



EUROPEAN PARLIAMENT

2009 - 2014

Committee on the Environment, Public Health and Food Safety

2012/0267(COD)

3.4.2013

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DRAFT REPORT

on the proposal for a regulation of the European Parliament and of the Council
on in vitro diagnostic medical devices
(COM(2012)0541 – C7-0317/2012 – 2012/0267(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Peter Liese

Symbols for procedures

- * Consultation procedure
- *** Consent procedure
- ***I Ordinary legislative procedure (first reading)
- ***II Ordinary legislative procedure (second reading)
- ***III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

In amendments by Parliament, amendments to draft acts are highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the draft act which may require correction when the final text is prepared – for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act that the draft act seeks to amend includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend. Passages in an existing act that Parliament wishes to amend, but that the draft act has left unchanged, are highlighted in **bold**. Any deletions that Parliament wishes to make in such passages are indicated thus: [...].

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices
(COM(2012)0541 – C7-0317/2012 – 2012/0267(COD))**

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2012)0541),
 - having regard to Article 294(2), Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0317/2012),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 14 February 2013¹,
 - after consulting the Committee of the Regions,
 - having regard to Rule 55 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A7-0000/2013),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

**Proposal for a regulation
Recital 5 a (new)**

Text proposed by the Commission

Amendment

(5a) The high number of SMEs active in the area of in-vitro diagnostic medical

¹ Not yet published in the Official Journal.

devices should be taken into account when regulating that area, while avoiding the creation of health and safety risks.

Or. en

Amendment 2

Proposal for a regulation

Recital 9

Text proposed by the Commission

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.

Amendment

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, *without putting an unnecessary burden on medical professionals that use in-vitro-diagnostic medical devices in a modified way to adapt to patients' needs.*

Or. en

Justification

Linked to amendment 37; specific needs of patients or group of patients needs to be respected.

Amendment 3

Proposal for a regulation

Recital 26

Text proposed by the Commission

(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

Amendment

(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.

obstacles to their placing on the market or putting into service for reasons related to the requirements laid down in this Regulation. ***However Member States should be allowed to decide whether to restrict the use of any specific type of in-vitro diagnostic device in relation to aspects that are not covered by this Regulation.***

Or. en

Justification

Linked to Amendment 13. It is a long-standing policy of the European Union that the question if to allow, prohibit or allow within limits of sensible ethical technologies such as preimplantation genetic testing is subject to the principle of subsidiarity. Member States that allow these kinds of tests should make sure that they comply with the standards of this regulation but member states that want to prohibit it according to the national ethical debate should continue to have this possibility. The wording is taken from a similar provision in the advanced therapies regulation.

Amendment 4

Proposal for a regulation Recital 44 a (new)

Text proposed by the Commission

Amendment

(44a) Interventional clinical performance studies and other clinical performance studies involving risk for the subject should only be allowed after assessment and approval by an ethics committee.

Or. en

Justification

Linked to the debate on the clinical trials regulation the rapporteur considers that the role of the ethic committee needs to be strengthened.

Amendment 5

Proposal for a regulation Recital 45 a (new)

Text proposed by the Commission

Amendment

(45a) Strict rules for persons unable to give informed consent such as children and incapacitated persons should be established at the same level as in Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use¹.

¹ OJ L 121, 1.5.2001, p. 34.

Or. en

Justification

Compared to the proposal on clinical trials for medicinal products the provisions on interventional clinical performance studies are very weak and imprecise. Interventional clinical performance studies may include a very significant risk for the patient, for example if the specimen is collected by spinal tap. Therefore the provisions need to be specified. The proposal seeks to maintain at least the standard of protection which is guaranteed for clinical trials with medicinal products since 2001 through Directive 2001/20 EC.

Amendment 6

Proposal for a regulation Recital 59

Text proposed by the Commission

Amendment

(59) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the

(59) This Regulation respects the fundamental rights and observes the principles recognized 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.

European Union and notably human dignity, the integrity of the person, ***the principle of free and informed consent of the person concerned***, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property, ***as well as the Convention on Human Rights and Biomedicine as well as the Additional Protocol to that Convention concerning Genetic Testing for Health Purposes***. This Regulation should be applied by the Member States in accordance with those rights and principles.

Or. en

Justification

The principle of free and informed consent is a key point in the Charta, Article 3 and should be mentioned here.

Amendment 7

Proposal for a regulation Recital 59 a (new)

Text proposed by the Commission

Amendment

(59a) The principle of informed consent, which is one of the key points of the Charter of Fundamental Rights and certain documents of international organisations such as the Council of Europe and the Organisation for Economic Co-operation and Development (OECD), should be respected in this Regulation. The quality of the in vitro medical devices as well as the framework of their application are crucial, especially with regard to DNA tests. A chapter of informed consent therefore needs to be introduced.

Justification

Linked to Amendment 31. The principle of free and informed consent is a key point in the Charta Article 3 and provisions to respect it should be included in the regulation.

Amendment 8

**Proposal for a regulation
Recital 59 b (new)**

Text proposed by the Commission

Amendment

(59b) This Regulation is in keeping with the United Nations Convention on the Rights of Persons with Disabilities of 13 December 2006, ratified by the European Union on 23 December 2010, by way of which the signatories commit themselves, in particular, to promote, protect and guarantee the full and equal exercise of all human rights and basic freedoms by all persons with disabilities and to promote the respect of their inherent dignity, inter alia by raising awareness about the abilities of disabled persons and the contribution they make.

Or. de

Justification

The European Union has ratified the UN-Convention on people with disability. This should be reflected in the regulation.

Amendment 9

Proposal for a regulation

Recital 60

Text proposed by the Commission

(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; 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. 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.

Amendment

(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 minimum requirements to be met by notified bodies, of the classification rules and of the documentation to be submitted for the approval of clinical performance studies; 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. ***However, substantial elements of this Regulation such as general safety and performance requirements, elements to be addressed in technical documentation, the minimum content of the Union declaration of conformity, amending or supplementing the conformity assessment procedures, should only be amended through the ordinary legislative procedure.*** 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.

Or. en

Justification

The mentioned parts are an essential element of the legislation and therefore according to article 290 of the treaty cannot be modified through a delegated act.

Amendment 10

Proposal for a regulation

Recital 64

Text proposed by the Commission

(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.

Amendment

(64) To allow economic operators, **especially SMEs, to adapt to the changes introduced by this Regulation and to ensure its proper application, it is appropriate to provide for a sufficient transitional period to enable organisational arrangements to be made. However, parts of the Regulation that concern Member States and the Commission should be implemented as soon as possible.** It is particularly important that a sufficient number of notified bodies **is designated** in accordance with the new requirements, **as soon as possible**, to avoid any shortage of *in-vitro* diagnostics medical devices on the market.

Or. en

Justification

See explanatory statement.

Amendment 11

Proposal for a regulation Recital 65

Text proposed by the Commission

(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 become fully effective only 18 months after the date of application of this Regulation. During this transitional period, Article 10 and points (a) and (b) 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 in compliance with the registration requirements adopted by the Member States pursuant to those provisions of the Directive to avoid multiple registrations.

Amendment

(65) In order to ensure a smooth transition to the registration of in vitro diagnostic medical devices the electronic systems put in place by this Regulation at Union level should become ***operational as soon as possible***. Economic operators and notified bodies who register in the relevant electronic systems provided for at Union level should be considered in compliance with the registration requirements adopted by the Member States pursuant to those provisions of the Directive to avoid multiple registrations.

Or. en

Justification

The electronic systems must be established as soon as possible. Economic operators should be able participate as soon as they are ready.

Amendment 12

Proposal for a regulation Recital 67 a (new)

Text proposed by the Commission

Amendment

(67 a) It is a long standing policy of the Union not to interfere with national policy allowing, prohibiting or limiting at

national level ethically controversial technologies, such as preimplantation genetic testing. This Regulation should not interfere with this principle, and the decision to allow, prohibit or restrict such technologies should therefore remain at national level. Where a Member State allows such technologies whether with or without restriction, the standards laid down in this Regulation should apply.

Or. en

Justification

It is a long-standing policy of the European Union that the question if to allow, prohibit or allow within limits of sensible ethical technologies such as preimplantation genetic testing is subject to the principle of subsidiarity. Member States that allow this kind of tests should make sure that they comply with the standards of this regulation but member states that want to prohibit it according to the national ethical debate should continue to have this possibility.

Amendment 13

Proposal for a regulation

Article 1 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7a. The regulation of in-vitro diagnostic medical devices at Union level shall not interfere with the freedom of Member States to decide whether to restrict the use of any specific type of in-vitro diagnostic device in relation to aspects that are not covered by this Regulation.

Or. en

Justification

It is a long-standing policy of the European Union that the question if to allow, prohibit or allow within limits of sensible ethical technologies such as preimplantation genetic testing is subject to the principle of subsidiarity. Member States that allow these kinds of tests should make sure that they comply with the standards of this regulation but member states that want

to prohibit it according to the national ethical debate should continue to have this possibility. The wording is taken from a similar provision in the advanced therapies regulation.

Amendment 14

Proposal for a regulation

Article 2 – point 1

Text proposed by the Commission

(1) ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological process or state,
- control or support of conception,
- disinfection or sterilisation of any of the above-mentioned products,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Amendment

(1) ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific ***direct or indirect*** medical purposes of:

- diagnosis, prevention, monitoring, ***prediction***, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological process or state,
- control or support of conception,
- disinfection or sterilisation of any of the above-mentioned products,

– ***providing information concerning direct or indirect impacts on health***,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Or. en

Justification

a) In Article 2(2), the definition of an in vitro diagnostic medical device has been extended to cover predictive and predisposition testing. However, the definition of a medical device has not been similarly extended. b) So called lifestyle-tests should fall under the regulation as they could have enormous consequences for the health of the patient/consumer. An extended scope therefore is important for protection of patients and consumer in Europe.

Amendment 15

Proposal for a regulation

Article 2 – point 2 – indent 2

Text proposed by the Commission

Amendment

- concerning **a** congenital **abnormality**;

– concerning congenital **physical or mental impairments**,

Or. de

Justification

The term 'congenital abnormality' is viewed by persons with disabilities and their representatives as discrimination. It should therefore be replaced.

Amendment 16

Proposal for a regulation

Article 2 – point 2 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

In vitro diagnostic medical devices used for DNA-testing shall be subject to this Regulation.

Or. en

Justification

So called lifestyle-tests should fall under the regulation as they could have enormous consequences for the health of the patient/consumer. An extended scope therefore is important for protection of patients and consumer in Europe.

Amendment 17

Proposal for a regulation Article 2 – point 8

Text proposed by the Commission

Amendment

(8) 'single-use device' means a device that is intended to be used on an individual patient during a single procedure; ***deleted***

The single procedure may involve several uses or prolonged use on the same patient.

Or. en

Justification

The concept of single use devices is not applicable to IVDs.

Amendment 18

Proposal for a regulation Article 2 – point 12 a (new)

Text proposed by the Commission

Amendment

(12a) 'genetic test' means a test that is carried out for health purposes, involving analysis of biological samples of human origin and aimed specifically at identifying the genetic characteristics of a person which are inherited or acquired during early prenatal development;

Or. en

Justification

The rapporteur introduces specific provisions for genetic tests. That it is why a definition is necessary. The wording is based on the protocol of the Council of Europe.

Amendment 19

Proposal for a regulation

Article 2 – point 16 – subparagraph 1

Text proposed by the Commission

(16) 'manufacturer' means the natural or legal person *who* manufactures *or* fully refurbishes *a device or has a device designed, manufactured or fully refurbished, and markets that device* under *his* name or trademark.

Amendment

(16) 'manufacturer' means the natural or legal person *with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under that person's own name, regardless of whether those operations are carried out by that person or on that person's behalf by a third party. The obligations of this Regulation to be met by* manufactures *also apply to natural or legal persons who assemble, package, process, fully refurbish or label one or more ready-made products and/or assign to them their intended purpose as devices with a view to their being placed on the market* under *that person's own* name or trademark.

Or. en

Justification

a) The definition of the term 'manufacturer' is less clear than in the existing IVD Directive, because important parts (e.g. packaging, labelling) are missing from the current definition (98/79/EC, Article 1 f). The natural or legal persons that labels a medical device under his own name is a manufacturer (see current legislative). b) A manufacturer markets products under his name. The trademark itself does not define the manufacturer.

Amendment 20

Proposal for a regulation Article 2 – point 21

Text proposed by the Commission

(21) 'health institution' means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health;

Amendment

(21) 'health institution' means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health; ***excluding commercial clinical service labs;***

Or. en

Justification

The regulation foresees some exceptions to meet the needs of hospitals and other healthcare institutions. It should be clarified that commercial labs do not fall under this division because they should not benefit from the same derogations.

Amendment 21

Proposal for a regulation Article 2 – point 25

Text proposed by the Commission

(25) 'conformity assessment body' means a body that performs third-party conformity assessment activities including ***calibration,*** testing, certification and inspection;

Amendment

(25) 'conformity assessment body' means a body that performs third-party conformity assessment activities including testing, certification and inspection;

Or. en

Justification

Conformity assessment bodies are never involved in the calibration of an IVD device – IVD devices need to be calibrated prior to use.

Amendment 22

Proposal for a regulation Article 2 – point 43 a (new)

Text proposed by the Commission

Amendment

(43a) 'calibrator' means a measurement standard used in the calibration of a device;

Or. en

Justification

Calibrators and control materials are very different not only from the point of view of their scientific use and characteristics, but also from the regulatory point of view as they are actually classified according to different rules. Therefore the definition needs to be split in two – one for calibrators and another for control materials.

Amendment 23

Proposal for a regulation Article 2 – point 44

Text proposed by the Commission

Amendment

(44) 'calibrators and control materials' means any substance, material or article intended by *the* manufacturer *either to establish measurement relationships or* to verify the performance characteristics of a device *in conjunction with the intended purpose of that device*;

(44) 'control material' means a substance, material or article intended by *its* manufacturer *to be used* to verify the performance characteristics of a device;

Or. en

Justification

Calibrators and control materials are very different not only from the point of view of their scientific use and characteristics, but also from the regulatory point of view as they are actually classified according to different rules. Therefore the definition needs to be split in two – one for calibrators and another for control materials.

Amendment 24

Proposal for a regulation

Article 2 – point 45

Text proposed by the Commission

(45) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation and management of a clinical performance study;

Amendment

(45) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation, management, **conduct or financing** of a clinical performance study;

Or. en

Justification

Annex XIII section II implies further responsibilities. Otherwise, if the study is customarily deemed to have been concluded following the last visit of the last test subject it would lack reference to the responsibility of the sponsor with regards to associated follow-up tasks, e. g. the archiving of documentation, the compilation of the clinical investigation report and the publishing of results. Supplementing this paragraph with a reference to the responsibility of the sponsor for financing corresponds to the definition in accordance with Article 2e) of Directive 2001/20/EC.

Amendment 25

Proposal for a regulation

Article 2 – point 48 a (new)

Text proposed by the Commission

Amendment

(48a) 'inspection' means an official review, carried out by a competent authority, of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by that authority to be related to a clinical performance study and that may be located at the site of the trial, at the sponsor's and/or contract research organisation's facilities, or at other establishments which the competent authority sees fit to inspect;

Or. en

Justification

In contrast to the proposal on clinical trials COM 2012, 369 final, the proposed Regulation contains no provisions dealing with inspections. It must not be left to the discretion of the Member States to decide whether to monitor the conduct of clinical performance studies. This could lead to decisions on whether to monitor an investigation being made dependent upon the availability of necessary budgetary funds. Furthermore, this could result in clinical performance studies being carried out preferentially in states which dispense with monitoring.

Amendment 26

Proposal for a regulation Chapter II – title

Text proposed by the Commission

Amendment

Making available of devices, obligations of economic operators, CE marking, free movement

Making available **and application** of devices, obligations of economic operators, CE marking, free movement

Or. en

Amendment 27

Proposal for a regulation Article 4 – paragraph 3

Text proposed by the Commission

Amendment

3. Demonstration of conformity with the general safety and performance requirements shall **be based** on clinical evidence in accordance with Article 47.

3. Demonstration of conformity with the general safety and performance requirements shall **include** clinical evidence in accordance with Article 47.

Or. en

Justification

Clinical evidence does not address all of the general safety and performance requirements - many of them are addressed in other ways (e.g. requirements on chemical safety, electrical

safety, mechanical safety, radiological safety etc. are not determined through clinical evidence.

Amendment 28

Proposal for a regulation Article 4 – paragraph 5

Text proposed by the Commission

5. With the exception of Article 59(4), the requirements of this Regulation shall not apply to devices classified as class A, B and C, in accordance with the rules set out in Annex VII, and manufactured and used only within a single health institution, provided manufacture and use occur solely under the health institution's single quality management system, and the health institution is compliant with standard EN ISO 15189 or any other equivalent recognised standard. Member States may require that the health institutions submit to the competent authority a list of such devices which have been manufactured and used on their territory and may make the manufacture and use of the devices concerned subject to further safety requirements.

Devices classified as class D in accordance with the rules set out in Annex VII, even if manufactured and used within a single health institution, shall comply with the requirements of this Regulation. However, the provisions regarding CE marking set out in Article 16 and the obligations referred to in Articles 21 to 25 shall not apply to those devices.

Amendment

5. With the exception of Article 59(4), the requirements of this Regulation shall not apply to devices classified as class A, B and C, ***unless those devices are companion diagnostics***, in accordance with the rules set out in Annex VII, and manufactured and used only within a single health institution, provided manufacture and use occur solely under the health institution's single quality management system, and the health institution is ***accredited to the*** standard EN ISO 15189 or any other equivalent recognised standard. Member States may require that the health institutions submit to the competent authority a list of such devices which have been manufactured and used on their territory and may make the manufacture and use of the devices concerned subject to further safety requirements.

Companion diagnostics and devices classified as class D in accordance with the rules set out in Annex VII, , even if manufactured and used within a single health institution, shall comply with the requirements of this Regulation. However, the provisions regarding CE marking set out in Article 16 and the obligations referred to in Articles 21 to 25 shall not apply to those devices.

Or. en

Justification

Companion Diagnostics are a particular class of devices which are subjected to an increased compliance requirements compared to other class C devices, notably all companion diagnostics undergo design dossier review and they are subject to an evaluation by the European Medicines Agencies. This increased level of compliance is there to ensure the safety and performance of the companion diagnostics.

Amendment 29

Proposal for a regulation

Article 4 – paragraph 6

Text proposed by the Commission

Amendment

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 85, amending or supplementing, in the light of technical progress and considering the intended users or patients, the general safety and performance requirements set out in Annex I, including the information supplied by the manufacturer. *deleted*

Or. en

Justification

The general safety and performance requirements constitute an essential element of the legislation and therefore according to article 290 of the treaty cannot be modified through a delegated act.

Amendment 30

Proposal for a regulation

Article 4 a (new)

Text proposed by the Commission

Amendment

Article 4a

Genetic information, counselling and free consent

- 1. A device may only be used for the purpose of a genetic test if that test is conducted by persons admitted to the medical profession under the applicable national legislation.***
- 2. A product may only be used for the purposes of a genetic test if the rights, safety and well-being of the test subjects are protected and the clinical data generated in the course of the testing are expected to be reliable and robust.***
- 3. Before using a device for the purpose of a genetic test the person referred to in paragraph 1 shall provide the test subject concerned with appropriate information on the nature, the significance and the implications of the genetic test.***
- 4. Before using a device for the purpose of a genetic test the person referred to in paragraph 1 shall provide the test subject concerned with appropriate and comprehensible genetic counselling without prejudging the outcome. The genetic counselling shall include medical, ethical, social, psychological and legal aspects.***

The form and extent of that genetic counselling shall be defined according to the implications of the results of the test and their significance for the person or the members of that person's family, including possible implications concerning procreation choices.

- 5. A device may only be used for the purpose of a genetic test after the test subject concerned has given free and informed consent to it. That consent shall be given explicitly in writing. The consent may be revoked at any time in writing or orally.***

In the case of minors, the informed consent of the parents or legal representative shall be obtained. That

consent shall represent the minor's presumed will and may be revoked at any time, without detriment to the minor. In the case of incapacitated adults who are unable to give informed legal consent, the informed consent of the legal representative shall be obtained. The consent shall represent the presumed will of the person concerned and may be revoked at any time, without detriment to that person.

6. A device may only be used for the determination of gender in connection with prenatal diagnosis, if the determination fulfils a medical purpose and if there is a risk of serious gender specific hereditary diseases. By way of derogation from Article 2(1) and (2) the same restriction on use shall apply to products which are not intended to fulfil a specific medical purpose.

7. The provisions of this Article on the use of devices for the purpose of genetic tests shall not prevent Member States from maintaining or introducing for reasons of health protection or public order more stringent national legislation in this field.

Or. en

Justification

See also Explanatory statement. This new chapter refers to long-standing requests of the European Parliament and other international institutions like the Council of Europe and OECD. Genetic Tests should be performed by a medical professional after appropriate genetic counselling. Informed consent is a prerogative of the Charta of Fundamental Rights and should therefore be introduced in the legislation.

Amendment 31

Proposal for a regulation

Article 7 – paragraph 1

Text proposed by the Commission

1. Where no harmonised standards exist or where **relevant harmonised standards are not sufficient**, the Commission shall be empowered to adopt common technical specifications (CTS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evidence and post-market follow-up set out in Annex XII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 84(3).

Amendment

1. Where no harmonised standards exist or where **there is a need to address public health concerns**, the Commission shall be empowered to adopt common technical specifications (CTS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evidence and post-market follow-up set out in Annex XII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 84(3).

Or. en

Justification

By way of harmonised standards, it is determined which fundamental requirements of the Regulation are fulfilled by compliance with the standard. The Commission lays down which standards are recognised as harmonised standards. Where a harmonised standard no longer reflects the state of the art, the Commission de-harmonises this standard. Then, the standard needs to be revised by the competent standardisation body. Therefore, sentence 1 of Article 7 ‘ ... or where relevant harmonised standards are not sufficient ... ’ is worded in a way that gives rise to misunderstandings and needs to be deleted.

Amendment 32

Proposal for a regulation

Article 8 – paragraph 2 – subparagraph 2

Text proposed by the Commission

The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annex II.

Amendment

deleted

Justification

The general safety and performance requirement constitute an essential element of the legislation and therefore according to article 290 of the treaty cannot be modified through a delegated act.

Amendment 33**Proposal for a regulation**
Article 8 – paragraph 7*Text proposed by the Commission*

7. Manufacturers shall ensure that ***the device is accompanied by*** the information to be supplied in accordance with Section 17 of Annex I in an official Union language which can be easily understood by the intended user. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user.

For devices for self-testing or near-patient-testing, the information supplied in accordance with Section 17 of Annex I shall be provided in the language(s) of the Member State where the device reaches its intended user.

Amendment

7. Manufacturers shall ensure that the information to be supplied ***for the device*** in accordance with Section 17 of Annex I ***is provided*** in an official Union language which can be easily understood by the intended user. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user.

For devices for self-testing or near-patient-testing, the information supplied in accordance with Section 17 of Annex I shall be provided in the ***official Union*** language(s) of the Member State where the device reaches its intended user.

Justification

It should be possible to provide the information electronically. It needs to be specified, that the information shall be provided in official union languages and not any other language. Both changes reduce the potential burden for SMEs.

Amendment 34

Proposal for a regulation

Article 9 – paragraph 3 – point a

Text proposed by the Commission

(a) keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any supplement, issued in accordance with Article 43 at the disposal of competent authorities for the period referred to in Article 8(4);

Amendment

(a) keep ***available the summary of technical documentation (STED) or on request*** the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any supplement, issued in accordance with Article 43 at the disposal of competent authorities for the period referred to in Article 8(4);

Or. en

Justification

The manufacturer keeps the technical documentation available, as this is archived at several places in the company. Alternatively, the summary of the technical documentation (STED) should be given (see also GHTF: Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED))

Amendment 35

Proposal for a regulation

Article 11 – paragraph 2 – point e

Text proposed by the Commission

(e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use ***and EU declaration of conformity***;

Amendment

(e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use;

Or. en

Justification

EU declaration of conformity should not accompany the product. There is no need and no extra value for this demand.

Amendment 36

Proposal for a regulation Article 14 – paragraph 1 – subparagraph 2

Text proposed by the Commission

The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (16) of Article 2, assembles or adapts a device already on the market to its intended purpose for an individual patient.

Amendment

The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (16) of Article 2, assembles or adapts a device already on the market to its intended purpose for an individual patient ***or a specific limited group of patients within a single healthcare institution.***

Or. en

Justification

The question of in-house tests is very controversial. The COM proposal foresees only very limited coverage of in-house tests of classes A, B& C but a full inclusion of in-house tests for class D. The rapporteur wants to keep the structure of the proposal in principal but in specific cases hospitals adapt tests of class D to the need of the patients. Not only in individual cases but also in form of guidelines for example for premature born children. This necessary adaptation should not require a full complete new conformity assessment by the health care institution.

Amendment 37

Proposal for a regulation Article 15 – paragraph 1

Text proposed by the Commission

1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be ***translated into*** the official Union ***language or languages required by the Member State(s) in which the device is made available.***

Amendment

1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be ***issued in one of*** the official Union ***languages.***

Justification

Generally, translation of declarations of conformity into all official Union languages where the device is made available is a disproportionate administrative and thus cost-intensive effort, especially for SMEs which is not justified. Like under the current directive, availability in one Union language should be sufficient.

Amendment 38**Proposal for a regulation****Article 15 – paragraph 4**

Text proposed by the Commission

Amendment

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the EU declaration of conformity set out in Annex III in the light of technical progress. *deleted*

Justification

As the main means of showing compliance to the legislation, the declaration of conformity is an essential element of the legislation and therefore according to article 290 of the treaty cannot be modified through a delegated act.

Amendment 39**Proposal for a regulation****Article 40 – paragraph 4 – subparagraph 2**

Text proposed by the Commission

Amendment

In addition, for devices for self-testing ***and near-patient testing***, the manufacturer shall fulfil the supplementary requirements set out in Section 6.1 of Annex VIII.

In addition, for devices for self-testing the manufacturer shall fulfil the supplementary requirements set out in Section 6.1 of Annex VIII.

Justification

Requirements are laid down for so-called devices for near-patient testing (these are tests performed outside a laboratory environment but always for professional use) as regards the conformity assessment procedure and irrespective of the risk classification of the test. Furthermore, a design examination according to Annex VIII no. 6.1 is invariably demanded. This demand it means enormous extra costs and workloads which are factually unjustified, given the risk classification.

Amendment 40

Proposal for a regulation

Article 40 – paragraph 5 – subparagraph 2 – point a

Text proposed by the Commission

Amendment

(a) in the case of devices for near-patient testing, to the requirements set out in Section 6.1 of Annex VIII, ***deleted***

Or. en

Justification

There should be a difference regarding the conformity assessment and the risk classes for near patient testing devices. Near patient testing devices classified as class A devices should be treated in Annex VIII in the same way as all other devices. So the classification rules are transferred into the conformity assessment routes and requirements.

Amendment 41

Proposal for a regulation

Article 40 – paragraph 5 – subparagraph 2 –point c

Text proposed by the Commission

Amendment

(c) in the case of devices with a measuring function, to the aspects of manufacture concerned with the conformity of the devices with the metrological requirements. ***deleted***

Or. en

Justification

All IVDs have by definition a measuring function. Most of the performance requirements and part of the clinical evidence which is required for every device is needed to assess the measuring function of the IVDs. This text, which is the general statement on measuring function from the Medical Devices proposal, fails to provide any additional safeguards for IVDs.

Amendment 42

Proposal for a regulation

Article 40 – paragraph 10

Text proposed by the Commission

Amendment

10. In the light of technical progress and any information which becomes available in the course of the designation or monitoring of notified bodies set out in Articles 26 to 38, or of the vigilance and market surveillance activities described in Articles 59 to 73, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the conformity assessment procedures set out in Annexes VIII to X.

deleted

Or. en

Justification

The conformity assessment procedures constitute an essential element of the legislation and therefore according to article 290 of the treaty cannot be modified through a delegated act.

Amendment 43

Proposal for a regulation

Article 47 – paragraph 1

Text proposed by the Commission

Amendment

1. The demonstration of conformity with the general safety and performance requirements set out in Annex I, under normal conditions of use, shall be based on

1. The demonstration of conformity with the general safety and performance requirements set out in Annex I, under normal conditions of use, shall be based on clinical evidence, ***or additional safety data***

clinical evidence.

for general safety and performance requirements not covered by clinical evidence.

Or. en

Justification

There are numerous general safety and performance requirements which are not covered by clinical evidence, such as the ones pertaining to chemical, mechanical and electrical safety. Thus clinical evidence must always be considered when demonstrating conformity to the general safety and performance requirements but other considerations are also important.

Amendment 44

Proposal for a regulation

Article 47 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Should the manufacturer claim and/or describe a clinical use, evidence attesting to this use shall constitute part of the requirements.

Or. de

Justification

Specific clinical performance studies are not required for all in vitro diagnostic devices. This would also be disproportionate, although according to EU legislation in other areas, for example health claims, manufacturers making claims for a clinical use are to provide evidence thereof.

Amendment 45

Proposal for a regulation

Article 48 – paragraph 1 – points a and b

Text proposed by the Commission

Amendment

(a) to verify that, under normal conditions of use, the devices are designed, manufactured and packaged in such a way that they are suitable for one or more of the

a) to verify that, under normal conditions of use, the devices are designed, manufactured and packaged in such a way that they are suitable for one or more of the

specific purposes of an *in vitro* diagnostic medical device referred to in number (2) of Article 2, and achieve the performance intended as specified by the manufacturers;

(b) to verify that devices achieve the intended benefits to the patient as specified by the manufacturer;

specific purposes of an *in vitro* diagnostic medical device referred to in number (2) of Article 2, and achieve the performance intended as specified by the manufacturers **or sponsor**;

b) to verify that devices achieve the intended benefits to the patient as specified by the manufacturer **or sponsor**;

Or. en

Justification

From the perspective of patient protection, it is irrelevant whether a clinical performance study is carried out under the responsibility of a manufacturer and is intended to form the basis for future CE marking, or whether a study is to be conducted for non-commercial, particularly scientific purposes. Clinical performance studies which are the responsibility or are managed by a person or organisation other than a potential manufacturer should also be subject to the provisions of the Regulation.

Amendment 46

Proposal for a regulation Article 48 – paragraph 4

Text proposed by the Commission

4. All clinical performance studies shall be designed and conducted in a way that the rights, safety and well-being of the subjects participating in such clinical performance studies are protected and that the clinical data generated in the clinical performance study are going to be reliable and robust.

Amendment

4. All clinical performance studies shall be designed and conducted in a way that the rights, safety and well-being of the subjects participating in such clinical performance studies are protected and that the clinical data generated in the clinical performance study are going to be reliable and robust.
Such studies shall not be conducted if the risks associated with the investigation are not medically justifiable in terms of the potential benefits of the device.

Or. en

Justification

The proposed amendment takes into account the fact that medical innovation cannot be reduced to the supply of new technological developments. In addition to proof of therapeutic

benefit, it must show an acceptable risk-benefit ratio.

Amendment 47

Proposal for a regulation Article 48 – paragraph 6

Text proposed by the Commission

6. For interventional clinical performance studies, as defined in number (37) of Article 2, and for other clinical performance studies, where the conduct of the study, including specimen collection, involves invasive procedures or other risks for the subjects of the studies, the requirements set out in Articles 49 to 58 and in Annex XIII shall apply, in addition to the obligations laid down in this Article.

Amendment

6. For interventional clinical performance studies, as defined in number (37) of Article 2, and for other clinical performance studies, where the conduct of the study, including specimen collection, involves invasive procedures or other risks for the subjects of the studies, the requirements set out in Articles 49 to 58 and in Annex XIII shall apply, in addition to the obligations laid down in this Article. ***The Commission shall be empowered to adopt delegated acts in accordance with Article 85 concerning the provision of a list with negligible risks, which allows a derogation to be made from the relevant Article.***

Or. en

Justification

Not every risk really justifies the very strict rules for interventional clinical performance studies, e.g. there are procedures of sampling the specimen like sweat sampling which has a risk, for example irritating the skin, but not at all a significant risk. The question what is in this regard neglect able risk needs to be specified.

Amendment 48

Proposal for a regulation Article 49 – paragraph 2 – subparagraph 1

Text proposed by the Commission

2. The sponsor of a clinical performance study shall submit an application to the Member State(s) in which the study is to be conducted accompanied by the

Amendment

2. The sponsor of a clinical performance study shall submit an application to the Member State(s) in which the study is to be conducted accompanied by the

documentation referred to in Annex XIII. Within **six days** after receipt of the application, the Member State concerned shall notify the sponsor whether the clinical performance study falls within the scope of this Regulation and whether the application is complete.

documentation referred to in Annex XIII. Within **14 days** after receipt of the application, the Member State concerned shall notify the sponsor whether the clinical performance study falls within the scope of this Regulation and whether the application is complete.

Or. en

Justification

The proposed time limit in Paragraph 2 does not take into consideration that weekends and public holidays could mean that no time remains for examination of the application by the competent authority, and that for this reason the participation of an ethics committee, which for its part may deem certain documentation as essential, is de facto excluded. Therefore, extensions of the time limits in Para. 2 and in Para. 3 accordingly are required.

Amendment 49

Proposal for a regulation

Article 49 – paragraph 3 – subparagraph 3

Text proposed by the Commission

Where the Member State has not notified the sponsor according to paragraph 2 within **three** days following receipt of the comments or of the completed application, the clinical performance study shall be considered as falling within the scope of this Regulation and the application shall be considered complete.

Amendment

Where the Member State has not notified the sponsor according to paragraph 2 within **seven** days following receipt of the comments or of the completed application, the clinical performance study shall be considered as falling within the scope of this Regulation and the application shall be considered complete.

Or. en

Justification

The proposed time limit in Para. 2 does not take into consideration that weekends and public holidays could mean that no time remains for examination of the application by the competent authority, and that for this reason the participation of an ethics committee, which for its part may deem certain documentation as essential, is de facto excluded. Therefore, extensions of the time limits in Para. 2 and in Para. 3 accordingly are required.

Amendment 50

Proposal for a regulation

Article 49 – paragraph 5 – point c

Text proposed by the Commission

c) after the expiry of **35** days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.

Amendment

c) after the expiry of **60** days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.

Or. en

Justification

The adjustment of the deadline is necessary in order to facilitate an effective assessment of the clinical performance study. Particularly, in the case of clinical performance studies conducted in several Member States, sufficient time must remain for coordinated evaluation in accordance with Article 56. As the draft Regulation does not provide for any special evaluation deadline for multinational clinical performance studies, the general evaluation deadline in this Regulation must be appropriately adjusted.

Amendment 51

Proposal for a regulation

Article 49 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. Member States shall ensure that a clinical performance study is suspended, cancelled or temporarily interrupted if in the light of new facts it would no longer be approved by the competent authority or if it would no longer receive a favourable opinion from the ethics committee.

Or. en

Justification

Article 54 provides for an exchange of information between Member States insofar as one

Member State orders the suspension, cancellation or temporary interruption of a clinical investigation. However, the draft Regulation does not regulate the circumstances under which a Member State is entitled to make such a decision. This can only be the case if new information is available which would stand in the way of an approval.

Amendment 52

Proposal for a regulation

Article 49 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6a. Every step in the clinical performance study, from first consideration of the need and justification for the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, such as those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th World Medical Assembly in Helsinki in 1964 and last amended by the 59th World Medical Association General Assembly in Seoul in 2008.

Or. en

Justification

Wording is moved from the Annex to Article 49. These important considerations should be within the text of the regulation and should not only be mentioned in the annexes.

Amendment 53

Proposal for a regulation

Article 49 – paragraph 6 b (new)

Text proposed by the Commission

Amendment

6b. Approval may only be granted if an independent ethics committee has previously submitted a positive evaluation of the clinical performance study. The statement of the ethics committee shall

cover, in particular, the medical justification for the study, the consent of the test subject following the provision of full information about the performance study and the suitability of the investigators and investigative facilities.

The ethics committee shall serve to protect the rights, safety and well-being of all test subjects, users and third parties. The committee shall be independent of the researcher, the sponsor and any other undue influence. It shall take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards. The ethics committee shall be made up of an appropriate number of members, who together are in possession of the relevant qualifications and experience in order to be able to assess the scientific, medical and ethical aspects of the clinical investigation under scrutiny.

Member States shall take the measures necessary to set up ethics committees and to facilitate their work.

Or. en

Justification

Paragraph 6b (new) Subparagraphs 1 and 2 are linked to the debate on Clinical Trials. The guarantee the protection of the subject, it is necessary to make approval by Member States dependent upon the decision of the competent, independent, interdisciplinary ethics committee. A negative decision by an ethics committee must result in the denial of approval for a clinical performance study. The proposal reflects international protection standards, as set out in the Declaration of Helsinki.

Amendment 54

**Proposal for a regulation
Article 49 a (new)**

Text proposed by the Commission

Amendment

Article 49a

Supervision by Member States

- 1. Member States shall appoint inspectors to supervise compliance with this Regulation and shall ensure that those inspectors are adequately qualified and trained.***
- 2. Inspections shall be conducted under the responsibility of the Member State where the inspection takes place.***
- 3. Where a Member State intends to carry out an inspection with regard to one or several interventional clinical performance studies which are conducted in more than one Member State, it shall notify its intention to the other Member States concerned, the Commission and the Agency, through the Union portal, and shall inform them of its findings after the inspection.***
- 4. The MDCG shall coordinate cooperation on inspections between Member States and on inspections conducted by Member States in third countries.***
- 5. Following an inspection, the Member State under whose responsibility the inspection has been conducted shall draw up an inspection report. That Member State shall make the inspection report available to the sponsor of the relevant clinical trial and shall submit the inspection report through the Union portal to the Union database. When making the inspection report available to the sponsor, the Member State concerned shall ensure that confidentiality is protected.***

6. The Commission shall specify the details for the arrangement of the inspection procedures by means of implementing acts in accordance with Article 85.

Or. en

Justification

In contrast to the proposal of the Commission for a Regulation on clinical trials on medicinal products for human use (COM 2012, 369 final), the proposed Regulation contains no provisions regarding inspections. It must not be left to the discretion of the Member States to decide whether to monitor the conduct of clinical investigations. This could lead to decisions on whether to monitor an investigation being made dependent upon the availability of appropriate budgetary means. This could result in clinical investigations being carried out preferentially in states which dispense with monitoring. The concrete wording of the proposal follows Articles 75 and 76 of the proposal of the Commission for a Regulation on clinical trials on medicinal products for human use (COM 2012, 369 final).

Amendment 55

**Proposal for a regulation
Article 61 – paragraph 2**

Text proposed by the Commission

2. The national competent authorities shall carry out a risk assessment with regard to reported serious incidents or field safety corrective actions, taking into account criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of harm and severity of harm, clinical benefit of the device, intended and potential users, and population affected. They shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action. They shall monitor the manufacturer's investigation of the incident.

Amendment

2. The national competent authorities shall carry out a risk assessment with regard to reported serious incidents or field safety corrective actions, taking into account criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of harm and severity of harm, clinical benefit of the device, intended and potential users, and population affected. They shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action. They shall monitor the manufacturer's investigation of the *serious* incident.

Or. en

Justification

In order to avoid misperception, incident should be referred as serious incidents throughout the whole Article 61 on "Analysis of serious incidents and field safety corrective"

Amendment 56

Proposal for a regulation

Article 90 – paragraph 3 – point a

Text proposed by the Commission

(a) Article 23(2) and (3) and Article 43(4) shall apply from [18 months after date of application referred to in paragraph 2];

Amendment

(a) **Article 23(1)** shall apply from ...*;

*** OJ: please insert the date: 18 months after the entry into force of this Regulation**

Or. en

Justification

The commission proposal includes a very long transition period of 5 years (see explanatory statement). There is an urgent need to improve the system. Article 23 paragraph 1 deals with the setting up of an electronic system by the commission in cooperation with the member states. This should be done as soon as possible. Articles 22.2, 23.3., 23.4 give an even longer period for companies to deal with the electronic system. When the electronic system introduced fast this longer period is not necessary.

Amendment 57

Proposal for a regulation

Article 90 – paragraph 3 – point b a (new)

Text proposed by the Commission

Amendment

(ba) **Article 74 shall apply from ...***);

*** OJ: please insert the date: six months after the entry into force of this Regulation.**

Justification

The commission proposal includes a very long transition period of 5 years (see explanatory statement). There is an urgent need to improve the system. Article 74 deals with the obligation of the member state to designate the competent authority or authorities. This should be done as soon as possible.

Amendment 58**Proposal for a regulation****Article 90 – paragraph 3 – point b b (new)**

Text proposed by the Commission

Amendment

(bb) Articles 75 to 77 shall apply from... *;

**** OJ: please insert the date: 12 months after the entry into force of this Regulation.***

Justification

The commission proposal includes a very long transition period of 5 years. This may be necessary for the elements where SMEs are subject to complete new approaches, for example when they need to do a conformity assessment in the future and did not have to do one under the current directive. There is an urgent need to improve the system. Article 75 -77 deal with the cooperation of the member states and the medical device coordination group. This should be done as soon as possible.

Amendment 59**Proposal for a regulation****Article 90 – paragraph 3 – point b c (new)**

Text proposed by the Commission

Amendment

(bc) Article 59 to 64 shall apply from... * ;

**** OJ: please insert the date: 24 months***

after the entry into force of this Regulation.

Or. en

Justification

The commission proposal includes a very long transition period of 5 years (see explanatory statement). There is an urgent need to improve the system. Articles 59 through 64 concern the Vigilance and market surveillance and should for reasons of patient protection entry into force within as soon as possible.

Amendment 60

Proposal for a regulation

Article 90 – paragraph 3 – point b d (new)

Text proposed by the Commission

Amendment

(bd) Article 78 shall apply from ...*.

**** OJ: please insert the date: 24 months after the entry into force of this Regulation***

Or. en

Justification

The commission proposal includes a very long transition period of 5 years (see explanatory statement). There is an urgent need to improve the system. Articles 78 concern the European Union reference laboratories and should for reasons of patient protection entry into force within 24 months.

Amendment 61

Proposal for a regulation

Article 90 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The implementing acts referred to in Articles 31(4), 40(9), 42(8), 46(2) and Articles 58 and 64 shall be adopted within

...*

*** OJ: please insert the date: 12 months after the entry into force of this Regulation.**

Or. en

Justification

To give the market participants, especially SMEs, enough time to prepare for the new situation the implementing acts should be adopted as soon as possible. This is also necessary to improve the quality of the system as soon as possible which is paramount for public health.

Amendment 62

Proposal for a regulation Annex I – point 16

Text proposed by the Commission

16. Protection against the risks posed by devices intended by the manufacturer for self-testing **or near-patient testing**

16.1 The devices intended for self-testing **or near-patient testing** shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply.

16.2 The devices intended for self-testing **or near-patient testing** shall be designed and manufactured in such a way as to

- ensure that the device is easy to use by the intended user at all stages of the procedure; and
- reduce as far as possible the risk of error by the intended user in the handling of the

Amendment

16. Protection against the risks posed by devices intended by the manufacturer for self-testing

16.1 The devices intended for self-testing shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply.

16.2 The devices intended for self-testing shall be designed and manufactured in such a way as to

- ensure that the device is easy to use by the intended user at all stages of the procedure; and
- reduce as far as possible the risk of error by the intended user in the handling of the

device and, if applicable, the specimen, and also in the interpretation of the results.

16.3 The devices intended for self-testing **and near-patient testing** shall, where reasonably possible, include a procedure by which the intended user can:

- verify that, at the time of use, the device will perform as intended by the manufacturer; and
- be warned if the device has failed to provide a valid result.

device and, if applicable, the specimen, and also in the interpretation of the results.

16.3 The devices intended for self-testing shall, where reasonably possible, include a procedure by which the intended user can:

- verify that, at the time of use, the device will perform as intended by the manufacturer; and
- be warned if the device has failed to provide a valid result.

Or. en

Justification

The Commission equated devices intended for self testing with devices intended for professional use. That is not appropriate because there is no difference between qualified persons and laypersons. The commission text would put unnecessary burden especially for SMEs.

Amendment 63

Proposal for a regulation Annex I – point 17.1 – point (vi)

Text proposed by the Commission

(vi) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, **contraindications**, precautions or warnings in the information supplied by the manufacturer.

Amendment

(vi) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, precautions or warnings in the information supplied by the manufacturer.

Or. en

Justification

There are no contraindications for IVDs, only limitations. An in vitro diagnostic medical device can still be applied but limitations have to be taken into account (e.g. when determining an immune status, it has to be taken into account if there was a recent vaccination, but no matter in which status the IVD test itself can be performed without any risk, the result has to be interpreted with regard to this limitation.).

Amendment 64

Proposal for a regulation

Annex I – point 17.2 – point (xv)

Text proposed by the Commission

Amendment

(xv) If the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;

deleted

Or. en

Justification

Almost every in-vitro diagnostic medical device is for single use which is obvious for all those that use it. It practically does not work if you try to use it a second time. A labelling is superficial and would only confuse patients and other users. See amendment 17.

Amendment 65

Proposal for a regulation

Annex I – point 17.3 – point (ii) – introductory part

Text proposed by the Commission

Amendment

(ii) The device's intended purpose:

(ii) The device's intended purpose ***which may include:***

Or. en

Justification

Listed points are not exhaustive and not always for every product applicable. Harmonized with wording Annex II, 1.1 (c).

Amendment 66

Proposal for a regulation Annex II – point 3.2 – point b

Text proposed by the Commission

(b) identification of all sites, including suppliers and sub-contractors, where manufacturing activities are performed.

Amendment

(b) identification of all sites, including suppliers and sub-contractors, where **critical** manufacturing activities are performed.

Or. en

Justification

Should be harmonized with GHTF-Document “Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices”

Amendment 67

Proposal for a regulation Annex V – Part B – point 13

Text proposed by the Commission

13. labelled as single use device (y/n),

Amendment

deleted

Or. en

Justification

The concept of single use devices is not applicable to IVDs. See amendment 17.

Amendment 68

Proposal for a regulation Annex VII – point 2.3 – point c

Text proposed by the Commission

c) detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or

Amendment

c) detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or

severe disability to the individual or foetus being tested, or to the individual's offspring;

severe disability to the individual, foetus or **embryo** being tested, or to the individual's offspring;

Or. en

Justification

Tests exist not only for foetus but also for embryos which is before the third month. They should be covered by the regulation and they should be treated in class C as the same risks are linked with low quality tests than for foetuses.

Amendment 69

**Proposal for a regulation
Annex VII – point 2.3 – point j**

Text proposed by the Commission

Amendment

(j) screening for congenital disorders in the foetus.

(j) screening for congenital disorders in the foetus **or embryo**.

Or. en

Justification

Tests for prenatal diagnostic and preimplantation genetic testing exist also for embryos, which is before the third month. They should be covered by the regulation and they should be treated in class C as the same risks are linked with low quality tests than for foetuses.

Amendment 70

**Proposal for a regulation
Annex VIII – point 4.4 – subparagraph 1**

Text proposed by the Commission

Amendment

4.4 The notified body shall randomly perform unannounced factory inspections to the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment.

4.4 The notified body shall randomly perform unannounced factory inspections to the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 4.3 or be performed in addition to this surveillance assessment.

The notified body shall establish a plan for the unannounced inspections which shall not be disclosed to the manufacturer.

The notified body shall establish a plan for the unannounced inspections which shall not be disclosed to the manufacturer. ***The notified body shall carry out such inspections at least once every three years.***

Or. en

Justification

The proposal does not specify minimum frequency of unannounced inspections. Unannounced inspections should be undertaken at least once every three years for each manufacturer and each product group, based on the certification cycle.

Amendment 71

**Proposal for a regulation
Annex VIII – point 6.1 – subparagraph 1 – title**

Text proposed by the Commission

Amendment

6.1. Examination of the design of devices for self-testing ***and near-patient testing*** classified as class A, B or C

6.1 Examination of the design of devices for self-testing classified as class A, B or C ***and of devices for near patient testing classified as class C***

Or. en

Justification

There should be a difference regarding the conformity assessment and the risk classes for near patient testing devices. Near patient testing devices classified as class B devices should be treated in Annex VIII in the same way as all other devices. So the classification rules are transferred into the conformity assessment routes and requirements.

Amendment 72

**Proposal for a regulation
Annex VIII – point 6.1 – point a**

Text proposed by the Commission

Amendment

(a) The manufacturer of devices for self-testing ***or near-patient testing*** classified as

(a) The manufacturer of devices for self-testing classified as class A, B and C ***and***

class A, B and C shall lodge with the notified body referred to in Section 3.1 an application for the examination of the design.

of devices for near patient testing classified as class C shall lodge with the notified body referred to in Section 3.1 an application for the examination of the design.

Or. en

Justification

There should be a difference regarding the conformity assessment and the risk classes for near patient testing devices. Near patient testing devices classified as class B devices should be treated in Annex VIII in the same way as all other devices. So the classification rules are transferred into the conformity assessment routes and requirements.

Amendment 73

Proposal for a regulation Annex XII – Part A – point 2.3 a (new)

Text proposed by the Commission

Amendment

2.3a Clinical performance study on incapacitated subjects

In the case of incapacitated subjects who have not given, or who have not refused to give, informed consent before the onset of their incapacity, clinical performance studies may be conducted only where, in addition to the general conditions, all of the following conditions are met:

– the informed consent of the legal representative has been obtained which represents the subject's presumed will and may be revoked at any time, without detriment to the subject;

– the incapacitated subject has received adequate information in relation to that person's capacity for understanding regarding the study and its risks and benefits;

– the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing this information to refuse participation in, or to be withdrawn

from, the clinical performance study at any time is duly taken into consideration by the investigator;

– no incentives or financial inducements are given other than compensation for participation in the clinical performance study;

– such research is essential to validate data obtained in a clinical performance study on persons able to give informed consent or by other research methods;

– such research relates directly to a life-threatening or debilitating medical condition from which the subject suffers;

– the clinical performance study has been designed to minimise pain, discomfort, fear, and any other foreseeable risk in relation to the disease and developmental stage and both the risk threshold and the degree of distress are specially defined and constantly observed;

– there are grounds for expecting that participation in the Clinical performance study will produce a benefit to the incapacitated subject outweighing the risks or will produce no risk at all;

– an ethics committee, with expertise regarding the relevant disease and the patient population concerned, or that has taken advice on clinical, ethical and psychosocial questions in the field of the relevant disease and patient population concerned, has endorsed the protocol;

The test subject shall as far as possible take part in the consent procedure.

Or. en

Justification

Compared to the proposal on clinical trials for medicinal products the provisions on interventional clinical performance studies are very weak and imprecise. Interventional clinical performance studies may include a very significant risk for the patient, for example if the specimen is collected by spinal tap. Therefore the provisions need to be specified. The

proposal seeks to maintain at least the standard of protection which is guaranteed for clinical trials with medicinal products since 2001 through Directive 2001/20 EC.

Amendment 74

Proposal for a regulation Annex XII – point 2.3 b (new)

Text proposed by the Commission

Amendment

2.3 b Clinical performance study on minors

A Clinical performance study on minors may be conducted only where, in addition to the general conditions, all of the following conditions are met:

- the informed consent of the legal representative has been obtained, whereby consent shall represent the minor's presumed will;***
- the minor has received all relevant information in a way adapted to the minor's age and maturity, from a medical doctor (either the investigator or member of the study team) trained or experienced in working with children, regarding the trial, the risks and the benefits;***
- the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to above to refuse participation in, or to be withdrawn from, the clinical performance study at any time, is duly taken into consideration by the investigator;***
- no incentives or financial inducements are given other than compensation for participation in the clinical performance study***
- such research is essential to validate data obtained in clinical performance studies on persons able to give informed consent or by other research methods;***
- such research either relates directly to a medical condition from which the minor***

concerned suffers or is of such a nature that it can only be carried out on minors;

– the clinical performance study has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage, and both the risk threshold and the degree of distress are specially defined and constantly observed;

– some direct benefit for the group of patients is obtained from the clinical performance study;

– the corresponding scientific guidelines of the Agency have been followed;

– an ethics committee, with paediatric expertise or after taking advice in clinical, ethical and psychosocial problems in the field of paediatrics, has endorsed the protocol.

The minor shall take part in the consent procedure in a manner adapted to his or her age and maturity.

Or. en

Justification

Compared to the proposal on clinical trials for medicinal products the provisions on interventional clinical performance studies are very weak and imprecise. Interventional clinical performance studies may include a very significant risk for the patient, for example if the specimen is collected by spinal tap. Therefore the provisions need to be specified. The proposal seeks to maintain at least the standard of protection which is guaranteed for clinical trials with medicinal products since 2001 through Directive 2001/20 EC.

EXPLANATORY STATEMENT

- **What are IVD medical devices?**

IVD medical devices are medical devices intended for diagnostic use outside the human body (in vitro) which may be in a laboratory or near the patient, for example at the bedside. It covers a huge variety of tests such as a self test for **blood sugar measuring, HIV tests and DNA tests.**

- **Why is it important to improve the regulation of IVD medical devices?**

Many people consider the IVD medical devices regulation as the "small sister" of the Medical Devices Regulation. In the Hearing we held on 26th February one of the experts, Mrs Sine Jensen from the Danish Consumer Council said that the IVD medical devices are not the "small sister" but the "parents" of the Medical Devices and maybe the parents of all therapies, including pharmaceutical products and surgery. Without a proper diagnostic there is no proper treatment or prevention of diseases. **Unfortunately the current directive does not assure that low quality IVD medical devices are not placed on the market.** In the past there have been cases where a low quality HIV test was placed on the European market with a CE-label. A scientific institute determined already before the notified bodies approved the CE-label **that these tests announced much more false negative results than other HIV tests available which means that the tests said there is no virus but in fact there is.** However, **this product was available for years for patients in the EU.** If a blood transfusion is performed on the basis of a false negative result on HIV, this is a life-threatening risk for the recipient of the blood transfusion. Also persons infected with HIV that receive a false negative test may put their partners at risk. In a way bad performing HIV tests are more threatening for people's health than low quality breast implants or hip implants. Similar cases have been reported with hepatitis C which is still a life threatening disease and cannot be treated properly. It has been reported that an expert for DNA-Tests has sent the same sample to four different laboratories and received four different results.

Examples for low-quality IVD medical devices under the current regulation:

- **HIV tests**
- **Hepatitis C tests**
- **DNA tests**

- **Why needs the EU to regulate these issues?**

IVD medical devices are products that can circulate free in the common market. **There are no national borders for these products** in the European market. That is why it is an **obligation for the European Union to ensure the highest possible safety.** The proposal is based on article 114 and 168 of the Treaty. Article 114 asks for high protection of human health. Article 168, paragraph 4c gives even a specific additional legal base.

- **Major improvements to address the current shortcomings**

The Commission includes major improvements to address the current shortcomings of the system for IVD Medical Devices similar to those for other medical devices. The **notified bodies** will be substantially improved and the **supervision** of the member states to the notified bodies will be **strengthened**. Very important is that the system of **market surveillance and vigilance** will be strengthened. **Unannounced inspections of the companies will be mandatory**. Moreover, the Commission proposes to introduce **a network of European reference laboratories** which have an important role in the control of high-risk medical devices. The rapporteur very much welcomes these proposals which will in his view improve the safety for patients dramatically.

- **Common issues of the proposal for a regulation on medical devices and in vitro medical devices**

There are many issues where the European Commission proposes to regulate IVD medical devices in the same way as other medical devices. A big part of the commissions' proposal is therefore identical. These parts must be assessed together by the two rapporteurs and the respective shadow rapporteurs. This covers for example the role, the structure and the necessary improvement of the notified bodies, the surveillance system, the joint assessment, the scrutiny, identification and traceability and the role of the Medical Device Coordination Group or MDCG.

Your rapporteur thinks that the fundamental structure of the Commission proposal is appropriate. He will not propose a system of pre-market approval by a state authority but proposes to continue working on the improvement of the system of the notified bodies. Of course your rapporteur is open for discussions and improvements of the text.

- **Clinical performance studies**

The proposal contains a chapter on clinical performance studies. This is **related to the proposed regulation on clinical trials and to the proposal on medical devices**. The proposal on clinical trials is subject to much criticism and many amendments have been tabled in the ENVI committee. The respective part of the IVD regulation needs to be adopted to address the concerns raised in the debate on the clinical trials regulation.

Especially **when a clinical performance study is linked to a significant risk for the subjects, for example when the specimen collection is done by spinal tap, best possible protection needs to be established.**

The rapporteur introduces three main improvements of the commission's proposal which are also tabled by many colleagues in the clinical trials regulation proposal process:

1. The clinical performance study should be positively assessed by an independent **ethics committee** before it starts.
2. The **protection of minors** and other persons not able to give informed consent should be specified in the same way as in the directive of clinical trials in 2001

3. The **timelines** should be moderately extended to give the ethic committee and the authorities the necessary time to assess the proposal.

Make the proposal acceptable for SMEs

In the area of in vitro diagnostic medical devices **many companies offering these devices are SMEs**. That is why the regulation needs to take into account the capacity of SMEs to cover the burden. Of course this should not compromise health and safety.

Amendments are tabled to take into account capacity and needs of SMEs. For example it should be possible to provide some requested information electronically and it needs to be specified; that the information accompanied the product shall be provided in an official union language and not in any other language. Both changes reduce the potential burden for SMEs. Translation of declarations of conformity into all official Union languages where the device is made available is a disproportionate administrative and thus cost-intensive effort, which is not justified. Like at present, availability in one Union language should be sufficient.

Classification

A completely new classification system (A-D) is proposed (A=low risk device - D=high risk device). Most stakeholders think it is appropriate and it is based on international consensus. The rapporteur supports this proposal.

In-house testing

In the current directive all in-house testing, which means tests performed in a single health care institution, for example in a hospital, is exempted from the requirements. The commission proposed to keep this in principle for the risk classes A, B, C but to include them fully when tests are in class D. This needs to be **slightly adapted with respect to the needs of doctors and patients in a single health care institution** without dramatically changing the concept of the European commission.

Companion diagnostics

Companion Diagnostics are DNA tests that give information if a specific therapy would most lightly work in a specific patient. The **huge opportunity of personalized and stratified medicine** needs to be addressed properly by the regulation. The commission proposal is a good base but needs to be further clarified. The rapporteur proposed to clarify that companion diagnostics are not subject to any in house derogation.

Self testing and near patient testing

Tests that are not performed by medical professionals but by patients need to be regulated even more carefully because medical professionals may include other elements of their diagnosis while laypersons may depend their decision only on the test. It is **subject to criticism that the commission regulates self testing and near patient testing by medical professionals in the same way**. This needs to be changed.

Scope

The scope needs to be further clarified. Under the commission proposal so called **nutrigenetic tests and lifestyle tests are not covered. But these tests may have at least indirectly very severe consequences to people's health.** If for example a test claims to help a patient to lose weight and the patient desperately needs to lose weight for health reasons, it is a severe health threat if the test is not really of high quality and does not deliver the results he claims.

Transition period

The Commission has proposed a very long transition period, **five years after adoption.** This may be **necessary** for parts of the regulation because it includes many complete new elements which are not easy to implement, **especially for SMEs.** On the other hand there is an **urgent need to improve the system and some elements of the proposal should be introduced much faster.** This applies definitely for those parts that only address the Commission and the member states. They are much better prepared to implement the regulation than for example SMEs.

Technical amendments

A significant number of technical amendments are necessary to reflect the concerns of people involved in the sector. In some cases the wish to have the same wording as in the MDD regulation leads to inappropriate wording for IVDs.

Non-discrimination for people with a handicap

The European Union has ratified the **UN Convention on non-discrimination on handicapped people.** This should be reflected in the text. For example in the definition the wording "congenital abnormality" may be seen as a discrimination of handicapped people and should be changed.

Delegated Act vs. Co-decision

The Commission foresees to amend many elements of the proposal in delegated acts. This applies also to essential parts of the regulation, for example

- the general safety and performance requirements,
- the elements to be addressed in the technical documentation,
- the EU declaration of conformity,
- amending or supplementing the conformity assessment procedures.

These essential parts should be the only amended in co-decision.

Informed consent

The Commission proposal focuses very much on the quality of the product. Experts and many international organisations, like the Council of Europe, OECD and the European Society for Human Genetics have again and again articulated their position that in many case **even more important than the quality of the product is the framework in which the product is**

applied. Especially in DNA testing it is very important to respect the principle of informed consent. This has also been asked for by the European Parliament several times. A **legal opinion** concludes that it is possible and appropriate to introduce respective wording in the proposal.¹ Therefore the rapporteur proposes amendments on this issue. There is consensus that it should not be the intention of the European Union to limit the access of patients to DNA tests but **appropriate genetic counselling should be offered in any case to inform about the consequences before a test is performed.** To respect the principle of subsidiarity it should be left to the Member States to regulate the details and member states should have the option to go further than the regulation requires. One can even argue that it is mandatory to include **informed consent** in the proposal because **it is a crucial element of the Charter of Fundamental Rights (Article 3)** and the Charter of Fundamental Rights is legally binding for the European Union in those areas where it acts.

¹ Centrum für Europarecht an der Universität Passau: "Options for Action of the European Union in the Area of Human Genetics and Reproductive Medicine in the Light of the Proposal for a Regulation on In Vitro Diagnostic Medical Devices"