may decide whether or not taking part in the coordinated assessment.*".
78 **AT** suggestion based on **HU** comments supported by **DE, AT, FI**.

(46) Sponsors should report certain adverse events occurring during interventional clinical performance studies and other ~~clinical~~[79] performance studies involving risks for the subjects to the Member States concerned. ~~which~~ ***Member States***[80] should have the possibility to terminate or suspend these studies if considered necessary to ensure a high level of protection of the subjects enrolled in such studies. Such information should be communicated to the other Member States.

(47) [81]***With exemption of some general requirements, the provisions of t***~~T~~his Regulation should only cover ~~clinical~~[82] performance studies which pursue regulatory purposes laid down in this Regulation.[83]

(47a) ~~While it~~ It is necessary to conduct performance studies using left-over specimens in accordance with strict data protection and ethical requirements and, for all performance studies intended to gather evidence in support of CE marking, it is not necessary to regulate such studies in accordance with this Regulation.[84]

(***51a) Manufacturers should play an active role during the post-market phase by systematically and actively gathering information from post-market experience with their devices in order to update their technical documentation and cooperate with the national competent authorities in charge of vigilance and market surveillance activates. To this end manufacturers should establish a comprehensive post-market surveillance (PMS) system, set up under the quality management system and based on a PMS plan. Relevant data and information gathered for the purpose of PMS, as well as lessons learned from any preventive and corrective actions triggered, should be used to update many other processes and documentations, such as risk assessment, clinical evaluation and should serve purpose of transparency.***[85]

---

79 "*Clinical*" deleted to correspond to the text in the Articles.
80 **DE** suggestion for better wording.
81 **DE** suggestion to reflect also general requirements on other types of studies.
82 "*Clinical*" deleted to correspond to the text in the Articles.
83 **DK, DE, IE,ES, AT, PT** review this recital.
84 **UK** suggestion to modify this recital in order to reflect the content of the main text.
85 **Pcy** proposal based on **ES, FR** recital on PMS.

(48) In order to better protect health and safety regarding devices on the market, the vigilance system for *in vitro* diagnostic medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.

(49) Healthcare professionals and patients should be empowered to report suspected serious incidents at national level using harmonised formats. The national competent authorities should inform manufacturers and share the information with their peers when they confirm that a serious incident has occurred in order to minimise recurrence of those incidents.

(50) The assessment of reported serious incidents and field safety corrective actions should be conducted at national level but coordination should be ensured where similar incidents have occurred or field safety corrective actions have to be carried out in more than one Member State, with the objective of sharing resources and ensuring consistency regarding the corrective action.

(51) The reporting of serious adverse events during interventional clinical performance studies and other ~~clinical~~[86] performance studies involving risks for the subjects, and the reporting of serious incidents occurring after an *in vitro* diagnostic medical device has been placed on the market should be clearly distinguished to avoid double reporting.

[87]

(52) Rules on market surveillance should be included in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.

---

[86] "*Clinical*" deleted to correspond to the text in the Articles.

[87] **7714/15 LV Pcy** Proposes adding a recital on the importance of inspections.

(52a) ~~*Any possible unacceptable risks that may adversely affect the conformity of an* in vitro *diagnostic medical device with the relevant safety and performance requirements should be brought to the attention of national competent authorities for evaluation and appropriate action.*~~[88] ***Any statistically significant increase in the number or severity of incidents or expected side effects that could have a significant impact on the risk-benefit analysis and which may lead to unacceptable risks should be reported to the competent authorities in order to permit their assessment and the adoption of appropriate measures.***[89]

~~(53) The Member States shall *should* levy fees for the designation and monitoring of notified bodies to ensure sustainability of the monitoring of those bodies by Member States and to establish a level playing field for notified bodies.~~[90]

(54) Whilst this Regulation should not affect the right of the Member States to levy fees for activities at national level, Member States should inform the Commission and the other Member States before they adopt the level and structure of the fees to ensure transparency.

(55) An expert committee, the Medical Device Coordination Group (MDCG), composed of persons designated by the Member States, based on their role and expertise in the field of medical devices and *in vitro* diagnostic medical devices, should be established in accordance with the conditions and modalities defined in Article 78 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices[91] to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation. ***The MDCG should be able to establish subgroups in order to provide necessary in-depth technical expertise in the field of medical devices and in vitro diagnostic medical devices.***[92] ***When establishing subgroups, appropriate consideration should be given to the possibility to involve existing groups at EU level in the field of medical devices*** ~~*as advisors to MDCG*~~***.***

---

88 Article 59a.

89 **Pcy** proposal based on **IE** recital on trend reporting according to Art. 59a.

90 **Pcy** proposal to delete this recital following request from **ES, FI**; **DE** against deletion.

91 OJ L […], […], p. […]

92 **DE** one single MDCG on MD and IVD.

(56) Closer coordination between national competent authorities through information exchange and coordinated assessments under the direction of a coordinating authority is fundamental for ensuring a uniform high level of health and safety within the internal market, in particular in the areas of ~~clinical~~[93] performance studies and vigilance. ~~This~~ ***The principle of coordinated exchange and assessment applies across authority activities described in this Regulation, such as notified body designation and should, when possible, be encouraged in the area of market surveillance of in vitro medical devices. Joint working, coordination and communication of activities*** should also lead to more efficient use of ~~scarce~~ resources ***and expertise*** at national level.[94]

(57) The Commission should provide scientific, technical and corresponding logistic support to the coordinating national authority and ensure that the regulatory system for *in vitro* diagnostic medical devices is effectively implemented at Union level based on sound scientific evidence.

(58) The Union ***and the Member States***[95] [96] should actively participate in international regulatory cooperation in the field of *in vitro* diagnostic medical devices to facilitate the exchange of safety-related information regarding *in vitro* diagnostic medical devices and foster the further development of international regulatory guidelines promoting the adoption of regulations in other jurisdictions with a level of health and safety protection equivalent to that set by this Regulation.

(59) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property. This Regulation should be applied by the Member States in accordance with those rights and principles.

---

93 "*Clinical*" deleted to correspond to the text in the Articles.

94 **IE** suggestion to review the recital on coordination of activities between MSs – Rationale: Coordinated assessments include all aspects of exchange of information and assessment across the regulation. It is suggested to include other aspects such as market surveillance and notified body oversight to reflect that coordinated exchange applies across the regulation as a whole and not just applicable to the activities of vigilance and clinical investigations.

95 Clarification to better reflect Article 75.

96 **DE** add "*where appropriate*".

(60) In order to maintain a high level of health and safety, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of ~~the adaptation to technical progress of the general safety and performance requirements, of~~ the elements to be addressed in the technical documentation, of the minimum content of the EU declaration of conformity and of the certificates issued by notified bodies, ~~of the minimum requirements to be met by notified bodies, of the classification rules,~~ of the conformity assessment procedures~~, and of the documentation to be submitted for the approval of clinical performance studies~~; ***certain aspects related to*** the establishment of the UDI system; the information to be submitted for the registration of *in vitro* diagnostic medical devices and certain economic operators~~; the level and structure of fees for the designation and monitoring of notified bodies; the publicly available information in respect of clinical performance studies; the adoption of preventive health protection measures at EU level; and the tasks of and criteria for European Union reference laboratories and the level and structure of fees for scientific opinions delivered by them~~.[97] [98]

It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(61) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission[99]. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[100].

---

[97] Recital adapted to the powers delegated to the Commission in the draft Regulation.

[98] **DE** fundamental problem with the use of delegated acts.

[99] It could be considered to specify the implementing powers. **Pcy** invites delegations to give their opinion on this.

[100] OJ L 55, 28.2.2011, p. 13.

(62) The advisory procedure should be used for the adoption of the form and presentation of the data elements of the manufacturers' summary of safety and performance~~, of the codes defining the notified bodies' scopes of designation~~ and of the model for certificates of free sale, given that those acts have a procedural character and do not directly ***have an*** impact ***on***[101] the health and safety at Union level.

~~(63) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the extension to the territory of the Union of a national derogation from the applicable conformity assessment procedures in exceptional cases; relating to the Commission's position whether a provisional national measure against an *in vitro* diagnostic medical device presenting a risk or a provisional national preventive health protection measure is justified or not; and relating to the adoption of a Union measure against an *in vitro* diagnostic medical device presenting a risk, imperative grounds of urgency so require.~~[102]

(64) To allow economic operators, notified bodies, Member States and the Commission to adapt to the changes introduced by this Regulation, it is appropriate to provide for a sufficient transitional period for that adaptation and for the organisational arrangements to be taken for its proper application. It is particularly important that by the date of application, a sufficient number of notified bodies are designated in accordance with the new requirements to avoid any shortage of *in vitro* diagnostic medical devices on the market.

---

101 Language improvement.

102 The corresponding Article 71(3) is deleted.

(65) In order to ensure a smooth transition to the registration of *in vitro* diagnostic medical devices, of relevant economic operators and of certificates, the obligation to submit the relevant information to the electronic systems put in place by this Regulation at Union level should***, in case the corresponding IT systems are developed according to plan,***[103] become fully effective only 18 months after the date of application of this Regulation. During this transitional period, Article 10 and point (a) of Article 12(1) of Directive 98/79/EC should remain in force. However, economic operators and notified bodies who register in the relevant electronic systems provided for at Union level should be considered ***to be*** in compliance with the registration requirements adopted by the Member States pursuant to those provisions of the Directives to avoid multiple registrations.

(65a) ~~It is furthermore appropriate to lay down provisions that, for the case the corresponding IT systems are not developed according to plan, delay the application of the provisions on registration of medical devices, relevant economic operators and certificates as well as those on performance evaluation until after those systems have achieved full functionality.~~[104] ***A transitional period of six months is needed for the application of provisions related to the use of the Eudamed and UDI system. This period starts from the date of publication of a notice in the Official Journal of the European Union which confirms that those systems have achieved full functionality.***[105]

(65b) In order to provide for a smooth introduction of the UDI system, the effective obligation to place the UDI carrier on the label of the device should moreover vary from one year to five years after the date of application of this Regulation depending upon the class of the **in vitro** ***diagnostic medical device concerned.***[106]

(66) Directive 98/79/EC should be repealed to ensure that only one set of rules applies to the placing of *in vitro* diagnostic medical devices on the market and the related aspects covered by this Regulation.

---

[103] Addition to reflect changes in Article 90.
[104] Addition to reflect changes in Article 90.
[105] **Pcy** proposal for alignment of the recital with Art. 90(3)(d).
[106] Addition to reflect changes in Article 90.

(66a) The European Data Protection Supervisor has given an opinion[107] pursuant to Article 28(2) of Regulation (EC) No 45/2001. [108]

(67) Since the objective of this Regulation, namely to ensure high standards of quality and safety for *in vitro* diagnostic medical devices, thus ensuring a high level of protection of health and safety of patients, users and other persons, cannot sufficiently be achieved by the Member States and can, by reason of the scale of the measure, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

---

107 OJ L XX, X.Y.20ZZ, p.X.

108 Modelled on the corresponding recital in CTR (Reg (EU) No 536/2014).