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from: General Secretariat
to: Permanent Representatives Committee/Council
Subject: Proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009
- Outcome of the European Parliament's first reading
(Strasbourg, 21 to 24 October 2013)

I. INTRODUCTION

The Rapporteur, Mrs Dagmar ROTH-BEHRENDT (S&D - DE), presented a report consisting of 348 amendments (amendments 1-348) on behalf of the Committee on the Environment, Public Health and Food Safety. In addition:

- the ECR political group tabled five amendments (amendments 349-353);
- the Greens/EFA political group tabled three amendments (amendments 354-356);
- the ALDE political group tabled ten amendments (amendments 357-366); and
- the EPP political group tabled nine amendments (amendments 367-379).

II. DEBATE

The debate, which took place on 22 October 2013, was a joint debate, which is summarised in document 14936/13.

III. VOTE

When it voted on 22 October 2013, the Parliament voted to adopt 260 amendments to the Commission's proposal (amendments 1-20, 22-39, 41-71, 73-188, 191-204, 206-224, 226-233, 235-254 and 259-272), but then postponed the vote on the legislative resolution to a later session - thereby not bringing the Parliament's first reading to a close. The proposal was instead referred back to the Committee on the Environment, Public Health and Food Safety, pursuant to Rule 57(2) of the European Parliament's Rules of Procedure.

The adopted amendments are set out in the Annex.

Medical devices ***I

Amendments adopted by the European Parliament on 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (COM(2012)0542 – C7-0318/2012 – 2012/0266(COD))¹

(Ordinary legislative procedure: first reading)

Amendment 1

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission

Amendment

(1a) The desire to provide swift access to new medical devices for patients should never take precedence over the need to ensure patient safety.

Amendment 2

Proposal for a regulation
Recital 2

Text proposed by the Commission

Amendment

(2) This Regulation aims to ensure the functioning of the internal market as regards medical devices, taking as a base a high level of protection of health. At the same time, this Regulation sets high standards of quality and safety for medical devices to meet common safety concerns as regards these products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article

(2) This Regulation aims to ensure the functioning of the internal market as regards medical devices, taking as a base a high level of protection of health **for patients, users and operators**. At the same time, this Regulation sets high standards of quality and safety for medical devices to meet common safety concerns as regards these products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being

¹ The matter was referred back to the committee responsible for reconsideration pursuant to Rule 57(2), second subparagraph (A7-0324/2013).

114 TFEU, this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market which may then benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for those medical devices by ensuring, among other things, that data generated in clinical investigations is reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.

secondary to the other. As regards Article 114 TFEU, this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market which may then benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for those medical devices by ensuring, among other things, that data generated in clinical investigations is reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.

Amendment 3

Proposal for a regulation

Recital 2 a (new) – sentence 1 (new)

Text proposed by the Commission

Amendment

(2a) Council Directive 2010/32/EU¹ guarantees safety not just for patients but also for users of sharp needles.

¹ ***Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU (OJ L 134, 1.6.2010, p. 66).***

Amendment 4

Proposal for a regulation

Recital 2 a (new) – sentence 2 (new)

Text proposed by the Commission

Amendment

Directive 2010/63/EU of the European Parliament and of the Council¹ states that tests on vertebrate animals must be replaced, restricted or refined.

¹ ***Directive 2010/63/EU of the European Parliament and of the Council of 22***

Amendment 5

Proposal for a regulation

Recital 3

Text proposed by the Commission

(3) Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding devices should be introduced, to improve health and safety.

Amendment

(3) Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding devices should be introduced, to improve health and safety *for health professionals, patients, users and operators, including in the waste disposal chain.*

Amendment 6

Proposal for a regulation

Recital 3 a (new)

Text proposed by the Commission

Amendment

(3a) In the area of medical devices many SMEs are active. This should be taken into account when regulating the sector without compromising the safety and health aspects.

Amendment 7

Proposal for a regulation

Recital 7

Text proposed by the Commission

(7) The scope of application of this Regulation should be clearly delimited from other Union harmonisation legislation concerning products, such as in vitro

Amendment

(7) The scope of application of this Regulation should be clearly delimited from other Union harmonisation legislation concerning products, such as in vitro

diagnostic medical devices, medicinal products, cosmetics and food. **Therefore**, Regulation (EC) No 178/2002 **of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety** should be amended **to exclude medical devices from its scope**.

diagnostic medical devices, medicinal products, cosmetics and food. **Since in some cases it is difficult to distinguish between medical devices and cosmetic, medicinal or food products, the possibility to take an Union-wide decision regarding the regulatory status of a product should be introduced in Regulation (EC) No 1223/2009 of the European Parliament and of the Council¹, Directive 2004/27/EC of the European Parliament and of the Council², Regulation (EC) No 178/2002 of the European Parliament and of the Council³ and Directive 2002/46/EC of the European Parliament and of the Council⁴. Those Union acts should therefore be amended.**

¹ **Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 342, 22.12.2009, p. 59).**

² **Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.4.2004, p. 34).**

³ **Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).**

⁴ **Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).**

Amendment 8

Proposal for a regulation Recital 7 a (new)

Text proposed by the Commission

Amendment

(7a) A multidisciplinary Medical Device Advisory Committee (MDAC) composed of experts and representatives of the relevant stakeholders should be set up to provide scientific advice to the Commission, the Medical Device Coordination Group (MDCG) and Member States on issues of medical technology, regulatory status of devices and other aspects of implementation of this Regulation as necessary.

Amendment 9

Proposal for a regulation Recital 8

Text proposed by the Commission

Amendment

(8) It should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. If necessary, the Commission may decide, on a case-by-case basis, whether or not a product falls within the definition of a medical device or of an accessory to a medical device. Since in some cases it is difficult to distinguish between medical devices and cosmetic products, the possibility to take an EU-wide decision regarding the regulatory status of a product should also be introduced in Regulation No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

(8) In order to ensure consistent classification across all Member States, particularly with regards to borderline cases, it should be the responsibility of the Commission, having consulted the MDCG and the MDAC, to decide on a case-by-case basis whether or not a product or groups of products fall within the scope of this Regulation. Member States should also have the possibility to request the Commission to take a decision on the appropriate regulatory status of a product, or category or group of products.

Amendment 10

Proposal for a regulation Recital 11 a (new)

(11a) Unregulated non-intrusive devices, such as non-corrective contact lenses for cosmetic purposes, can cause health complications - such as Microbial Keratitis - when manufactured or used incorrectly. Appropriate safety standards must be in place to protect the safety of consumers who decide to use such products.

Amendment 11

Proposal for a regulation

Recital 12

Text proposed by the Commission

(12) Like for products that contain viable tissues or cells of human or animal origin, that are explicitly excluded from Directives 90/385/EEC and 93/42/EEC and hence from this Regulation, it should be clarified that products that contain living biological substances of other origin are also not covered by this Regulation.

Amendment

(12) Like for products that contain viable tissues or cells of human or animal origin, that are explicitly excluded from Directives 90/385/EEC and 93/42/EEC and hence from this Regulation, it should be clarified that products that contain living biological substances of other origin ***that achieve their intended purpose by pharmacological, immunological or metabolic means*** are also not covered by this Regulation.

Amendment 12

Proposal for a regulation

Recital 12 a (new)

Text proposed by the Commission

Amendment

(12a) Devices for use in blood donation and blood therapy should meet the requirements laid down in Directive 2002/98/EC of the European Parliament and of the Council¹.

¹ ***Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality***

and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).

Amendment 13

Proposal for a regulation

Recital 12 b (new)

Text proposed by the Commission

Amendment

(12b) The advertising of cosmetic surgery should be better regulated, in order to ensure that patients are fully aware of the risks as well as the benefits.

Amendment 14

Proposal for a regulation

Recital 13

Text proposed by the Commission

Amendment

(13) There is scientific uncertainty about the risks and benefits of nanomaterials used for medical devices. In order to ensure a high level of health protection, free movement of goods *and* legal certainty for manufacturers, it is necessary to introduce a uniform definition for nanomaterials based on Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial, with the necessary flexibility to adapt this definition to scientific and technical progress and subsequent regulatory development at Union and international level. In the design and manufacture of medical devices, the manufacturers should take special care when using nanoparticles *that can be released to* the human body *and those devices* should be subject to the most severe conformity assessment procedure.

(13) There is scientific uncertainty about the risks and benefits of nanomaterials used for medical devices. In order to ensure a high level of health *and safety* protection *for health professionals, operators and patients, as well as* free movement of goods, legal certainty for manufacturers *and responsibility on their part*, it is necessary to introduce a uniform definition for nanomaterials based on Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial, with the necessary flexibility to adapt this definition to scientific and technical progress and subsequent regulatory development at Union and international level. In the design and manufacture of medical devices, the manufacturers should take special care when using nanoparticles *which are intended to be intentionally* released *in* the human body should be subject to the most severe conformity assessment procedure.

Amendment 15

Proposal for a regulation Recital 13 a (new)

Text proposed by the Commission

Amendment

(13a) Medical devices used in the donation of substances of human origin and their subsequent use for treatment must conform to Union public health legislation ensuring minimum standards for quality and safety, including Directive 2002/98/EC on minimum standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and its additional directives.

Amendment 16

Proposal for a regulation Recital 15 a (new)

Text proposed by the Commission

Amendment

(15a) This Regulation includes requirements regarding the design, safety and performance characteristics of medical devices intended to prevent occupational injuries as laid down in Directive 2010/32/EU.

Amendment 17

Proposal for a regulation Recital 19

Text proposed by the Commission

Amendment

(19) To recognise the important role of standardisation in the field of medical devices, compliance with harmonised standards as defined in Regulation (EU) No [.../...] on European standardisation should be a means for manufacturers to

(19) To recognise the important role of standardisation **and traceability** in the field of medical devices, compliance with harmonised standards as defined in Regulation (EU) No **1025/2012 of the European Parliament and of the Council**¹

demonstrate conformity with the general safety and performance requirements and other legal requirements, such as quality and risk management.

should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as quality and risk management.

¹ *Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).*

Amendment 18

Proposal for a regulation Recital 19 a (new)

Text proposed by the Commission

Amendment

(19a) With devices that consist of more than one implantable part, such as hip implants, compatibility of the parts of different manufacturers should be ensured in order to avoid the replacement of the functional part of the device and thus unnecessary risks and inconvenience for patients. The Commission should investigate the need for further measures to ensure the compatibility of the equivalent parts of hip implants from different manufacturers, bearing in mind that the hip operations are most often made on older people for whom the health risks of operations are higher.

Amendment 19

Proposal for a regulation Recital 21 a (new)

(21a) Directive 2013/35/EU of the European Parliament and of the Council¹ should be the reference text for ensuring that people working in the vicinity of magnetic resonance imaging equipment when it is functioning are properly protected.

¹ ***Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC (OJ L 179, 29.6.2013, p. 1).***

Amendment 20

Proposal for a regulation

Recital 24

Text proposed by the Commission

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

Amendment

(24) It is appropriate to set out clearly the general obligations of the different economic operators, including importers and distributors as laid down in the New Legislative Framework for the Marketing of Products, without prejudice to the specific obligations laid down in the different parts of this Regulation, to enhance understanding of the legal requirements and thus to improve regulatory compliance by the relevant operators. ***Conditions enabling small and medium-sized enterprises with smart specialisation to have easier access to that market should be established.***

Amendment 21

Proposal for a regulation

Recital 25 a (new)

Text proposed by the Commission

Amendment

(25a) To ensure that patients harmed are compensated for any damage and associated treatment as a result of a faulty medical device, that the risk of damage as well as the risk of the manufacturer's insolvency are not shifted to patients harmed by a faulty medical device, manufacturers should be obliged to take liability insurance with sufficient minimum coverage.

Amendment 22

Proposal for a regulation

Recital 27

Text proposed by the Commission

Amendment

(27) It should be ensured that supervision and control of the manufacture of medical devices is carried out within the manufacturer's organisation by a person who fulfils minimum conditions of qualification.

(27) It should be ensured that supervision and control of the manufacture of medical devices is carried out within the manufacturer's organisation by a person who fulfils minimum conditions of qualification. ***In addition to regulatory compliance, that person could also be responsible for compliance in other fields such as manufacturing processes and quality assessment. The required qualifications of the person responsible for the regulatory compliance should be without prejudice to national provisions regarding professional qualifications, in particular for manufacturers of custom-made devices where such requirements could be met through different educational and professional training systems at national level.***

Amendment 24

Proposal for a regulation

Recital 31 a (new)

Text proposed by the Commission

Amendment

(31a) The current possibility to reprocess medical devices labelled as single-use is not acceptable from a safety point of view. Only devices labelled as reusable should therefore be reprocessed. Consequently, medical devices labelled as single-use should be real single-use and there should be only two possibilities: single-use or reusable. In order to avoid any systematic labelling of devices as single-use, all devices should be reusable as a rule, except if they are included in a list established by the Commission, after consultation of the MDAC, of categories and groups of medical devices which are unsuitable for reprocessing. The reprocessing of devices encompasses various activities to ensure that a medical device can be safely reused, ranging from decontamination, sterilisation, cleaning, disassembly, repair, component replacement and packaging. These activities should be subject to comparable and transparent standards.

Amendment 25

Proposal for a regulation

Recital 32

Text proposed by the Commission

Amendment

(32) Patients who are implanted with a device should be given essential information related to the implanted device allowing it to be identified and containing any necessary warnings or precautions to be taken, for example indications as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls.

(32) Patients who are implanted with a device should be given ***clear and easily accessible*** essential information related to the implanted device allowing it to be identified and containing ***information about the principal characteristics of the device, and*** any necessary ***health risk*** warnings or precautions to be taken, for example indications as to whether or not it is compatible with certain diagnostic devices or with scanners used for security

controls.

Amendment 26

Proposal for a regulation Recital 33

Text proposed by the Commission

(33) 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.

Amendment

(33) 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. ***However Member States should be allowed to decide whether to restrict the use of any specific type of medical device in relation to aspects that are not covered by this Regulation.***

Amendment 27

Proposal for a regulation Recital 34

Text proposed by the Commission

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

Amendment

(34) The traceability of medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve purchase-policy and stock-management by hospitals, ***wholesalers and pharmacists and be compatible with the safety features as referred to in Directive 2011/62/EU of the European Parliament and of the Council¹ and other authentication systems already***

in place in those settings.

¹ *Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ L 174, 1.7.2011, p. 74).*

Amendment 28

Proposal for a regulation Recital 35

Text proposed by the Commission

(35) Transparency and *better* information are essential to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

Amendment

(35) Transparency and *adequate access to* information, *appropriately presented for the intended user*, are essential to empower patients, *users* and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

Amendment 29

Proposal for a regulation Recital 36

Text proposed by the Commission

(36) One key aspect is the creation of a central database that should integrate different electronic systems, with the UDI as an integral part of it, to collate and process information regarding medical devices on the market and the relevant economic operators, certificates, clinical investigations, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States

Amendment

(36) One key aspect is the creation of a central database that should integrate different electronic systems, with the UDI as an integral part of it, to collate and process information regarding medical devices on the market and the relevant economic operators, certificates, clinical investigations, vigilance and market surveillance. The objectives of the database are to enhance overall transparency *through better access to information for the public and healthcare professionals*, to streamline and facilitate the flow of information between economic operators,

among themselves and with the Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) set up by Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices.

notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) set up by Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices.

Amendment 30

Proposal for a regulation

Recital 37

Text proposed by the Commission

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

Amendment

(37) Eudamed's electronic systems should enable the public and healthcare professionals to be adequately informed about devices on the Union market. ***Adequate levels of access for the public and healthcare professionals to those parts of Eudamed's electronic systems which provide key information on medical devices that may pose a risk to public health and safety is essential. Where such access is limited, it should be possible, upon a reasoned request, to disclose the existing information on medical devices, unless the limitation of access is justified on grounds of confidentiality.*** The electronic system on clinical investigations should serve as tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and, in this case, to report serious adverse events. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of their assessment by national competent authorities. The electronic system regarding market

surveillance should be a tool for the exchange of information between competent authorities. ***A regular overview of vigilance and market surveillance information should be made available to healthcare professionals and the public.***

Amendment 31

Proposal for a regulation

Recital 39

Text proposed by the Commission

(39) For high-risk medical devices, manufacturers should ***summarise the main*** safety and performance aspects of the device and the outcome of the clinical evaluation ***in a document that*** should be publicly available.

Amendment

(39) For high-risk medical devices, ***in the interests of increased transparency,*** manufacturers should ***draw up a report of the*** safety and performance aspects of the device and the outcome of the clinical evaluation. ***A summary of the safety and performance report*** should be publicly available ***via Eudamed.***

Amendment 32

Proposal for a regulation

Recital 39a (new)

Text proposed by the Commission

Amendment

(39a) According to the policy of the European Medicines Agency (EMA) on access to documents, the EMA releases documents submitted as part of applications for marketing authorisation for medicinal products, including clinical trial reports, on request once the decision-making process for the medicinal product in question has been completed. Corresponding standards on transparency and access to documents should be upheld and reinforced for high-risk medical devices, in particular as they are not subject to pre-market approval. For the purposes of this Regulation, in general the data included in clinical investigations should not be considered commercially sensitive once compliance of a device with the applicable requirements has been

demonstrated following the applicable conformity assessment procedure. This should be without prejudice to intellectual property rights concerning the data in clinical investigations by the manufacturer with regard to the use of these data by other manufacturers.

Amendment 33

Proposal for a regulation Recital 39 b (new)

Text proposed by the Commission

Amendment

(39b) As regards invasive devices with a diagnostic and measuring function, Member States should take all necessary measures to prevent the risk of infection and microbial contamination between patients. To this end, the Member States should eliminate the known or foreseeable risks to patient safety by advocating inter alia the safest levels of and guidelines for disinfection and ensure their effective implementation by users and health establishments. In accordance with this Regulation, the Commission should ensure that these preventive health protection measures are appropriate.

Amendment 34

Proposal for a regulation Recital 40

Text proposed by the Commission

Amendment

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

(40) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection **for health professionals, users and operators, including in the waste disposal chain,** and **for ensuring** citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, **and where applicable by the EMA,** in accordance with detailed and strict criteria, should therefore be subject to controls at

Amendment 35

Proposal for a regulation Recital 42

Text proposed by the Commission

Amendment

(42) For high risk medical devices, authorities should be informed at an early stage about devices which are subject to conformity assessment and be given the right, on scientifically valid grounds, to scrutinise the preliminary assessment conducted by notified bodies, in particular regarding novel devices, devices for which a novel technology is being used, devices belonging to a category of devices with increased serious incident rates, or devices for which significant discrepancies in the conformity assessments by different notified bodies have been identified in respect of substantially similar devices. The process foreseen in this Regulation does not prevent a manufacturer from informing voluntarily a competent authority of his intention to file an application for conformity assessment for a high risk medical device before submitting the application to the notified body.

deleted

Amendments 363 and 370

Proposal for a regulation Recital 42 a (new)

Text proposed by the Commission

Amendment

(42a) For high-risk medical devices, such as devices in class III, implantable devices and devices intended to administer medicinal products when failure or malfunctioning of these devices would have a major impact on health and safety, the conformity assessment should be the responsibility of special notified bodies. Those special notified bodies should be

designated by the EMA on the basis of the reinforced requirements on staff qualification and training as referred to in Section 3.5a of Annex VI. These special notified bodies should meet in a Network in order in particular to exchange good practice and ensure convergence in their work. The Assessment Committee for Medical Devices (ACMD) shall provide an opinion on the robustness of the clinical data by way on an assessment in specific cases. The need for such additional assessment should decrease once the new rules have been fully implemented and applied in particular to all notified bodies and as common technical standards are developed. The Commission should therefore review the functioning of and the experience with the additional assessment procedure after five years with a view to assessing whether it can be further restricted.

Amendment 379

Proposal for a regulation Recital 42 b (new)

Text proposed by the Commission

Amendment

(42b) As this Regulation now combines active implantable medical devices covered by Directive 90/385/EEC, and implantable medical devices covered by Directive 93/42/EEC, and places all active implantable medical devices and implantable devices of public health concern in the highest risk class III category attracting the strictest controls, and as the vast majority of class IIb implantable medical devices such as pins, bone-screws, plates, staples etc., have a long history of safe implantation within the human body, and as special notified bodies will be specifically designated for such class IIb implantable devices, class IIb implantable devices need not be subjected to the scrutiny procedure.

Amendment 364

Proposal for a regulation

Recital 42 c (new)

Text proposed by the Commission

Amendment

(42c) The ACMD should be composed of clinical experts in the medical fields relevant to the medical device being assessed, one representative of the EMA and one representative of patients' organisations. The ACMD should meet on request from the MDCG or the Commission and its meetings should be chaired by a Commission representative. The Commission should provide logistic support to the secretariat and operations of the ACMD.

Amendment 38

Proposal for a regulation

Recital 45

Text proposed by the Commission

Amendment

(45) The conformity assessment procedures should be ***simplified*** and streamlined whilst the requirements for notified bodies as regards the performance of their assessments should be clearly specified to ensure a level playing field.

(45) The conformity assessment procedures should be ***strengthened*** and streamlined whilst the requirements for notified bodies as regards the performance of their assessments should be clearly specified to ensure a level playing field.

Amendment 39

Proposal for a regulation

Recital 47

Text proposed by the Commission

Amendment

(47) The rules on clinical investigations should be in line with major international guidance in this field, such as the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for

(47) The rules on clinical investigations should be in line with major international guidance in this field, such as the international standard ISO 14155:2011 ***or any subsequent version of it*** on good clinical practice for clinical investigations

human subjects and the most recent (2008) version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects to ensure that clinical investigations conducted in the Union are accepted elsewhere and that clinical investigations conducted outside the Union in accordance with international guidelines can be accepted under this Regulation.

of medical devices for human subjects and the most recent version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects to ensure that clinical investigations conducted in the Union are accepted elsewhere and that clinical investigations conducted outside the Union in accordance with international guidelines can be accepted under this Regulation.

Amendment 40

Proposal for a regulation Recital 47 a (new)

Text proposed by the Commission

Amendment

(47a) The Declaration of Helsinki of the World Medical Association¹ states in Article 15 that "the research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins". Clinical investigations involving risk for the subject should only be allowed after assessment and approval by an ethics committee. The reporting Member State and the other concerned Member States need to organise themselves in a way that the competent authority concerned receives approval by an ethics committee on the clinical performance study protocol.

¹ WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and lastly amended by the 59th WMA General Assembly, Seoul, Korea, October 2008

[http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=\[page\]/\[toPage\]](http://www.wma.net/en/30publications/10policies/b3/index.html.pdf?print-media-type&footer-right=[page]/[toPage])

Amendment 41

Proposal for a regulation Recital 48 a (new)

Text proposed by the Commission

Amendment

(48a) For the sake of transparency, sponsors should submit the results of a clinical investigation together with a layperson summary within the deadlines specified by the regulation. The Commission should be empowered to adopt delegated acts on the preparation of the layperson's summary and the communication of the clinical investigation report. The Commission should provide guidelines for managing and facilitating the sharing of raw data from all clinical investigations.

Amendment 43

Proposal for a regulation Recital 50

Text proposed by the Commission

Amendment

(50) Sponsors should report ***certain*** adverse events occurring during clinical investigations to the Member States concerned, which ***should*** have the possibility to terminate or suspend the investigations if considered necessary to ensure a high level of protection of the subjects enrolled in a clinical investigation. Such information ***should*** be communicated to the other Member States.

(50) Sponsors should report adverse events occurring during clinical investigations to the Member States concerned, which ***shall*** have the possibility to terminate or suspend the investigations if considered necessary to ensure a high level of protection of the subjects enrolled in a clinical investigation. Such information ***shall*** be communicated to the other Member States, ***the MDCG and the Commission.***

Amendment 44

Proposal for a regulation Recital 51 a (new)

Text proposed by the Commission

Amendment

(51a) 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 Council¹.

¹ *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 use (OJ L 121, 1.5.2001, p. 34).*

Amendment 45

Proposal for a regulation Recital 52

Text proposed by the Commission

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

Amendment

(52) In order to better protect *the* health and safety *of health professionals, patients, users and operators, including in the waste disposal chain*, regarding devices on the market, the vigilance system for medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.

Amendment 46

Proposal for a regulation Recital 53

Text proposed by the Commission

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

Amendment

(53) *Member States should take all necessary measures to raise awareness among healthcare professionals, users and patients about the importance of reporting incidents.* Healthcare professionals, *users* and patients should be empowered *and enabled* to report such incidents at national level using harmonised formats *and guaranteeing anonymity, where appropriate. In order to*

minimise the recurrence of such incidents, the national competent authorities should inform manufacturers, *and, if appropriate, their subsidiaries and sub-contractors,* and *report* the information *via the respective electronic system in Eudamed* when they confirm that an incident has occurred.

Amendment 47

Proposal for a regulation

Recital 54

Text proposed by the Commission

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

Amendment

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

Amendment 48

Proposal for a regulation

Recital 54 a (new)

Text proposed by the Commission

Amendment

(54a) Manufacturers should report periodically on medical devices classified as class III as regards the data relevant to the risk benefit ratio and the exposition of the population in order to evaluate whether any action concerning the medical device concerned is necessary.

Amendment 49

Proposal for a regulation

Recital 56

Text proposed by the Commission

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

Amendment

(56) Rules on market surveillance should be included in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures. ***The Commission should clearly define the way these inspections should be conducted in order to ensure a full and harmonised implementation within the Union.***

Amendment 50

Proposal for a regulation

Recital 57

Text proposed by the Commission

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

Amendment

(57) The Member States ***should*** levy fees for the designation and monitoring of notified bodies to ensure sustainability of the monitoring of those bodies by Member States and to establish a level playing field for notified bodies. ***These fees should be comparable across Member States and should be made public.***

Amendment 51

Proposal for a regulation

Recital 57 a (new)

Text proposed by the Commission

Amendment

(57a) Member States are invited to set and enforce serious penalties for manufacturers that commit fraud and cheat with regard to medical devices. Those penalties should be at least as large as the revenue gains from fraud or cheating. Penalties may include imprisonment.

Amendment 52

Proposal for a regulation

Recital 58

Text proposed by the Commission

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

Amendment

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

Amendment 53

Proposal for a regulation

Recital 58 a (new)

Text proposed by the Commission

Amendment

(58a) Member States should adopt provisions on standard fees for notified bodies, which should be comparable across Member States. The Commission should provide guidelines to facilitate the comparability of those fees. Member States should transmit their list of standard fees to the Commission and ensure that the notified bodies registered on their territory make the lists of standard fees for their conformity assessment activities publicly available.

Amendment 54

Proposal for a regulation

Recital 59

Text proposed by the Commission

(59) ***An expert committee, the Medical Device Coordination Group (MDCG)***, composed of persons designated by the Member States based on their role and expertise in the field of medical devices and in vitro diagnostic medical devices should be established to fulfil the tasks

Amendment

(59) A MDCG, composed of persons designated by the Member States based on their role and expertise in the field of medical devices and in vitro diagnostic medical devices should be established to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) [.../...]

conferred on it by this Regulation and by Regulation (EU) [.../...] on in vitro diagnostic medical devices, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation.

on in vitro diagnostic medical devices, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation.

Amendment 55

Proposal for a regulation

Recital 61

Text proposed by the Commission

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

Amendment

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

Amendment 56

Proposal for a regulation

Recital 63

Text proposed by the Commission

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

Amendment

(63) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the **principle of free and informed consent**, 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 European Convention on Human Rights**. This Regulation should be applied by the Member States in accordance with those rights and principles.

Amendment 57

Proposal for a regulation

Recital 64

Text proposed by the Commission

(64) In order to maintain a high level of health and safety, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the products subject to this Regulation that are similar to medical devices but do not necessarily have a medical purpose; adaptation of the definition of nanomaterial to technical progress and to developments at Union and international level; 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 investigations; the establishment of the UDI system; the information to be submitted for the registration of 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 investigations; 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

(64) In order to maintain a high level of health and safety, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the products subject to this Regulation that are similar to medical devices but do not necessarily have a medical purpose; adaptation of the definition of nanomaterial to technical progress and to developments at Union and international level; 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 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 investigations; the establishment of the UDI system the information to be submitted for the registration of 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 investigations; 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, basic aspects of this Regulation such as general safety and performance requirements, stipulations on technical documentation and the requirements for CE marking certification, as well as any amendments or additions to it, should be provided for only 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.

Amendment 58

Proposal for a regulation

Recital 68

Text proposed by the Commission

(68) 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 medical devices on the market.

Amendment

(68) 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 for the organisational arrangements to be taken. **However, parts of the Regulation that affect directly Member States and the Commission should be implemented as soon as possible**. 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 medical devices on the market. **Also at the date of application, existing notified bodies that handle class III devices, shall be subject to an application for notification in accordance with this Regulation**.

Amendment 59

Proposal for a regulation

Article 1 – paragraph 1 – subparagraph 1

Text proposed by the Commission

This Regulation establishes rules to be complied with by medical devices **and** accessories to medical devices that are placed on the market or put into service in the Union **for human use**.

Amendment

This Regulation establishes rules to be complied with by medical devices **for human use**, accessories to medical devices **and medical devices for aesthetic purposes** that are placed on the market or put into

service in the Union.

Amendment 60

Proposal for a regulation

Article 1 – paragraph 1 – subparagraph 2

Text proposed by the Commission

For the purposes of this Regulation, medical devices **and** accessories to medical devices shall hereinafter be referred to as ‘devices’.

Amendment

For the purposes of this Regulation, medical devices, accessories to medical devices **and devices for aesthetic purposes** shall hereinafter be referred to as ‘devices’.

Amendment 61

Proposal for a regulation

Article 1 – paragraph 2 – point f

Text proposed by the Commission

(f) products that contain or consist of biological substances or organisms other than those referred to in points (c) and (e) that are viable, including living micro-organisms, bacteria, fungi or virus;

Amendment

(f) **all** products that contain or consist of biological substances or organisms other than those referred to in points (c) and (e) that are viable **and that achieve their intended purpose by pharmacological, immunological or metabolic means**, including **certain** living micro-organisms, bacteria, fungi or virus;

Amendment 62

Proposal for a regulation

Article 1 – paragraph 4 – subparagraph 1

Text proposed by the Commission

Where a device, when placed on the market or used in accordance with the manufacturer's instructions, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in Article 1(2) of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in Article 1(10) of that Directive, with action ancillary to that of the device, that device

Amendment

Where a device, when placed on the market or used in accordance with the manufacturer's instructions, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in Article 1(2) of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in Article 1(10) of that Directive, with action ancillary to that of the device, that device

shall be assessed and authorised in accordance with this Regulation.

shall be assessed and authorised in accordance with this Regulation ***following consultation with the national medicine agency or with the EMA.***

Amendment 63

Proposal for a regulation Article 1 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. This Regulation shall not impede the continued application of measures within Directive 2002/98/EC and its five Daughter Directives setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.

Articles 10 (Personnel), 14 (Traceability), 15 (Notification of serious adverse events and reactions), 19 (Examination of donors) and 29 (Technical requirements and their adaptation to technical and scientific progress) of Directive 2002/98/EC ensure donor and patient safety and as such those existing standards shall be maintained.

Amendment 64

Proposal for a regulation Article 1 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7a. The regulation of 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 device in relation to aspects that are not covered by this Regulation.

Amendment 65

Proposal for a regulation

Article 2 – paragraph 1 – point 1 – introductory part

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:

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:

Amendment 66

Proposal for a regulation

Article 2 – paragraph 1 – point 1 – indent 1

Text proposed by the Commission

– diagnosis, prevention, monitoring, treatment or alleviation of disease,

Amendment

– diagnosis, prevention, monitoring, ***prediction***, treatment or alleviation of disease,

Amendment 67

Proposal for a regulation

Article 2 – paragraph 1 – point 1 – paragraph 2

Text proposed by the Commission

The implantable or other invasive products, intended to be used for human beings, which are listed in Annex XV shall be considered medical devices, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose.

Amendment

The implantable or other invasive products, ***as well as products using external physical agents***, intended to be used for human beings, which are listed ***on a non-exhaustive basis*** in Annex XV, shall be considered medical devices ***for the purposes of this Regulation***, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose.

Amendment 68

Proposal for a regulation

Article 2 – paragraph 1 – point 2

Text proposed by the Commission

(2) ‘accessory to a medical device’ means an article which, whilst not being a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable **or assist** the device(s) to be used in accordance with its/their intended purpose(s);

Amendment

(2) ‘accessory to a medical device’ means an article which, whilst not being a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the device(s) to be used in accordance with its/their intended purpose(s); **or to specifically assist the medical functionality of the medical device(s) in view of its/their intended purpose(s);**

Amendment 69

Proposal for a regulation

Article 2 – paragraph 1 – point 2 a (new)

Text proposed by the Commission

Amendment

(2a) ‘device for aesthetic purposes’ means any instrument, apparatus, appliance, software, implant, material, substance or other article, intended by the manufacturer to be used, alone or in combination, for the purposes of modifying the physical appearance of human beings, without any therapeutic or reconstructive intent, by implanting it in the human body, attaching it to the surface of the eye or using it to induce a tissue or cell reaction on external or non-external parts of the human body.

Tattooing products and piercings shall not be considered devices for aesthetic purposes.

Amendment 70

Proposal for a regulation

Article 2 – paragraph 1 – point 3

Text proposed by the Commission

Amendment

(3) ‘custom-made device’ means any device specifically made **in accordance**

(3) ‘custom-made device’ means any device specifically made **by an**

with a written prescription of a doctor of medicine, of a dental practitioner or of any other person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics, **and is intended for the sole use of a particular patient.**

appropriately qualified person exclusively to meet a specific patient's individual requirements and needs. In particular a 'custom-made device' may be produced on the basis of a written prescription of a doctor of medicine, of a dental practitioner or of any other person authorised by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics. **However, mass-produced devices which need to be adapted to meet the specific requirements of a doctor of medicine, a dental practitioner or any other professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of doctors of medicine, dental practitioners or any other authorised person shall not be considered to be custom-made devices;**

However, mass-produced devices which need to be adapted to meet the specific requirements of a doctor of medicine, a dental practitioner or any other professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of doctors of medicine, dental practitioners or any other authorised person shall not be considered to be custom-made devices;

Amendment 71

Proposal for a regulation

Article 2 – paragraph 1 – point 4 – paragraph 1

Text proposed by the Commission

(4) 'active device' means any device, the operation of which depends on a source of electrical energy or any source of power other than that directly generated by gravity and which acts by changing the density of or converting this energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any

Amendment

(4) 'active device' means any device, the operation of which depends on a source of electrical energy or any source of power other than that directly generated **by the human body or** by gravity and which acts by changing the density of or converting this energy. Devices intended to transmit energy, substances or other elements between an active device and the patient,

significant change, shall not be considered to be active devices.

without any significant change, shall not be considered to be active devices.

Amendment 72

Proposal for a regulation

Article 2 – paragraph 1 – point 4 – paragraph 2

Text proposed by the Commission

Amendment

Stand alone software shall be considered an active device;

deleted

Amendment 73

Proposal for a regulation

Article 2 – paragraph 1 – point 8 – paragraph 1

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.

(8) ‘single-use device’ means a device that is intended to be used on an individual patient during a single procedure ***and which has been tested and demonstrated to be impossible to reuse.***

Amendment 357

Proposal for a regulation

Article 2 – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

(8a) ‘reusable device’ means a device that is suitable for reprocessing and that is intended to be used on multiple patients or during multiple procedures;

Amendment 75

Proposal for a regulation

Article 2 – paragraph 1 – point 9

Text proposed by the Commission

Amendment

(9) ‘single-use device for critical use’ means a single-use device intended to be

deleted

used for surgically invasive medical procedures;

Amendment 354

Proposal for a regulation

Article 2 – paragraph 1 – point 10

Text proposed by the Commission

(10) 'intended purpose' means the use for which the device is intended according to the *data supplied by the manufacturer on the label*, in the instructions for use *or* in promotional or sales materials or statements;

Amendment

(10) 'intended purpose' means the use for which the device is intended according to the *clinical evaluation, to be reflected in the conformity certificate, the product label*, in the instructions for use *and if applicable* in promotional or sales materials or statements;

Amendment 76

Proposal for a regulation

Article 2 – paragraph 1 – point 16

Text proposed by the Commission

(16) 'making available on the market' means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market *in the course of a commercial activity*, whether in return for payment or free of charge;

Amendment

(16) 'making available on the market' means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market, whether in return for payment or free of charge;

Amendment 77

Proposal for a regulation

Article 2 – paragraph 1 – point 24

Text proposed by the Commission

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

Amendment

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

Amendment 78

Proposal for a regulation

Article 2 – paragraph 1 – point 27

Text proposed by the Commission

(27) ‘reprocessing’ means the process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoration of the technical and functional safety of the used device;

Amendment

(27) ‘reprocessing’ means the process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoration of the technical and functional safety of the used device; ***routine device maintenance service activities are not included in this definition;***

Amendment 79

Proposal for a regulation

Article 2 – paragraph 1 – point 31 a (new)

Text proposed by the Commission

Amendment

(31a) ‘performance’ means any technical characteristics, any effects and any benefit of the device when used for the intended purpose and in accordance with the instructions of use;

Amendment 80

Proposal for a regulation

Article 2 – paragraph 1 – point 31 b (new)

Text proposed by the Commission

Amendment

(31b) ‘benefit’ means the positive health impact of a medical device based on clinical and non-clinical data;

Amendment 82

Proposal for a regulation

Article 2 – paragraph 1 – point 32

Text proposed by the Commission

Amendment

(32) ‘clinical evaluation’ means the assessment and analysis of clinical data pertaining to a device in order to verify the safety **and** performance of the device when used as intended by the manufacturer;

(32) ‘clinical evaluation’ means the assessment and analysis of clinical data pertaining to a device in order to verify the safety, performance **and clinical benefits** of the device when used as intended by the manufacturer;

Amendment 83

Proposal for a regulation

Article 2 – paragraph 1 – point 33 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Clinical investigations for medical devices, where made compulsory in accordance with this Regulation, shall include clinical investigations in the appropriate target population and well-controlled investigations.

Amendment 84

Proposal for a regulation

Article 2 – paragraph 1 – point 36 – introductory part

Text proposed by the Commission

Amendment

(36) ‘clinical data’ means the information concerning the safety or performance that is generated from the use of a device and that are sourced from the following:

(36) ‘clinical data’ means **all** the information concerning the safety or performance that is generated from the use of a device and that are sourced from the following:

Amendment 86

Proposal for a regulation

Article 2 – paragraph 1 – point 37

Text proposed by the Commission

Amendment

(37) ‘sponsor’ means an individual, company, institution or organisation which takes responsibility for the initiation and

(37) ‘sponsor’ means an individual, company, institution or organisation which takes responsibility for the initiation and management, **conduct or financing** of a

management of a clinical investigation;

clinical investigation;

Amendment 87

Proposal for a regulation

Article 2 – paragraph 1 – point 37 a (new)

Text proposed by the Commission

Amendment

(37a) ‘conformity assessment’ means, in relation to a clinical study, the checking by the authorities responsible of the relevant official documentation, facilities and records and of the existence of sufficient insurance cover. Such checking may be carried out on the premises of the sponsor and/or the research establishment or wherever the authority responsible may deem checks to be necessary.

Amendment 88

Proposal for a regulation

Article 2 - paragraph 1 - point 37 b (new)

Text proposed by the Commission

Amendment

(37b) ‘ethics committee’ means an independent body in a Member State, consisting of health-care professionals and non-medical members including at least one well-experienced, knowledgeable patient or patient representative. Its responsibility is to protect the rights, safety, physical and mental integrity, dignity and well-being of subjects involved in clinical investigations and to provide public assurance of that protection in full transparency. In cases of such investigations involving minors, the ethics committee shall include at least one healthcare professional with paediatric expertise;

Amendment 89

Proposal for a regulation

Article 2 – paragraph 1 – point 39 – indent 2 – point iii

Text proposed by the Commission

(iii) hospitalisation or ***extending the duration of*** hospitalisation,

Amendment

(iii) hospitalisation or ***prolongation of patient*** hospitalisation,

Amendment 90

Proposal for a regulation

Article 2 – paragraph 1 – point 39 – indent 3

Text proposed by the Commission

– foetal distress, foetal death or a congenital ***abnormality*** or birth defect;

Amendment

– foetal distress, foetal death or a congenital ***physical or mental impairments*** or birth defect;

Amendment 91

Proposal for a regulation

Article 2 – paragraph 1 – point 40

Text proposed by the Commission

(40) ‘device deficiency’ means any inadequacy in the identity, quality, durability, reliability, safety or performance of ***an investigational*** device, including malfunction, ***use errors*** or inadequacy in the information supplied by the manufacturer;

Amendment

(40) ‘device deficiency’ means any inadequacy in the identity, quality, durability, reliability, safety or performance of ***a device, as defined in points 1 to 6 of this paragraph***, including malfunction, or inadequacy in the information supplied by the manufacturer;

Amendment 92

Proposal for a regulation

Article 2 – paragraph 1 – point 48 a (new)

Text proposed by the Commission

Amendment

(48a) ‘unannounced inspection’ means an inspection conducted without advance notice;

Amendment 93

Proposal for a regulation

Article 3

Text proposed by the Commission

1. The Commission may, at the request of a Member State **or on its own initiative**, by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory to a medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

2. The Commission shall ensure the sharing of expertise between Member States in the fields of medical devices, in vitro diagnostic medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.

Amendment

1. The Commission may **on its own initiative or shall** at the request of a Member State, by means of implementing acts **on the basis of the opinions of the MDCG and the MDAC referred to in Articles 78 and 78a respectively**, determine whether or not a specific product, or category or group of products, **including borderline products**, falls within the definitions of 'medical device' or 'accessory to a medical device'. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Amendment 256

Proposal for a regulation Chapter II - title

Text proposed by the Commission

Chapter **II**

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

Amendment

Chapter **VI***

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

** As a consequence of this amendment, this Chapter will cover Articles 4 to 14 and 16 to 22*

Amendment 94

Proposal for a regulation

Article 4 – paragraph 4

Text proposed by the Commission

4. Devices that are manufactured and used within a single health institution shall be considered as being put into service. The provisions regarding CE marking referred to in Article 18 and the obligations laid down in Articles 23 *to* 27 shall not apply to those devices, provided that manufacture and use of those devices occur under the health institution's single quality management system.

Amendment

4. Devices that are manufactured and used within a single health institution shall be considered as being put into service. The provisions regarding CE marking referred to in Article 18 and the obligations laid down in Articles 23, **26 and** 27 shall not apply to those devices, provided that manufacture and use of those devices occur under the health institution's single quality management system.

Amendment 95

Proposal for a regulation

Article 4 – paragraph 5

Text proposed by the Commission

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 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.

Amendment

deleted

Amendment 96

Proposal for a regulation

Article 5 – paragraph 1

Text proposed by the Commission

1. A device offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation at the latest **when** the device is placed on the market.

Amendment

1. A device offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation at the latest **by the day on which the** device is placed on the market.

Amendment 97

Proposal for a regulation Article 5 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Service providers providing means of distance communication shall be obliged, upon receiving a request from the competent authority, to disclose the details of entities engaging in distance selling.

Amendment 98

Proposal for a regulation Article 5 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2b. There shall be a prohibition on the marketing, placing in use, distribution, delivery and making available of products whose names, labelling or instructions for use may mislead with regard to the product's characteristics and effects by:

(a) ascribing characteristics, functions and effects to the product which the product does not have;

(b) creating the false impression that treatment or diagnosis using the product is sure to be successful, or failing to inform of a likely risk associated with the use of the product in line with its intended use or for a longer-than-anticipated period;

(c) suggesting uses or characteristics of the product other than those declared when the conformity assessment was carried out.

Promotional materials, presentations and information about the products may not mislead in the manner referred to in the first subparagraph.

Amendment 99

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 evaluation and post-market clinical follow-up set out in Annex XIII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 88(3).

Amendment

1. Where no harmonised standards exist or where ***there is a need to address public health concerns***, the Commission, ***after having consulted the MDCG and the MDAC***, 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 evaluation and post-market clinical follow-up set out in Annex XIII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 88(3).

1a. Before adopting CTS referred to in paragraph 1, the Commission shall ensure that the CTS have been developed with the appropriate support of the relevant stakeholders and that they are coherent with the European and international standardisation system. CTS are coherent if they do not conflict with European standards, meaning they cover areas where no harmonised standards exist, the adoption of new European standards is not envisaged within a reasonable period, where existing standards have not gained market uptake or where those standards have become obsolete or have been demonstrated as clearly insufficient according to vigilance or surveillance data, and where the transposition of the technical specifications into European standardisation deliverables is not envisaged within a reasonable period.

Amendment 100

Proposal for a regulation

Article 8 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Amendment

The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annex II.

deleted

Amendment 101

Proposal for a regulation

Article 8 – paragraph 6 – subparagraph 2

Text proposed by the Commission

Amendment

If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures.

If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures, ***including immediate notification to Eudamed as established by Article 27.***

Amendment 102

Proposal for a regulation

Article 8 – paragraph 8

Text proposed by the Commission

Amendment

8. Manufacturers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform the distributors and, where applicable, the authorised representative accordingly.

8. Manufacturers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform the distributors, ***the importers*** and, where applicable, the authorised representative accordingly.

Amendment 103

Proposal for a regulation

Article 8 – paragraph 9 – subparagraph 1 a (new)

If a competent authority considers or has reason to believe that a device has caused damages, it shall ensure, where this is not already foreseen by national litigation or judicial proceedings, that the potentially harmed user, the user's successor in title, the user's health insurance company or other third parties affected by the damage caused to the user may request the information referred to in the first subparagraph from the manufacturer or his authorised representative while ensuring due respect to the intellectual property rights.

Amendment 104

Proposal for a regulation Article 8 – paragraph 10 a (new)

10a. Before placing a medical device on the market, manufacturers shall ensure they are covered by an appropriate liability insurance covering any damages to patients or users that can be directly attributed to a manufacturing defect of the same medical device, with a level of coverage proportionate to the potential risk associated with the medical device produced, and in accordance with Council Directive 85/374/EEC¹.

¹ *Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).*

Amendment 105

Proposal for a regulation Article 11 – paragraph 2 – subparagraph 1 – point -a (new)

Text proposed by the Commission

Amendment

(-a) that the manufacturer is identifiable and has the technical, scientific and financial capacity to produce a medical device compliant with this Regulation, and that importers make available to the national authorities and on their website a report on the investigation procedures attesting to the expertise of the manufacturer.

Amendment 106

Proposal for a regulation

Article 11 – paragraph 2 – subparagraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(fa) that the manufacturer has taken out appropriate liability insurance coverage pursuant to Article 8(10a), unless the importer himself ensures sufficient coverage that meets the requirements of that paragraph.

Amendment 107

Proposal for a regulation

Article 11 – paragraph 7

Text proposed by the Commission

Amendment

7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and his authorised representative and, if appropriate, **take** the necessary corrective action to bring that device **into** conformity, withdraw or recall it. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 45 for the device in question,

7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and his authorised representative and, if appropriate, **ensure that** the necessary corrective action to bring that device **in** conformity, withdraw or recall it, **is taken and, implement that action**. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with

giving details, in particular, of the non-compliance and of any corrective action *taken*.

Article 45 for the device in question, giving details, in particular, of the non-compliance and of any corrective action *they have implemented*.

Amendment 108

Proposal for a regulation

Article 12 – paragraph 2 – subparagraph 1 – point c

Text proposed by the Commission

(c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article **24 and Article** 11(3) *respectively*.

Amendment

(c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article 11(3).

Amendment 109

Proposal for a regulation

Article 12 – paragraph 4

Text proposed by the Commission

4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

Amendment

4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure, *within the scope of their respective activities*, that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

Amendment 110

Proposal for a regulation

Article 13

Text proposed by the Commission

Person responsible for regulatory compliance

1. Manufacturers shall have available within their organisation at least one **qualified** person who possesses **expert knowledge** in the field of medical devices. The **expert knowledge** shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline, **and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices**;

(b) **five** years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate their expert knowledge referred to in the first subparagraph by at least two years of professional experience within the relevant field of manufacture.

This paragraph shall not apply to manufacturers of custom-made devices who are micro-enterprises as defined by Commission Recommendation 2003/361/EC.

2. The **qualified** person shall at least be responsible for ensuring the following matters:

(a) that the conformity of the devices is appropriately assessed before a batch is

Amendment

Person responsible for regulatory compliance

1. Manufacturers shall have available within their organisation at least one person **responsible for regulatory compliance** who possesses **the requisite expertise** in the field of medical devices. The **requisite expertise** shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in **law**, natural sciences, medicine, pharmacy, engineering or another relevant discipline;

(b) **three** years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate their expert knowledge referred to in the first subparagraph by at least two years of professional experience within the relevant field of manufacture.

This paragraph shall not apply to manufacturers of custom-made devices who are micro-enterprises as defined by Commission Recommendation 2003/361/EC.

2. The person **responsible for regulatory compliance** shall at least be responsible for ensuring the following matters:

(a) that the conformity of the devices is appropriately assessed before a batch is

released;

(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;

(c) that the reporting obligations in accordance with Articles 61 to 66 are fulfilled;

(d) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued.

3. The *qualified* person shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.

4. Authorised representatives shall have available within their organisation at least one *qualified* person who possesses *expert knowledge* regarding the regulatory requirements for medical devices in the Union. The *expert knowledge* shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline, *and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices*;

(b) *five* years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

released;

(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;

(c) that the reporting obligations in accordance with Articles 61 to 66 are fulfilled;

(d) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued.

If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs 1 and 2, their respective areas of responsibility shall be stipulated in writing.

3. The person *responsible for regulatory compliance* shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.

4. Authorised representatives shall have available within their organisation at least one person *responsible for regulatory compliance* who possesses *the requisite expertise* regarding the regulatory requirements for medical devices in the Union. The *requisite expertise* shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline;

(b) *three* years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Amendment 111

Proposal for a regulation

Article 14 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

A distributor, importer or other natural or legal person shall assume the obligations incumbent on the manufacturer under paragraph 1(a) only if the device in question was manufactured outside the Union. In the case of devices manufactured within the Union, the manufacturer's proof of compliance with this Regulation shall suffice.

Amendment 112

Proposal for a regulation

Article 14 – paragraph 4

Text proposed by the Commission

Amendment

4. Prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample ***or a mock-up*** of the relabelled or repackaged device, including any translated label and instructions for use. He shall submit to the competent authority a certificate, issued by a notified body referred to in Article 29, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.

4. ***At least 28 calendar days*** prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample of the relabelled or repackaged device, including any translated label and instructions for use. ***Within the same period of 28 calendar days***, he shall submit to the competent authority a certificate, issued by a notified body referred to in Article 29, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.

Amendment 113

Proposal for a regulation

Article 15

Text proposed by the Commission

Amendment

Article 15

deleted

Single-use devices and their reprocessing

1. Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation.

2. Only single-use devices that have been placed on the Union market in accordance with this Regulation, or prior to [date of application of this Regulation] in accordance with Directive 90/385/EEC or Directive 93/42/EEC may be reprocessed.

3. In the case of reprocessing of single-use devices for critical use, only reprocessing that is considered safe according to the latest scientific evidence may be carried out.

4. The Commission, by means of implementing acts, shall establish and regularly update a list of categories or groups of single-use devices for critical use which may be reprocessed in accordance with paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

5. The name and address of the legal or natural person referred to in paragraph 1 and the other relevant information in accordance with Section 19 of Annex I shall be indicated on the label and, where applicable, in the instructions for use of the reprocessed device.

The name and address of the manufacturer of the original single-use device shall no longer appear on the label,

but shall be mentioned in the instructions for use of the reprocessed device.

6. A Member State may maintain or introduce national provisions prohibiting, within its territory, on grounds of protection of public health specific to that Member State the following:

(a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;

(b) the making available of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of the national provisions and the grounds for introducing them. The Commission shall keep the information publicly available.

Amendment 257

Proposal for a regulation Chapter VI a (new)

Text proposed by the Commission

Amendment

Chapter VIa*

Labelling and safe reprocessing of medical devices

** As a consequence of this amendment, this Chapter will cover Articles 15a to 15d*

Amendment 358

Proposal for a regulation Article 15 a (new)

Text proposed by the Commission

Amendment

Article 15a

General principles on safe reprocessing

1. Any natural or legal person, including health institutions as specified in Article 4(4), who wishes to reprocess a single-use device to make it suitable for further use within the Union, and who can provide

scientific evidence that such a device could be safely reprocessed shall be considered to be the manufacturer of its reprocessed device and shall be held liable for its reprocessing activities. The natural or legal person shall ensure the traceability of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation, with the exception of obligations linked to the conformity assessment procedure.

2. Only reusable devices that have been placed on the Union market in accordance with this Regulation, or prior to [date of application of this Regulation] in accordance with Directive 90/385/EEC or Directive 93/42/EEC may be reprocessed.

3. Unless they are placed on the list of single-use devices referred to in Article 15b, medical devices shall be considered as suitable for reprocessing and reusable devices in accordance with the provisions laid down in Article 15c, and providing the highest level of patient safety is guaranteed.

4. A Member State may maintain or introduce national provisions prohibiting, within its territory, on grounds of protection of public health specific to that Member State the following:

(a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;

(b) the making available of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of the national provisions and the grounds for introducing them. The Commission shall keep the information publicly available.

Proposal for a regulation
Article 15 b (new)

Text proposed by the Commission

Amendment

Article 15b

List of single-use devices unsuitable for reprocessing

1. In accordance with Article 15a(3), the Commission, after the mandatory consultation of the MDAC shall establish, by means of delegated acts, a list of medical devices or types of medical device which are unsuitable for reprocessing. The Commission shall regularly update that list, including by adding or removing items. A first list shall be established no later than six months before the date of entry into force of this Regulation.

2. The decision to include or remove any device or type of device from the list shall be made in particular by taking into account:

- their intended use in or on the human body and the body parts they will be in contact with;***
- the conditions of their use;***
- their intended purpose;***
- the material which of which they are composed;***
- the severity of the disease that is being treated;***
- a genuine safety risk; and***
- the latest scientific and technological advancements in the relevant fields and disciplines.***

3. The delegated acts referred to in paragraph 1 shall be adopted in accordance with Article 89.

Amendment 118

Proposal for a regulation Article 15 c (new)

Text proposed by the Commission

Amendment

Article 15c

Reprocessing of medical devices labelled as reusable

1. Any natural or legal person, including health institutions as specified in Article 4(4), who reprocesses a device labelled as 'reusable' shall:

- comply with the EU standards referred to in paragraph 2;*
- ensure that, where a single-use device is removed from the list referred to in Article 15b, the reusable device is reprocessed in accordance with the opinion of the EU reference laboratory;*
- ensure that the reusable device is not reprocessed beyond the maximum number of times specified for that device;*

2. The Commission shall, by means of implementing acts, and in collaboration with the International Medical Devices Regulatory Forum and international standardisation bodies, define a clear set of high quality and safety standards for reprocessing of single use devices, including specific requirements for the manufacturers of reprocessed devices.

3. In drawing up these quality and safety standards, the Commission shall notably include:

- cleaning, disinfection and sterilisation processes in line with the risk assessment for the respective devices,*
- requirements in relation to systems for hygiene, infection-prevention, quality management and documentation applicable to the natural or legal persons reprocessing the medical devices,*
- functionality testing of the devices after reprocessing.*

These standards shall be consistent with the latest scientific evidence and guarantee the highest level of quality and safety, in accordance with the severity of the condition, as reflected in European standards from the European standardisation organisations, where the latter take into account the provisions of relevant international standards, in particular those of ISO and IEC, or any other international technical standards able to guarantee, at the very least, a higher level of quality, safety and performance than ISO and IEC standards.

3. The natural or legal person referred to in paragraph 1 shall comply with EU standards referred to in paragraph 1 to ensure the quality of the reprocessing of medical devices labelled as 'reusable' and the safety of reprocessed devices.

4. Where no harmonised standards exist or where relevant harmonised standards are not sufficient, the Commission shall be empowered to adopt CTS, as referred to in Article 7(1).

Amendment 377

Proposal for a regulation Article 15 d (new)

Text proposed by the Commission

Amendment

Article 15d

*Report on the functioning of the system
No later than four years after the date of application of this Regulation, the Commission shall assess and draw up an evaluation report. The report shall be submitted to the European Parliament and the Council. Where appropriate, the report shall be accompanied by a legislative proposal.*

Amendment 120

Proposal for a regulation

Article 16

Text proposed by the Commission

Implant card

1. The manufacturer of an implantable device shall provide together with the device an implant card which shall be made available to the *particular patient who has been implanted with the device*.

2. This card shall contain the following:
- (a) the information allowing identification of the device, including the Unique Device Identification;
 - (b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences or environmental conditions;
 - (c) any information about the expected lifetime of the device and any necessary

Amendment

Implant card *and information about implantable devices*

1. The manufacturer of an implantable device shall provide together with the device an implant card which shall be made available to *the healthcare professional implanting the device who shall be responsible for:*

- *submitting the implant card to the patient, and*
- *recording all the information contained on the implant card in the patient's medical records;*

The implant card shall also be made available by the manufacturer in an electronic format and Member States shall ensure that hospitals and clinics keep an electronic version on record.

The following implants shall be exempted from this obligation: sutures, staples, dentals implants, screws and plates.

The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing this list of exempted implants.

2. This card shall contain the following:
- (a) the information allowing identification of the device, including the Unique Device Identification;
 - (b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences or environmental conditions;
 - (*ba*) *description of potential adverse effects;*
 - (c) any information about the expected lifetime of the device and any necessary

follow-up.

The information shall be written in a way that is readily understood by a lay person.

Amendment 121

Proposal for a regulation Article 21 – paragraph 1

Text proposed by the Commission

1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the device without **significantly** changing its performance or safety characteristics, shall ensure that the article does not adversely affect the safety and performance of the device. Substantiating evidence shall be kept available to the competent authorities of the Member States.

Amendment 122

Proposal for a regulation Article 21 – paragraph 2

Text proposed by the Commission

2. An article that is intended specifically to

follow-up.

(ca) principal characteristics of the device, including the materials used;

Member States may introduce national provisions requiring that the implant card includes also information on post-operative follow-up care measures.

The information shall be written in a way that is readily understood by a lay person.

Amendment

1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the device without changing its performance or safety characteristics, shall ensure that the article does not adversely affect the safety and performance of the device. **When the article is a part of an implantable device, the natural or legal person who makes it available on the market shall cooperate with the manufacturer of the device to ensure its compatibility with the functioning part of the device in order to avoid the replacement of the whole device and its consequences for patient safety.** Substantiating evidence shall be kept available to the competent authorities of the Member States.

2. An article that is intended specifically to

replace a part or component of a device and that **significantly** changes the performance or safety characteristics of the device shall be considered a device.

replace a part or component of a device and that changes the performance or safety characteristics of the device shall be considered **as a device and shall meet the requirements laid down in this Regulation.**

Amendment 258

Proposal for a regulation Chapter III - title

Text proposed by the Commission

Chapter III

Identification and traceability of devices, registration of devices and of economic operators, **summary of safety and clinical performance**, European databank on medical devices

Amendment

Chapter VIII*

Identification and traceability of devices, registration of devices and of economic operators, European databank on medical devices

** As a consequence of this amendment, this Chapter will cover Articles 23, 24, 25, 27*

Amendment 123

Proposal for a regulation Article 24 – paragraph 1 – introductory part

Text proposed by the Commission

1. For devices, other than custom-made and investigational devices, a system for Unique Device Identification shall be put in place in the Union. The UDI system shall allow the identification and traceability of devices and shall consist of the following:

Amendment

1. For devices, other than custom-made and investigational devices, a **single** system for Unique Device Identification (UDI) shall be put in place in the Union. The UDI system shall allow the identification and traceability of devices, **be coherent if possible with the global regulatory approach for UDI in medical devices**, and shall consist of the following:

Amendment 124

Proposal for a regulation Article 24 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The UDI system shall be updated with the results of the post-market clinical follow-up evaluation report referred to in Section 3 of Part B of Annex XIII.

Amendment 125

Proposal for a regulation

Article 24 – paragraph 2 – point e – point i

Text proposed by the Commission

Amendment

(i) to operate its system for the assignment of UDIs for the period to be determined in the designation which shall at least be **three** years after its designation;

(i) to operate its system for the assignment of UDIs for the period to be determined in the designation which shall at least be **five** years after its designation;

Amendment 126

Proposal for a regulation

Article 24 – paragraph 8 – point b

Text proposed by the Commission

Amendment

(b) the legitimate interest in protecting commercially sensitive information;

(b) the legitimate interest in protecting commercially sensitive information, ***providing that it does not conflict with public health protection;***

Amendment 127

Proposal for a regulation

Article 24 – paragraph 8 – point e a (new)

Text proposed by the Commission

Amendment

(ea) compatibility with other traceability systems used by the stakeholders involved with medical devices

Amendment 128

Proposal for a regulation

Article 24 – paragraph 8 – point e b (new)

Text proposed by the Commission

Amendment

(eb) the compatibility of the UDI systems with the safety features established under Directive 2011/62/EU.

Amendment 129

Proposal for a regulation

Article 25 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

Steps shall be taken to ensure that no additional national registration procedures are necessary.

Amendment 261

Proposal for a regulation

Chapter II a (new)

Text proposed by the Commission

Amendment

Chapter IIa*

Conformity assessment

** As a consequence of this amendment, this Chapter will cover Articles 26, 42, 44a, 45, 46, 47, 48*

Amendment 130

Proposal for a regulation

Article 26

Text proposed by the Commission

Amendment

Summary of safety and clinical performance

1. In the case of devices classified as class III and implantable devices, other than custom-made or investigational devices, the manufacturer shall draw up ***a summary of safety and clinical performance***. ***It*** shall be written in a way that is ***clear to the***

Safety and clinical performance report

1. In the case of devices classified as class III and implantable devices, other than custom-made or investigational devices, the manufacturer shall draw up ***a report on the safety and clinical performance of the device based on the full information***

intended user. The draft of this *summary* shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 42 *and shall be validated by that body*.

2. The Commission may, by means of implementing acts, set out *the form and the presentation of the data elements to be included in the summary of safety and clinical performance*. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(2).

collected during the clinical investigation. The manufacturer shall also draw up a summary of that report which shall be written in a way that is easy for a lay person to understand in the official language(s) of the country where the medical device is made available on the market. The draft report shall be part of the documentation to be submitted to and validated by the special notified body involved in the conformity assessment in accordance with Article 43a.

1a. The summary referred to in paragraph 1 shall be made available to the public through Eudamed in accordance with provisions under point (b) of Article 27(2) and point 18 of Annex V Part A.

2. The Commission may, by means of implementing acts, set out *the format of the presentation of the data elements to be included in both the report and the summary referred to in paragraph 1*. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(2).

Amendment 131

Proposal for a regulation Article 27

Text proposed by the Commission

1. The Commission shall develop and manage the European databank on medical devices (Eudamed) for the following purposes:

(a) to enable the public to be adequately informed about devices placed on the market, about the corresponding certificates issued by notified bodies and about the relevant economic operators;

(b) to enable traceability of devices within the internal market;

(c) to enable the public to be adequately

Amendment

1. The Commission shall develop, and manage the European databank on medical devices (Eudamed) for the following purposes:

(a) to enable the public to be adequately informed about devices placed on *or removed from* the market, about the corresponding certificates issued by notified bodies and about the relevant economic operators, *with due regard to commercial confidentiality where justified*;

(b) to enable traceability of devices within the internal market;

(c) to enable the public to be adequately

informed about clinical investigations and to enable sponsors of clinical investigations to be conducted in more than one Member State to comply with information obligations under Articles 50 to 60;

(d) to enable manufacturers to comply with information obligations under Articles 61 to 66;

(e) to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well informed basis and to enhance the cooperation between them.

2. Eudamed shall include the following as integral parts:

(a) the electronic system on UDI referred to in Article 24;

(b) the electronic system on registration of devices and economic operators referred to in Article 25;

(c) the electronic system on information on certificates referred to in Article 45(4);

(d) the electronic system on clinical investigations referred to in Article 53,

(e) the electronic system on vigilance referred to in Article 62;

(f) the electronic system on market surveillance referred to in Article 68.

3. The data shall be entered into Eudamed by the Member States, notified bodies, economic operators *and* sponsors as specified in the provisions concerning the electronic systems referred to in paragraph 2.

informed about clinical investigations, *and to have an overview of vigilance data and market surveillance activities as well as to enable healthcare professionals to have adequate access to the results of clinical investigations*, and to enable sponsors of clinical investigations to be conducted in more than one Member State to comply with information obligations under Articles 50 to 60 ;

(d) to enable manufacturers to comply with information obligations under Articles 61 to 66;

(e) to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well informed basis and to enhance the cooperation between them.

2. Eudamed shall include the following as integral parts:

(a) the electronic system on UDI referred to in Article 24;

(b) the electronic system on registration of devices and economic operators referred to in Article 25;

(c) the electronic system on information on certificates referred to in Article 45(4);

(d) the electronic system on clinical investigations referred to in Article 53,

(e) the electronic system on vigilance referred to in Article 62;

(f) the electronic system on market surveillance referred to in Article 68;

(fa) the electronic system on registration of subsidiaries and subcontracting referred to in Article 30a;

(fb) the electronic system on special notified bodies referred to in Article 43b .

3. The data shall be entered into Eudamed by *the Commission*, the Member States, notified bodies, economic operators, sponsors *and healthcare professionals* as specified in the provisions concerning the electronic systems referred to in paragraph 2.

4. All the information collated and processed by Eudamed shall be accessible to the Member States and to the Commission. The information shall be accessible to notified bodies, economic operators, sponsors and the public to the extent defined in the provisions referred to in paragraph 2.

5. Eudamed shall contain personal data only insofar as this is necessary for the electronic systems referred to in paragraph 2 to collate and process the information in accordance with this Regulation. Personal data shall be kept in a form which permits identification of the data subjects for no longer than the periods referred to in Article 8(4).

6. The Commission and the Member States shall ensure that the data subjects may effectively exercise their rights to information, to access, to rectify and to object in accordance with Regulation (EC) No 45/2001 and Directive 95/46/EC, respectively. They shall ensure that the data subjects may effectively exercise the right of access to data relating to them, and the right to have inaccurate or incomplete data corrected and erased. Within their respective responsibilities, the Commission and the Member States shall ensure that inaccurate and unlawfully processed data is deleted, in accordance with the applicable legislation. Corrections and deletions shall be carried out as soon as possible, but no later than within 60 days after a request is made by a data subject.

7. The Commission shall, by means of implementing acts, lay down the modalities necessary for the development and management of Eudamed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

4. All the information collated and processed by Eudamed shall be accessible to the Member States and to the Commission. The information shall be accessible to notified bodies, economic operators, sponsors, *healthcare professionals* and the public to the extent defined in the provisions referred to in paragraph 2.

5. Eudamed shall contain personal data only insofar as this is necessary for the electronic systems referred to in paragraph 2 to collate and process the information in accordance with this Regulation. Personal data shall be kept in a form which permits identification of the data subjects for no longer than the periods referred to in Article 8(4).

6. The Commission and the Member States shall ensure that the data subjects may effectively exercise their rights to information, to access, to rectify and to object in accordance with Regulation (EC) No 45/2001 and Directive 95/46/EC, respectively. They shall ensure that the data subjects may effectively exercise the right of access to data relating to them, and the right to have inaccurate or incomplete data corrected and erased. Within their respective responsibilities, the Commission and the Member States shall ensure that inaccurate and unlawfully processed data is deleted, in accordance with the applicable legislation. Corrections and deletions shall be carried out as soon as possible, but no later than within 60 days after a request is made by a data subject.

7. The Commission shall, by means of implementing acts, lay down the modalities necessary for the development and management of Eudamed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

7a. The information contained in the European Databank shall be robust, transparent and user-friendly, enabling the public and healthcare professionals to compare information on registered

devices, economic operators, clinical investigations, vigilance data and market-surveillance activities.

When developing and managing Eudamed, the Commission shall, in consultation with relevant stakeholders including patient and consumer organisations, ensure that all publicly accessible parts of Eudamed are presented in a user-friendly format.

8. In relation to its responsibilities under this Article and the processing of personal data involved therein, the Commission shall be considered controller of Eudamed and its electronic systems.

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Amendment 259

Proposal for a regulation Chapter IV - title

Text proposed by the Commission

Chapter IV
Notified bodies

Amendment

Chapter IV*
Notified bodies

** As a consequence of this amendment, this Chapter will cover Articles 28 to 40a and 43 to 43c*

Amendment 132

Proposal for a regulation Article 28 - paragraphs 5 to 8

Text proposed by the Commission

5. The national authority responsible for notified bodies shall safeguard the **confidentiality** of the information it obtains. However, it shall exchange information on a notified body with other Member States and the Commission.

6. The national authority responsible for notified bodies shall have a sufficient number of competent personnel **at its disposal** for the proper performance of its

Amendment

5. The national authority responsible for notified bodies shall safeguard the **confidential aspects** of the information it obtains. However, it shall exchange information on a notified body with other Member States and the Commission.

6. The national authority responsible for notified bodies shall have a sufficient number of **permanent** and competent personnel **"in house"**, for the proper

tasks.

performance of its tasks. ***Compliance with that requirement shall be assessed in the peer-review referred to in paragraph 8.***

In particular, the personnel of the national authority responsible for auditing the work of personnel of notified bodies in charge of carrying out product related reviews shall have proven qualifications equivalent to those of the personnel of the notified bodies as laid down in point 3.2.5. of Annex VI.

Similarly, the personnel of the national authority responsible for auditing the work of personnel of notified bodies in charge of carrying out audits of the manufacturer's quality management system shall have proven qualifications equivalent to those of the personnel of the notified bodies as laid down in point 3.2.6. of Annex VI.

Without prejudice to Article 33(3), where a national authority is responsible for the designation of notified bodies in the field of products other than medical devices, the competent authority for medical devices shall be consulted on all aspects specifically related to medical devices.

7. Member States shall provide the Commission and the other Member States with information on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any changes thereto.

Where a national authority is responsible for the designation of notified bodies in the field of products other than medical devices, the competent authority for medical devices shall be consulted on all aspects specifically related to medical devices.

7. The ultimate responsibility for the notified bodies and the national authority responsible for notified bodies lies with the Member State in which they are located. The Member State is required to check that the designated national authority responsible for notified bodies performs its work on the assessment, designation and notification of conformity assessment bodies and for the monitoring of the notified bodies properly and that the designated national authority responsible for notified bodies works impartially and objectively. Member States shall provide the Commission and the other Member States with ***all*** information ***they request*** on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any changes thereto. ***Such information shall be publicly available subject to provisions***

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

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

under Article 84.

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

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

Amendment 133

Proposal for a regulation Article 29 – paragraph 1

Text proposed by the Commission

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

Amendment

1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil their tasks for which they are designated in accordance with this Regulation. ***In this respect, permanent in-house administrative, technical and scientific personnel, with medical, technical and where needed pharmacological knowledge shall be ensured. Permanent in-house personnel shall be used, but notified bodies may hire external experts on an ad hoc and temporary basis as and when needed.*** Minimum requirements to be met by notified bodies are set out in Annex VI. ***In particular, in accordance with point 1.2. of Annex VI, the notified body shall be organised and operated so as to safeguard***

the independence, objectivity and impartiality of its activities and avoid conflict of interests.

The notified body shall publish a list of its staff responsible for the conformity assessment and certification of medical devices. This list shall at least contain the qualifications, curriculum vitae and declaration of interests for each member of staff. The list shall be sent to the national authority responsible for notified bodies which shall check that the staff satisfies the requirements of this Regulation. The list shall also be sent to the Commission.

Amendment 134

Proposal for a regulation Article 30

Text proposed by the Commission

Amendment

-1. Notified bodies shall have permanent in-house competent personnel and expertise, both in technical fields linked with the assessment of the performance of the devices, and in the medical field. They shall have the capacity to evaluate in house the quality of subcontractors.

Contracts may be awarded to external experts for the assessment of medical devices or technologies in particular where clinical expertise is limited.

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the relevant requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.
2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the relevant requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.
2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only with the agreement of the legal or natural person that applied for conformity assessment.

4. Notified bodies shall **keep at the disposal of** the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

2a. Notified bodies shall make publicly available the list of subcontractors or subsidiaries, the specific tasks for which they are responsible and the declarations of interest of their personnel.

3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only with the **explicit** agreement of the legal or natural person that applied for conformity assessment.

4. **At least once a year**, notified bodies shall **submit to** the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

4a. The annual assessment of notified bodies as provided for in Article 35(3) shall include verification of the compliance of the subcontractor(s) or the subsidiary/ies of notified bodies with the requirements set out in Annex VI.

Amendment 135

Proposal for a regulation Article 30 a (new)

Text proposed by the Commission

Amendment

Article 30a

Electronic system on registration of subsidiaries and subcontractors

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information on subcontractors and subsidiaries, as well as on the specific tasks for which they are responsible.

2. Before subcontracting can effectively take place, the notified body which intends to subcontract specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity

assessment, shall register their name(s) together with their specific tasks.

3. Within one week of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system.

4. The data contained in the electronic system shall be accessible to the public.

Amendment 136

Proposal for a regulation

Article 31 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

In case a conformity assessment body wants to be notified for devices referred to in Article 43a(1), it shall indicate so and submit an application for notification to the EMA in accordance with Article 43a.

Amendment 137

Proposal for a regulation

Article 32 – paragraphs 3 to 6

Text proposed by the Commission

Amendment

3. Within 14 days of the submission referred to in paragraph 2, the Commission shall designate a joint assessment team made up of at least **two** experts chosen from a list of experts who are qualified in the assessment of conformity assessment bodies. The list shall be drawn up by the Commission in cooperation with the MDCG. At least one of these experts shall be a representative of the Commission **who** shall lead the joint assessment team.

3. Within 14 days of the submission referred to in paragraph 2, the Commission shall designate a joint assessment team made up of at least **three** experts chosen from a list of experts who are qualified in the assessment of conformity assessment bodies **and free of conflicts of interest with the applicant conformity assessment body**. The list shall be drawn up by the Commission in cooperation with the MDCG. At least one of these experts shall be a representative of the Commission, **and at least one other shall come from a Member State other than the one in which the applicant conformity assessment body is established. The Commission representative** shall lead the joint assessment team. **In case the conformity**

4. Within 90 days after designation of the joint assessment team, the national authority responsible for notified bodies and the joint assessment team shall review the documentation submitted with the application in accordance with Article 31 and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or subcontractor, located inside or outside the Union, to be involved in the conformity assessment process. Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 31(2), unless the Commission representative mentioned in Article 32(3) requests the on-site assessment.

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

5. The national authority responsible for notified bodies shall submit its assessment report and its draft notification to the Commission which shall immediately transmit those documents to the MDCG and to the members of the joint assessment team. Upon request by the Commission, those documents shall be submitted by the

assessment body has asked to be notified for devices referred to in Article 43a(1), the EMA shall also be part of the joint assessment team.

4. Within 90 days after designation of the joint assessment team, the national authority responsible for notified bodies and the joint assessment team shall review the documentation submitted with the application in accordance with Article 31 and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or subcontractor, located inside or outside the Union, to be involved in the conformity assessment process. Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 31(2), unless the Commission representative mentioned in Article 32(3) requests the on-site assessment.

Findings regarding non-compliance of **an applicant conformity assessment** body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team. **The national authority shall set out in the assessment report the measures that the notify body shall take to ensure compliance of that applicant conformity assessment body with the requirements set out in Annex VI. In the event of a disagreement, a separate opinion drawn up by the assessment team setting out its reservations regarding notification shall be appended to** the assessment report of the national authority responsible.

5. The national authority responsible for notified bodies shall submit its assessment report and its draft notification to the Commission which shall immediately transmit those documents to the MDCG and to the members of the joint assessment team. **If the assessment team draws up a separate opinion, this too shall be**

authority in up to three official Union languages.

6. The joint assessment team shall provide its opinion regarding the assessment report **and** the draft notification within 21 days of receipt of those documents and the Commission shall immediately submit this opinion to the MDCG. Within 21 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft notification **which the** relevant national authority **shall duly take into consideration for** its decision on the designation of the notified body.

submitted to the Commission for forwarding to the MDCG. Upon request by the Commission, those documents shall be submitted by the authority in up to three official Union languages.

6. The joint assessment team shall provide its **final** opinion regarding the assessment report, the draft notification **and, where appropriate, the separate opinion drawn up by the assessment team,** within 21 days of receipt of those documents and the Commission shall immediately submit this opinion to the MDCG. Within 21 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft notification. **The** relevant national authority shall **base** its decision on the designation of the notified body **on the recommendation by the MDCG. In case where its decision differs from the MDCG recommendation, the relevant national authority shall provide the MDCG in writing with all the necessary justification for its decision.**

Amendment 138

Proposal for a regulation

Article 33 – paragraphs 2 to 4 and 8 to 9

Text proposed by the Commission

2. Member States **may** notify only conformity assessment bodies which satisfy the requirements set out in Annex VI.

3. Where a national authority responsible for notified bodies is responsible for designation of notified bodies in the field of products other than medical devices, the competent authority for medical devices shall provide, prior to the notification, a positive opinion on the notification and its scope.

4. The notification shall clearly specify the

Amendment

2. Member States **shall** notify only conformity assessment bodies which satisfy the requirements set out in Annex VI **and for which the application assessment procedure has been completed in accordance with Article 32.**

4. The notification shall clearly specify the

scope of the designation indicating the conformity assessment activities, the conformity assessment procedures and the type of devices which the notified body is authorised to assess.

The Commission may, by means of implementing acts, set up a list of codes and the corresponding types of devices to define the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(2).

8. When a Member State or the Commission raises objections in accordance with paragraph 7, the effect of the notification shall be suspended. In this case, the Commission shall bring the matter before the MDCG within 15 days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within 28 days after the matter has been brought before it. If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion.

9. Where no objection is raised in accordance with paragraph 7 or where the MDCG or the Commission, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted fully **or partially**, the Commission shall publish the notification accordingly.

scope of the designation indicating the conformity assessment activities, the conformity assessment procedures, the **risk class and the** type of devices which the notified body is authorised to assess.

The Commission may, by means of implementing acts, set up a list of codes and the corresponding **risk-classes** and types of devices to define the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 88(2).

8. When a Member State or the Commission raises objections in accordance with paragraph 7, the effect of the notification shall be **immediately** suspended. In this case, the Commission shall bring the matter before the MDCG within 15 days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within 28 days after the matter has been brought before it. If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion.

9. Where no objection is raised in accordance with paragraph 7 or where the MDCG or the Commission, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted fully, the Commission shall publish the notification accordingly.

The Commission shall also enter information on the notification of the notified body into the electronic system referred to in Article 27(2). That information shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the opinion of the joint assessment team and the recommendation of the MDCG, as referred to in this article.

The full details of the notification, including the class and the typology of devices, as well as the annexes, shall be

made publicly available.

Amendment 139

Proposal for a regulation Article 34 – paragraph 1

Text proposed by the Commission

1. The Commission shall assign an identification number to each notified body for which the notification is accepted in accordance with Article 33. It shall assign a single identification number even when the body is notified under several Union acts.

Amendment

1. The Commission shall assign an identification number to each notified body for which the notification is accepted in accordance with Article 33. It shall assign a single identification number even when the body is notified under several Union acts. ***If they are successfully renotified, bodies notified pursuant to Directives 90/385/EEC and 93/42/EEC shall retain the identification number assigned to them.***

Amendment 140

Proposal for a regulation Article 34 – paragraph 2

Text proposed by the Commission

2. The Commission shall make the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified, accessible to the public. The Commission shall ensure that the list is kept up to date.

Amendment

2. The Commission shall make the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified, ***easily*** accessible to the public. The Commission shall ensure that the list is kept up to date

Amendment 141

Proposal for a regulation Article 35

Text proposed by the Commission

1. The national authority responsible for notified bodies shall continuously monitor the notified bodies to ensure ongoing compliance with the requirements set out

Amendment

1. The national authority responsible for notified bodies, ***and where applicable the EMA***, shall continuously monitor the notified bodies to ensure ongoing

in Annex VI. The notified bodies shall, on request, supply all relevant information and documents, required to enable the authority to verify compliance with those criteria.

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

2. Notified bodies shall respond without delay to requests relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission. The national authority responsible for notified bodies of the Member State in which the body is established shall enforce requests submitted by authorities of any other Member State or by the Commission **unless** there is a legitimate reason for not doing so **in which case both sides may** consult the MDCG. **The notified body or their national authority responsible for notified bodies may request that any information transmitted to the authorities of another Member State or to the Commission shall be treated confidential.**

3. At least once a year, the national authority responsible for notified bodies shall assess whether each notified body under its responsibility still satisfies the requirements set out in Annex VI. This assessment shall include an on-site visit to each notified body.

compliance with the requirements set out in Annex VI. The notified bodies shall, on request, supply all relevant information and documents, required to enable the authority to verify compliance with those criteria.

Notified bodies shall, without delay, **and within 15 days at the latest**, inform the national authority responsible for notified bodies of any changes, in particular regarding their personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment procedures relating to the devices for which they have been designated.

2. Notified bodies shall respond without delay, **and within 15 days at the latest, to** requests relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission. The national authority responsible for notified bodies of the Member State in which the body is established shall enforce requests submitted by authorities of any other Member State or by the Commission. **Where** there is a legitimate reason for not doing so, **the notified bodies shall explain these reasons in writing and shall** consult the MDCG, **which shall then issue a recommendation. The national authority responsible for notified bodies shall comply with the MDCG's recommendation.**

3. At least once a year, the national authority responsible for notified bodies shall assess whether each notified body under its responsibility still satisfies the requirements set out in Annex VI, **including an assessment of whether its subcontractor(s) and subsidiary/-ies satisfy these requirements.** This assessment shall include an **unannounced inspection through an** on-site visit to each notified body, **and to each subsidiary or subcontractor within or outside the Union, if relevant.**

The assessment shall also include a

4. **Three** years after notification of a notified body, and again every **third** year thereafter, the assessment to determine whether the notified body still **satisfies** the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 32(3) and (4). At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body with the requirements set out in Annex VI.

5. The Member States shall report to the Commission and to the other Member States, at least once a year, on their monitoring activities. This report shall contain a summary which shall be made publicly available.

review of samples of the design dossier assessments carried out by the notified body to determine the ongoing competence of the notified body and quality of its assessments, in particular the notified body's ability to evaluate and assess clinical evidence.

4. **Two** years after notification of a notified body, and again every **second** year thereafter, the assessment to determine whether the notified body **and its subsidiaries and subcontractors** still **satisfy** the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 32(3) and (4). At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body, **or a subsidiary or subcontractor of a notified body**, with the requirements set out in Annex VI.

For special notified bodies under Article 43a, the assessment referred to in this paragraph shall be performed every year.

The comprehensive results of the assessments shall be published.

5. The Member States shall report to the Commission and to the other Member States, at least once a year, on their monitoring activities. This report shall contain a summary which shall be made publicly available.

5a. Every year, the notified bodies shall forward an annual activity report setting out the information referred to in point 3.5 of Annex VI to the competent authority and to the Commission, which shall forward it to the MDCG.

Amendment 142

Proposal for a regulation

Article 35 a (new)

Text proposed by the Commission

Amendment

Article 35a

Penalties

Member States shall ensure they have a system of penalties in place in case notified bodies do not fulfil the minimum requirements. This system should be transparent and proportionate to the nature and level of the non-compliance.

Amendment 143

Proposal for a regulation

Article 36

Text proposed by the Commission

Amendment

1. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification. The procedures described in Article 32(2) to (6) and in Article 33 shall apply to changes where they entail an extension of the scope of the notification. In all other cases, the Commission shall immediately publish the amended notification in the electronic notification tool referred to in Article 33(10).

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

1. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification. The procedures described in Article 32(2) to (6) and in Article 33 shall apply to changes where they entail an extension of the scope of the notification. In all other cases, the Commission shall immediately publish the amended notification in the electronic notification tool referred to in Article 33(10).

2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations, the authority shall suspend, restrict, or fully or partially withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. ***Suspension shall apply until a decision to annul the suspension has been reached by the MDCG, which shall follow an assessment by a joint assessment team designated in accordance with the procedure described in Article 32(3).***

shall withdraw the notification.

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

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

4. The national authority responsible for notified bodies shall assess whether the reasons which gave rise to the *change to* the notification have an impact on the certificates issued by the notified body and, within three months after having notified the changes to the notification, shall submit a report on its findings to the Commission and the other Member States. Where necessary to ensure the safety of devices on the market, that authority shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued. If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.

Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.

The national authority responsible for notified bodies shall immediately *and within 10 days at the latest*, inform the Commission, the other Member States *and the relevant manufacturers and health professionals* of any suspension, restriction or withdrawal of a notification.

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

4. The national authority responsible for notified bodies shall assess whether the reasons which gave rise to the *suspension, restriction or withdrawal of* the notification have an impact on the certificates issued by the notified body and, within three months after having notified the changes to the notification, shall submit a report on its findings to the Commission and the other Member States. Where necessary to ensure the safety of devices on the market, that authority shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, *and at the latest 30 days after the publication of the report*, any certificates which were unduly issued. If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.

With a view to verifying whether the reasons for the suspension, restriction or withdrawal of the notification have implications for the certificates issued, the national authority responsible shall ask the relevant manufacturers to supply

5. The certificates, other than those unduly issued, which were issued by the notified body for which the notification has been suspended, restricted or withdrawn shall remain valid in the following circumstances:

(a) in the case of suspension of a notification: on condition that, within three months of the suspension, ***either the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate is established, or*** another notified body confirm in writing that it is assuming the functions of the notified body during the period of suspension;

(b) in the case of restriction or withdrawal of a notification: for a period of three months after the restriction or withdrawal. The competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate is established may extend the validity of the certificates for further periods of three months, which altogether may not exceed twelve months, provided it is assuming the functions of the notified body during this period.

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

evidence of conformity at notification, and the manufacturers shall have 30 days in which to respond to that request.

5. The certificates, other than those unduly issued, which were issued by the notified body for which the notification has been suspended, restricted or withdrawn shall remain valid in the following circumstances:

(a) in the case of suspension of a notification: on condition that, within three months of the suspension another notified body confirm in writing that it is assuming the functions of the notified body during the period of suspension;

(b) in the case of restriction or withdrawal of a notification: for a period of three months after the restriction or withdrawal. The competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate is established may extend the validity of the certificates for further periods of three months, which altogether may not exceed twelve months, provided it is assuming the functions of the notified body during this period.

The authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately ***and within 10 days at the latest***, inform the Commission, the other Member States and the other notified bodies thereof.

The Commission shall immediately and within 10 days at the latest enter information on the changes to the notification of the notified body into the electronic system referred to in Article 27(2).

Amendment 144

Proposal for a regulation

Article 37 – paragraph 3 – subparagraph 1

Text proposed by the Commission

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

Amendment

Where the Commission ascertains that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the notification if necessary. ***The Commission shall make a report with the opinions of Member States publicly available after the assessment.***

Amendment 145

Proposal for a regulation

Article 39 – paragraph 1

Text proposed by the Commission

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

Amendment

The Commission, ***in consultation with the MDCG***, shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of a coordination group of notified bodies in the field of medical devices, including *in vitro* diagnostic medical devices. ***This group shall meet on a regular basis and at least twice a year.***

Amendment 146

Proposal for a regulation

Article 39 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

The Commission or the MDCG may request the participation of any notified body.

Amendment 147

Proposal for a regulation Article 39 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

The Commission may, by means of implementing acts, adopt measures setting out the modalities for the functioning of the coordination group of notified bodies as set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

Amendment 148

Proposal for a regulation Article 40

Text proposed by the Commission

Amendment

Fees

Fees for the activities of national authorities

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

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

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

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

2003/361/EC.

These fees shall be proportionate and consistent with national standards of living. The level of fees shall be made public.

Amendment 149

Proposal for a regulation Article 40 a (new)

Text proposed by the Commission

Amendment

Article 40 a

Transparency on fees charged by notified bodies for conformity assessment activities

- 1. Member States shall adopt provisions on standard fees for notified bodies.*
- 2. Fees shall be comparable across Member States. The Commission shall provide guidelines to facilitate comparability of those fees within 24 months from the date of entry into force of this Regulation.*
- 3. Member States shall transmit their list of standard fees to the Commission.*
- 4. The national authority shall ensure that the notified bodies make the lists of standard fees for the conformity assessment activities publicly available.*

Amendment 260

Proposal for a regulation Chapter V - title

Text proposed by the Commission

Amendment

Chapter V

Chapter II*

Classification *and conformity assessment*

Classification *of medical devices*

** As a consequence of this amendment, this Chapter will cover Article 41*

Amendment 150

Proposal for a regulation

Article 41 – paragraph 2 – subparagraph 2

Text proposed by the Commission

At least 14 days prior to any decision, the competent authority shall notify the MDCG and the Commission of its envisaged decision.

Amendment

At least 14 days prior to any decision, the competent authority shall notify the MDCG and the Commission of its envisaged decision. ***The final decision shall be made publically available in the Eudamed.***

Amendment 151

Proposal for a regulation

Article 41 – paragraph 3 – subparagraph 1

Text proposed by the Commission

The Commission may, at the request of a Member State or on its own initiative, by means of implementing acts, decide on the application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view to determining their classification.

Amendment

The Commission may, at the request of a Member State or on its own initiative, by means of implementing acts, decide on the application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view to determining their classification. ***Such decision should in particular be taken in order to resolve diverging decisions between Member States.***

Amendment 152

Proposal for a regulation

Article 41 – paragraph 3 – subparagraph 2

Text proposed by the Commission

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

Amendment

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3). ***Before adopting implementing acts, the Commission shall consult with relevant stakeholders and take into account their suggestions.***

Amendment 153

Proposal for a regulation

Article 41 – paragraph 4 – introductory part

Text proposed by the Commission

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

Amendment

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

Amendment 154

Proposal for a regulation

Article 42 – paragraph 4

Text proposed by the Commission

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

Amendment

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

Amendment 155

Proposal for a regulation

Article 42 – paragraph 10 – subparagraph 1 – introductory part

Text proposed by the Commission

Amendment

The Commission *may*, by means of implementing acts, specify the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies for any of the following aspects:

The Commission *shall*, by means of implementing acts, specify the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies for any of the following aspects:

Amendment 156

Proposal for a regulation

Article 42 – paragraph 10 – subparagraph 1 – indent 2

Text proposed by the Commission

Amendment

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

deleted

Amendment 157

Proposal for a regulation

Article 42 – paragraph 10 a (new)

Text proposed by the Commission

Amendment

10a. Unannounced inspections, in terms of their nature and extent, may be counted as regular inspections, with offsetting of economic operators' costs resulting from unannounced inspections, provided that no significant non-conformities are recorded during unannounced inspections. Account must be taken at all times, when ordering unannounced inspections and carrying them out, of the proportionality principle, with due regard, in particular, for the risk potential of each individual product.

Amendment 158

Proposal for a regulation Article 42 – paragraph 11

Text proposed by the Commission

11. 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 28 to 40, or of the vigilance and market surveillance activities described in Articles 61 to 75, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the conformity assessment procedures set out in Annexes VIII to XI.

Amendment

deleted

Amendment 159

Proposal for a regulation Article 43 – title and paragraph 1

Text proposed by the Commission

Involvement of notified bodies

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

Amendment

Involvement of notified bodies ***in conformity assessment procedures***

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer ***of devices other than those listed in Article 43a(1)*** may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned. ***Where a manufacturer applies to a notified body located in a Member State other than the one where it is registered, the manufacturer shall inform its national authority responsible for the notified bodies of the application.*** An application may not be lodged in parallel with more than one notified body for the same conformity assessment activity.

Amendment 160

Proposal for a regulation

Article 43 – paragraph 2

Text proposed by the Commission

2. The notified body concerned shall inform the other notified bodies of any manufacturer who withdraws his application prior to the notified body's decision regarding the conformity assessment.

Amendment

2. The notified body concerned shall inform the other notified bodies of any manufacturer who withdraws his application prior to the notified body's decision regarding the conformity assessment. ***It shall also inform all of the competent national bodies without delay.***

Amendment 161

Proposal for a regulation

Chapter V - Section 2 a (new) - title (new)

Text proposed by the Commission

Amendment

Section 2a – Additional provisions for the conformity assessment of high-risk devices: Involvement of special notified bodies

Amendments 360 and 371

Proposal for a regulation

Article 43 a (new)

Text proposed by the Commission

Amendment

Article 43a

Involvement of the special notified bodies in the conformity assessment procedures of high-risk devices

1. Only special notified bodies shall be entitled to conduct conformity assessments for the following devices:

(a) implantable devices;

(b) devices incorporating a substance, as referred to in Article 1(4) and point 6.1. of

Annex VII (Rule 13);

(c) Class IIb devices intended to administer and/or remove a medicinal product, as referred to in Article 1(5) and point 5.3. of Annex VII (Rule 11);

(d) devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable; or

(e) all other class III devices.

2. Applicant special notified bodies which consider they fulfil the requirements for special notified bodies referred to in Annex VI, point 3.6, shall submit their application to the EMA.

3. The application shall be accompanied by the fee payable to the EMA to cover the costs relating to the examination of the application.

4. The EMA shall designate the special notified body or bodies in accordance with requirements listed in Annex VI, and adopt its opinion on the authorisation to perform conformity assessments for devices listed in paragraph 1 within 90 days and send it to the Commission.

5. The Commission shall then publish the notification accordingly and the name of the special notified body or bodies.

6. This notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the special notified body.

This notification shall be valid for five years and subject to renewal every five years, following a new application to the EMA.

7. The manufacturer of devices listed in paragraph 1 may apply to a special notified body of his choice, whose name

appears in the electronic system of Article 43b (new).

8. An application may not be lodged in parallel with more than one special notified body for the same conformity assessment activity.

9. The special notified body shall notify the Commission of applications for conformity assessments for devices listed in paragraph 1.

10. Article 43 (2), (3) and (4) apply to special notified bodies.

Amendment 372

Proposal for a regulation Article 43 b (new)

Text proposed by the Commission

Amendment

Article 43b

Electronic system on special notified bodies

1. The Commission shall establish and regularly update an electronic registration system for:

- the registration of applications and granted authorisations to perform conformity assessments as special notified bodies under this Section and to collate and process information on the name of the special notified bodies;***
- the exchange of information with national authorities; and***
- the publication of assessment reports.***

2. The information collated and processed in the electronic system which relates to the application process for special notified bodies shall be entered into the electronic registration system by the EMA.

3. The information collated and processed in the electronic system and which relates to special notified bodies shall be accessible to the public.

4. The Commission shall regularly update the system.

Amendments 361 and 373

Proposal for a regulation Article 43 c (new)

Text proposed by the Commission

Amendment

Article 43c

Network of special notified bodies

1. The Commission and the MDCG shall establish, host, coordinate and manage the network of special notified bodies.

2. The network shall have the following objectives:

(a) to help realise the potential of European cooperation regarding highly specialised medical technologies in the area of medical devices;

(b) to contribute to the pooling of knowledge regarding medical devices;

(c) to encourage the development of conformity assessment benchmarks and to help develop and spread best practice within and outside the network;

(d) to help identify the experts in innovative fields;

(e) to develop and update rules on conflicts of interest;

(f) to find common answers to similar challenges concerning the conduct of conformity assessment procedures in innovative technologies; and

(g) to identify and notify significant discrepancies in the conformity assessments carried out by different Special notified bodies on substantially similar devices and to communicate these to the MDCG.

3. Meetings of the network shall be convened whenever requested by at least two of its members or by the EMA. It shall

meet at least twice a year.

Amendment 165

Proposal for a regulation Article 44

Text proposed by the Commission

Amendment

Article 44

deleted

Mechanism for scrutiny of certain conformity assessments

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

2. Within 28 days of receipt of the information referred to in paragraph 1, the MDCG may request the notified body to submit a summary of the preliminary conformity assessment prior to issuing a certificate. Upon suggestion by any of its members or by the Commission, the MDCG shall decide on making such request in accordance with the procedure set out in Article 78(4). In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file for submission of a summary of the preliminary conformity assessment. When selecting a specific file for submission, the principle of equal treatment shall be duly taken into account.

Within 5 days after receipt of the request

by the MDCG, the notified body shall inform the manufacturer thereof.

3. The MDCG may submit comments on the summary of the preliminary conformity assessment at the latest 60 days after submission of this summary. Within that period and at the latest 30 days after submission, the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this subparagraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.

4. The notified body shall give due consideration to any comments received in accordance with paragraph 3. It shall convey to the Commission an explanation of how they have been taken into consideration, including any due justification for not following the comments received, and its final decision regarding the conformity assessment in question. The Commission shall immediately transmit this information to the MDCG.

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

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

(a) the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof;

(b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;

(c) an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices;

(d) significant discrepancies in the conformity assessments carried out by different notified bodies on substantially similar devices;

(e) public health concerns regarding a specific category or group of devices or the technology on which they are based.

6. The Commission shall make a summary of the comments submitted in accordance with paragraph 3 and the outcome of the conformity assessment procedure accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.

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

8. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the summary of the preliminary conformity assessment in accordance with paragraphs 2 and 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Text proposed by the Commission

Amendment

Article 44a

Assessment procedure in specific cases

1. Special notified bodies shall notify the Commission of applications for conformity assessments for implantable Class III devices, Class IIb devices intended to administer and/or remove a medicinal product, as referred to in Article 1(5) and point 5.3. of Annex VII (Rule 11), and devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable with the exception of applications to renew or supplement existing certificates and devices for which specifications referred to in Articles 6 and 7 have been published for the clinical evaluation and the post-market clinical follow-up. The notification shall be accompanied by the draft instructions for use referred to in Section 19.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 26. In its notification the special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the Medical Device Coordination Group (MDCG) for an opinion. In making its opinion, the MDCG may seek a clinical assessment from the relevant experts of the Assessment Committee for Medical Devices (ACMD), referred to in Article 78.

2. Within 20 days of receipt of the information referred to in paragraph 1, the MDCG may decide to request the special notified body to submit the following documents prior to issuing a

certificate:

– the clinical evaluation report as referred to in Annex XIII, including the clinical investigations report as referred to in Annex XIV,

– the post market clinical follow-up plan referred to in Annex XIII, and

– any information regarding the marketing or not of the device in third countries and, where available, the results of evaluation conducted by competent authorities in those countries.

The members of the MDCG shall decide on making such a request only on the basis of the following criteria:

(a) the novelty of the device with possible major clinical or health impact;

(b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in the case of failure;

(c) an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices.

In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing these criteria.

In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file.

In the absence of request from the MDCG within 20 days of receipt of the information referred to in paragraph 1, the special notified body may continue with the conformity assessment procedure.

3. The MDCG, following the consultation of the ACMD shall issue a MDCG opinion on the documents referred to in paragraph 2 at the latest 60 days after its

submission. Within that period and at the latest 30 days after submission, the ACMD through the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the documents referred to in paragraph 2. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this paragraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.

4. In its opinion the MDCG shall take into account the clinical assessment of the ACMD. The MDCG may recommend modifications of the documents referred to in paragraph 2.

5. The MDCG shall immediately inform the Commission, the special notified body and the manufacturer of its opinion.

6. Within 15 days after receipt of the opinion referred to in paragraph 5, the special notified body shall indicate whether or not it agrees with the opinion of the MDCG. In the latter case, it may give written notice to the MDCG that it wishes to request a re-examination of the opinion. In that case, the special notified body shall forward to the MDCG the detailed grounds for the request within 30 days after receipt of the opinion. The MDCG shall immediately transmit this information to the ACMD and the Commission.

Within 30 days following receipt of the grounds for the request, the MCDG shall re-examine its opinion, after consultation of the ACMD where necessary. The reasons for the conclusion reached shall be annexed to the final opinion.

7. Immediately after its adoption, the MCDG shall send its final opinion to the Commission, the special notified body and

the manufacturer.

8. In the case of a favourable opinion MDCG opinion, the special notified body may proceed with the certification.

However if the favourable MDCG opinion is dependent on the application of specific measures (e.g. adaptation of the post-market clinical follow-up plan, certification with a time limit), the special notified body shall issue the certificate of conformity only on the conditions that those measures are fully implemented.

Following the adoption of a favourable opinion, the Commission shall always explore the possibility of adopting, common technical standards for the device or group of devices concerned and adopt them where possible (in accordance with Article 7).

In the case of an unfavourable MDCG opinion, the special notified body shall not yet deliver the certificate of conformity. Nevertheless, the special notified body may submit new information in response to the explanation included in the MDCG assessment. If the new information is substantially different to that which has been previously submitted the MDCG shall reassess the application.

At the request of the manufacturer, the Commission shall organise a hearing allowing discussion on the scientific grounds for the unfavourable scientific assessment and any action that the manufacturer may take or data that may be submitted to address the MDCG concerns.

9. Where deemed necessary for the protection of patient safety and public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 to determine, specific categories or groups of devices, other than devices referred to in paragraph 1, to which paragraphs 1 to 8 shall apply during a predefined period of time.

Measures pursuant to this paragraph may be justified only by one or more of the criteria referred to in paragraph 2.

10. The Commission shall make a summary of the opinion referred to in paragraph 6 and 7 accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.

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

12. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the documentation provided in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

13. The company concerned shall not be charged for the additional cost due to this assessment.

Amendment 369

Proposal for a regulation Article 44 b (new)

Text proposed by the Commission

Amendment

Article 44b

Five years after the entry into force of this Regulation, the Commission shall publish a report on the experience acquired as a result of the operation of the procedure referred to in Article 44a. The report shall assess in particular how many products were subject to an additional assessment, what factors triggered the assessment and what was the final decision on the products. It shall also analyse the effects of the full impact of the new rules on

Amendment 167

Proposal for a regulation Article 45 – paragraph 1

Text proposed by the Commission

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

Amendment

1. ***Before issuing a certificate, the notified conformity assessment body shall take into account any findings set out in the clinical investigation report referred to in Article 59(4).*** The certificates issued by the notified bodies in accordance with Annexes VIII, IX and X shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates is set out in Annex XII.

Amendment 168

Proposal for a regulation Article 45 – paragraph 3

Text proposed by the Commission

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

Amendment

3. Where a notified body finds that requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision ***and shall notify them to the competent authorities of the Member States in which the medical device is manufactured and placed on the market, the Commission and the MDCG.***

Amendment 169

Proposal for a regulation Article 46 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. It shall notify the competent authorities of the Member States affected by the manufacture and placing on the market of the relevant medical device, the Commission and the MDCG.

Amendment 170

Proposal for a regulation Article 47 – paragraph 1

Text proposed by the Commission

Amendment

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

1. By way of derogation from Article 42, any competent authority may authorise, on duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific device for which the procedures referred to in Article 42 have not been carried out and use of which is in the interest of public health or patient safety, ***provided that the MDCG has authorised it. This derogation shall be possible only if the manufacturer submits the requisite clinical data to the competent authority within the prescribed period.***

Amendment 171

Proposal for a regulation Article 47 – paragraph 2

Text proposed by the Commission

Amendment

2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1

2. The Member State shall inform the Commission, ***the notified body responsible for assessing the relevant medical device, the MDCG*** and the other Member States of any decision to authorise the placing on the

where such authorisation is granted for use other than for a single patient.

market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.

Amendment 262

Proposal for a regulation Chapter VI - title

Text proposed by the Commission

Chapter VI
Clinical evaluation and clinical investigations

Amendment

Chapter V*
Clinical evaluation and clinical investigations

** As a consequence of this amendment, this Chapter will cover Articles 49 to 60*

Amendment 172

Proposal for a regulation Article 49 – paragraph 3

Text proposed by the Commission

3. Where demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performances intended and the claims of the manufacturer. The adequacy of demonstration of conformity with the general safety and performance requirements based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, has to be duly substantiated in the technical documentation referred to in Annex II.

Amendment

3. ***Except for class III devices***, where demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performances intended and the claims of the manufacturer. The adequacy of demonstration of conformity with the general safety and performance requirements based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, has to be duly substantiated in the technical documentation referred to in Annex II.

Exemption from demonstration of conformity with general safety and

performance requirements based on clinical data under the first subparagraph shall be subject to prior approval by the competent authority.

Amendment 173

Proposal for a regulation

Article 49 – paragraph 5 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

For devices classified as class III and implantable devices, the summary of safety and clinical performance referred to in Article 26(1) shall be updated at least annually with clinical evaluation reports.

Amendment 174

Proposal for a regulation

Article 50 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) to verify that, under normal conditions of use, devices are designed, manufactured and packaged in such a way that they are suitable for one or more of the specific purposes of a medical device referred to in number (1) of Article 2(1), and achieve the performances intended as specified by the manufacturer;

(a) to verify that, under normal conditions of use, devices are designed, manufactured and packaged in such a way that they are suitable for one or more of the specific purposes of a medical device referred to in number (1) of Article 2(1), and achieve the performances intended as specified by the manufacturer **or sponsor**;

Amendment 175

Proposal for a regulation

Article 50 – paragraph 1 – point b

Text proposed by the Commission

Amendment

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

(b) to verify **the clinical safety and efficacy of the device, including the intended benefits to the patient, when used for the intended purpose, in the target population and in accordance with the instructions of use**;

Amendment 177

Proposal for a regulation Article 51 – paragraph 2

Text proposed by the Commission

The sponsor of a clinical investigation shall submit an application to the Member State(s) in which the investigation is to be conducted accompanied by the documentation referred to in Chapter II of Annex XIV. Within *six* days after receipt of the application, the Member State concerned shall notify the sponsor whether the clinical investigation falls within the scope of this Regulation and whether the application is complete.

Where the Member State has not notified the sponsor within the time period referred to in the first subparagraph, the clinical investigation shall be considered as falling within the scope of this Regulation and the application shall be considered complete.

Amendment

The sponsor of a clinical investigation shall submit an application to the Member State(s) in which the investigation is to be conducted accompanied by the documentation referred to in Chapter II of Annex XIV. 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.

In case of more than one Member State concerned, where a Member State disagrees with the coordinating Member State on whether the clinical investigation should be approved, on grounds other than intrinsically national, local or ethical concerns, the Member States concerned shall make an attempt to agree on a conclusion. If no conclusion is found, the Commission shall take a decision after having consulted the Member States concerned, and if appropriate, having taken advice from the MDCG. In case where the concerned Member States object the clinical investigation for intrinsically national, local or ethical concerns the clinical investigation should not take place in the Member States concerned.

Where the Member State has not notified the sponsor within the time period referred to in the first subparagraph, the clinical investigation shall be considered as falling within the scope of this Regulation and the application shall be considered complete.

Amendment 178

Proposal for a regulation

Article 51 – 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 investigation 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 **six** days following receipt of the comments or of the completed application, the clinical investigation shall be considered as falling within the scope of this Regulation and the application shall be considered complete.

Amendment 179

Proposal for a regulation

Article 51 – 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.

Amendment 180

Proposal for a regulation

Article 51 – paragraph 6

Text proposed by the Commission

6. Member States shall ensure that the persons assessing the application do not have conflicts of interest and that they are independent of the sponsor, the institution of the investigation site(s) and the investigators involved, as well as free of any other undue influence.

Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. In the assessment, the view of at least one person whose primary area of

Amendment

6. Member States shall ensure that the persons assessing the application do not have conflicts of interest and that they are independent of the sponsor, the institution of the investigation site(s) and the investigators involved, as well as free of any other undue influence.

Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. In the assessment, the view of at least one person whose primary area of

interest is non-scientific shall be taken into account. The view of *at least one patient* shall be taken into account.

interest is non-scientific shall be taken into account. The view of *patients* shall be taken into account.

The list of the reviewers should be made available to the sponsor

Amendment 181

Proposal for a regulation

Article 51 – paragraphs 6 a to 6 e (new)

Text proposed by the Commission

Amendment

6a. Every step in the clinical investigation, 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.

6b. Authorisation by the concerned Member State for conducting a clinical investigation under this Article shall be granted only after examination and approval by an independent ethics committee in accordance with the World Medical Association's Declaration of Helsinki.

6c. The examination of the Ethics Committee shall cover in particular the medical justification for the clinical investigation, the consent of the test subjects participating in the clinical investigation following the provision of full information about the clinical investigation and the suitability of the investigators and investigation facilities.

The ethics committee shall act in accordance with the respective laws and regulations of the country or countries in which the investigation is to be conducted

and must abide by all relevant international norms and standards. It shall also work with such efficiency as to enable the Member State concerned to comply with the procedural deadlines set out in this Chapter.

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.

The members of the Ethics Committee assessing the application for a clinical investigation shall be independent from the sponsor, the institution of the investigation site, and the investigators involved, as well as free of any other undue influence. Names, qualifications, and declaration of interest of the assessors of the application shall be made publicly available.

6d. Member States shall take the necessary measures to establish Ethics Committees in the field of clinical investigations where such committees do not exist, and to facilitate their work.

6e. The Commission shall facilitate cooperation of ethics committees and the sharing of best practices on ethical issues including the procedures and principles of ethical assessment.

The Commission shall develop guidelines on patient involvement in ethics committees, drawing upon existing good practices.

Amendment 182

Proposal for a regulation

Article 52 – paragraph 1 – point g a (new)

Text proposed by the Commission

Amendment

(ga) the methodology to be used, the number of subjects involved and the

intended result of the study.

Amendment 183

Proposal for a regulation

Article 52 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Upon completion of the clinical investigation, the sponsor shall enter in the electronic system referred to in Article 53a summary of its results drawn up in a way that is easy for a lay person to understand.

Amendment 184

Proposal for a regulation

Article 52 – paragraph 3 – point b

Text proposed by the Commission

Amendment

(b) protection of commercially sensitive information;

(b) protection of commercially sensitive information; ***data on adverse events and safety data shall not be considered commercially sensitive information;***

Amendment 185

Proposal for a regulation

Article 53 – paragraphs 1, 2 and 2a (new)

Text proposed by the Commission

Amendment

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to create the single identification numbers for on clinical investigations referred to in Article 51(1) and to collate and process the following information:

(a) the registration of on clinical investigations in accordance with Article 52;

(b) the exchange of information between the Member States and between them and

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to create the single identification numbers for on clinical investigations referred to in Article 51(1) and to collate and process the following information:

(a) the registration of on clinical investigations in accordance with Article 52;

(b) the exchange of information between the Member States and between them and

the Commission in accordance with Article 56;

(c) the information related to on clinical investigations conducted in more than one Member State in case of a single application in accordance with Article 58;

(d) the reports on serious adverse events and device deficiencies referred to in Article 59(2) in case of single application in accordance with Article 58.

2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article [...] of Regulation (EU) No [Ref. of future Regulation on clinical trials]. With the exception of the information referred to in Article 52, the information collated and processed in the electronic system shall be accessible only to the Member States and to the Commission.

the Commission in accordance with Article 56;

(c) the information related to on clinical investigations conducted in more than one Member State in case of a single application in accordance with Article 58;

(d) the reports on serious adverse events and device deficiencies referred to in Article 59(2) in case of single application in accordance with Article 58.

(da) the clinical investigation report and summary submitted by the sponsor in accordance with Article 57(3)

2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article [...] of Regulation (EU) No [Ref. of future Regulation on clinical trials]. With the exception of the information referred to in Article 52 ***and in points (d) and (da) of Article 53***, the information collated and processed in the electronic system shall be accessible only to the Member States and to the ***Commission. The Commission shall also ensure that healthcare professionals have access to the electronic system.***

The information referred to in points (d) and (da) of Article 53 shall be accessible to the public in accordance with Article 52(3) and (4).

2a. Upon a reasoned request, all information on a specific medical device available in the electronic system shall be made accessible to the party requesting it, save where the confidentiality of all or parts of the information is justified in accordance with Article 52(3).

Amendment 186

Proposal for a regulation Article 55 – paragraph 2 a (new)

2a. Assessment by the Member State of the request by the sponsor for a substantial modification to a clinical investigation shall be in accordance with Article 51(6).

Amendment 187

Proposal for a regulation Article 56 – paragraph 1

Text proposed by the Commission

1. Where a Member State has refused, suspended or terminated a clinical investigation, or has called for a substantial modification or temporary halt of a clinical investigation, or has been notified by the sponsor of the early termination of a clinical investigation on safety grounds, that Member State shall communicate its decision and the grounds **therefor** to all Member States and the Commission by means of the electronic system referred to in Article 53.

Amendment

1. Where a Member State has refused, suspended or terminated a clinical investigation, or has called for a substantial modification or temporary halt of a clinical investigation, or has been notified by the sponsor of the early termination of a clinical investigation on safety **or efficacy** grounds, that Member State shall communicate **such facts and** its decision and the grounds **for that decision** to all Member States and the Commission by means of the electronic system referred to in Article 53.

Amendment 188

Proposal for a regulation Article 57 – paragraph 1

Text proposed by the Commission

1. If the sponsor has temporarily halted a clinical investigation on safety grounds, he shall inform the Member States concerned within 15 days of the temporary halt.

Amendment

1. If the sponsor has temporarily halted a clinical investigation on safety **or efficacy** grounds, he shall inform the Member States concerned within 15 days of the temporary halt.

Amendment 189

Proposal for a regulation

Article 57 – paragraph 2

Text proposed by the Commission

2. The sponsor shall notify each Member State concerned of the end of a clinical investigation in relation to that Member State, providing a justification in the event of early termination. That notification shall be made within 15 days from the end of the clinical investigation in relation to that Member State.

If the investigation is conducted in more than one Member State the sponsor shall notify all Member States concerned of the overall end of the clinical investigation. That notification shall be made within 15 days from the *overall* end of the clinical investigation.

Amendment

2. The sponsor shall notify each Member State concerned of the end of a clinical investigation in relation to that Member State, providing a justification in the event of early termination, *so that all Member States can inform sponsors conducting similar clinical investigations at the same time within the Union of the results of that clinical investigation.* That notification shall be made within 15 days from the end of the clinical investigation in relation to that Member State.

If the investigation is conducted in more than one Member State the sponsor shall notify all Member States concerned of the *early termination in one Member State and of the overall end of the clinical investigation. Information on the reasons for the early termination of the clinical investigation shall also be provided to all Member States, so that all Member States can inform sponsors conducting similar clinical investigations at the same time within the Union of the results of that clinical investigation.* That notification shall be made within 15 days from the end of the clinical investigation *in one or more Member States.*

Amendment 190

Proposal for a regulation

Article 57 - paragraph 3

Text proposed by the Commission

3. *Within* one year from the end of the clinical investigation, the sponsor shall submit to the Member States concerned *a summary of* the results of the clinical investigation in form of a clinical investigation report referred to in Section 2.7 of Chapter I of Annex XIV. Where, for

Amendment

3. *Irrespective of the outcome of the clinical investigation, within* one year from the end of the clinical performance study *or from its early termination*, the sponsor shall submit to the Member States concerned the results of the clinical investigation in form of a clinical

scientific reasons, it is not possible to submit the clinical investigation report within one year, it shall be submitted as soon as it is available. In this case, the clinical investigation plan referred to in Section 3 of Chapter II of Annex XIV shall specify when the results of the clinical investigation are going to be submitted, together with *an explanation*.

investigation report referred to in Section 2.7 of Chapter I of Annex XIV. *It shall be accompanied by a summary presented in terms that are easily understandable to a layperson. Both the report and the summary shall be submitted by the sponsor by means of the electronic system referred to in Article 53.* Where, for *justified* scientific reasons, it is not possible to submit the clinical investigation report within one year, it shall be submitted as soon as it is available. In this case, the clinical investigation plan referred to in Section 3 of Chapter II of Annex XIV shall specify when the results of the clinical investigation are going to be submitted, together with *a justification*.

3a. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 in order to define the content and structure of the layperson's summary.

The Commission shall be empowered to adopt delegated acts in accordance with Article 89 in order to establish rules for the communication of the clinical investigation report.

For cases where the sponsor decides to share raw data on a voluntary basis, the Commission shall produce guidelines for the formatting and sharing of the data.

Amendment 191

Proposal for a regulation Article 58 – paragraph 1

Text proposed by the Commission

1. By means of the electronic system referred to in Article 53, the sponsor of a clinical investigation *to be conducted in more than one Member State* may submit, for the purpose of Article 51, *a single* application that, upon receipt, is transmitted electronically to the Member States concerned.

Amendment

1. By means of the electronic system referred to in Article 53, the sponsor of a clinical investigation may submit, for the purpose of Article 51, *the* application that, upon receipt, is transmitted electronically to the Member States concerned.

Amendment 192

Proposal for a regulation

Article 58 – paragraph 2

Text proposed by the Commission

2. In the single application, the sponsor shall propose one of the Member States concerned as coordinating Member State. If that Member State does not wish to be the coordinating Member State, it shall agree, within six days of submission of the single application, with another Member State concerned that the latter shall be the coordinating Member State. If no other Member State accepts to be the coordinating Member State, the Member State proposed by the sponsor shall be the coordinating Member State. If another Member State than the one proposed by the sponsor becomes coordinating Member State, the deadline referred to in Article 51(2) shall start on the day following the acceptance.

Amendment

2. Concerned Member States shall agree, within six days of submission of the single application, **which** Member State shall be the coordinating Member State. Member States and the Commission shall agree, in the framework of the attributions of the MDCG, on clear rules for designating the coordinating Member State.

Amendment 193

Proposal for a regulation

Article 58 – paragraph 3 – subparagraph 2 – point b

Text proposed by the Commission

(b) establish the results of the coordinated assessment in a report to be **taken into account** by the other Member States concerned when deciding on the sponsor's application in accordance with Article 51(5).

Amendment

(b) establish the results of the coordinated assessment in a report to be **approved** by the other Member States concerned when deciding on the sponsor's application in accordance with Article 51(5).

Amendment 194

Proposal for a regulation

Article 58 – paragraph 5

Text proposed by the Commission

5. For the purpose of Article 57(3), the sponsor shall submit the clinical

Amendment

deleted

performance study report to the Member States concerned by means of the electronic system referred to in Article 53.

Amendment 195

Proposal for a regulation

Article 59 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

Information regarding incidents that are caused by user errors shall also be collected, as they are a major source of incidents with medical devices. This information shall contribute to improve the safety and knowledge of the device.

Amendment 196

Proposal for a regulation

Article 59 – paragraph 1 – subparagraph 1 b (new)

Text proposed by the Commission

Amendment

Member States shall put in place non-electronic formats of reporting to ensure that patients who do not have online access are able to report.

Amendment 197

Proposal for a regulation

Article 59 – paragraph 4 – subparagraph 1

Text proposed by the Commission

Amendment

In the case of a clinical investigation for which the sponsor has used the single application referred to in Article 58, the sponsor shall report any event as referred to in *paragraph 2* by means of the electronic system referred to in Article 53. Upon receipt, this report shall be transmitted electronically to all Member States concerned.

In the case of a clinical investigation for which the sponsor has used the single application referred to in Article 58, the sponsor shall report any event as referred to in *paragraphs 1 and 2* by means of the electronic system referred to in Article 53. Upon receipt, this report shall be transmitted electronically to all Member States concerned.

Amendment 263

Proposal for a regulation Chapter VII - title

Text proposed by the Commission

Chapter VII

Vigilance and market surveillance

Amendment

Chapter IX*

Vigilance and market surveillance

** As a consequence of this amendment, this Chapter will cover Articles 61 to 75*

Amendment 198

Proposal for a regulation Article 61

Text proposed by the Commission

1. Manufacturers of devices other than custom-made or investigational devices, shall report through the electronic system referred to in Article 62 the following:

(a) any *serious* incident in respect of devices made available on the Union market;

(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market if the reason for the field safety corrective action is not limited to the device made available in the third country.

Manufacturers shall make the report referred to in the first subparagraph without delay, and no later than 15 days after they have become aware of the event and the causal relationship with their device or that such causal relationship is reasonably possible. The time period for

Amendment

1. Manufacturers of devices other than custom-made or investigational devices, shall report through the electronic system referred to in Article 62 the following:

(a) any incident, *including date and place of incident, with an indication of whether it is serious in accordance with the definition under Article 2*, in respect of devices made available on the Union market; *where available, the manufacturer shall include information on the patient or user and healthcare professional involved in the incident;*

(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market if the reason for the field safety corrective action is not limited to the device made available in the third country.

Manufacturers shall make the report referred to in the first subparagraph without delay, and no later than 15 days after they have become aware of the event and the causal relationship with their device or that such causal relationship is reasonably possible. The time period for

reporting shall take account of the severity of the incident. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.

2. For similar *serious* incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented, manufacturers may provide periodic summary reports instead of individual incident reports, on condition that the competent authorities referred to in points (a), (b) and (c) of Article 62(5) have agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.

3. The Member States shall take all appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities suspected *serious* incidents referred to in point (a) of paragraph 1.

They shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall ***take the necessary steps to ensure that*** the manufacturer of the device concerned ***is informed of the incident***. The manufacturer shall ensure the appropriate follow-up.

The Member States shall ***coordinate between them the development of standard web-based structured*** forms for reporting of *serious* incidents by healthcare professionals, users and patients.

reporting shall take account of the severity of the incident. Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.

2. For similar incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented, manufacturers may provide periodic summary reports instead of individual incident reports, on condition that the competent authorities referred to in points (a), (b) and (c) of Article 62(5) have agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.

3. The Member States shall take all appropriate measures, ***including targeted information campaigns***, to encourage ***and enable*** healthcare professionals, ***including doctors and pharmacists***, users and patients to report to their competent authorities suspected incidents referred to in point (a) of paragraph 1. They ***shall inform the Commission of those measures***.

The competent authorities of the Member States shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall ***inform*** the manufacturer of the device concerned ***without delay***. The manufacturer shall ensure the appropriate follow-up.

The competent authority of a Member State shall notify the reports referred to in the first subparagraph to the electronic system referred to in Article 62 without delay, unless the same incident has already been reported by the manufacturer.

The ***Commission, in cooperation with the Member States and in consultation with the relevant stakeholders***, shall ***develop*** standard forms for ***electronic and non-electronic*** reporting of incidents by healthcare professionals, users and

4. Manufacturers of custom-made devices shall report any *serious* incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the device in question has been made available.

patients.

4. Manufacturers of custom-made devices shall *immediately* report any incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the device in question has been made available.

Amendment 199

Proposal for a regulation Article 62

Text proposed by the Commission

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:

(a) the reports by manufacturers on *serious* incidents and field safety corrective actions referred to in Article 61(1);

(b) the periodic summary reports by manufacturers referred to in Article 61(2);

(c) the reports by competent authorities on *serious* incidents referred to in the second subparagraph of Article 63(1)

(d) the reports by manufacturers on trends referred to in Article 64;

(e) the field safety notices by manufacturers referred to in Article 63(5);

(f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 63(4) and (7).

2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission and to the notified bodies.

Amendment

1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:

(a) the reports by manufacturers on incidents and field safety corrective actions referred to in Article 61(1);

(b) the periodic summary reports by manufacturers referred to in Article 61(2);

(c) the reports by competent authorities on incidents referred to in the second subparagraph of Article 63(1)

(d) the reports by manufacturers on trends referred to in Article 64;

(da) the periodic safety update reports drawn up by manufacturers, as referred to in Article 63a;

(e) the field safety notices by manufacturers referred to in Article 63(5);

(f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 63(4) and (7).

2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission, to the notified bodies, ***to healthcare professionals and also to manufacturers where the***

3. The Commission shall ensure that **healthcare professionals and** the public **have** appropriate **levels** of access to the electronic system.

4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.

5. The reports on serious incidents and field safety corrective actions referred to in points (a) and (b) of Article 61(1), the periodic summary reports referred to in Article 61(2), the reports on **serious** incidents referred to in the second subparagraph of Article 63(1) and the trend reports referred to in Article 64 shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States:

- (a) the Member State where the incident occurred;
- (b) the Member State where the field safety corrective action is being or is to be undertaken;
- (c) the Member State where the manufacturer has his registered place of business;
- (d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 45 for the device in question, is established.

information pertains to their own product.

3. The Commission shall ensure that the public **has an** appropriate **level** of access to the electronic system. ***In case where information is requested on a specific medical device, that information shall be made available without delay and within 15 days at the latest.***

4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.

5. The reports on serious incidents and field safety corrective actions referred to in points (a) and (b) of Article 61(1), the periodic summary reports referred to in Article 61(2), the reports on incidents referred to in the second subparagraph of Article 63(1) and the trend reports referred to in Article 64 shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States:

- (a) the Member State where the incident occurred;
- (b) the Member State where the field safety corrective action is being or is to be undertaken;
- (c) the Member State where the manufacturer has his registered place of business;
- (d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 45 for the device in question, is established.

5a. The reports and information referred to in Article 62(5), shall also be automatically transmitted for the device in question via the electronic system to the notified body that issued the certificate in accordance with Article 45.

Amendment 200

Proposal for a regulation

Article 63 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Member States shall take the necessary steps to ensure that any information regarding **a serious** incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 61 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer.

Amendment

Member States shall take the necessary steps to ensure that any information regarding **an** incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 61 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer. ***The competent authority shall take into account the views of all relevant stakeholders, including patient and healthcare professionals' organisations.***

Amendment 201

Proposal for a regulation

Article 63 – paragraph 1 – subparagraph 2

Text proposed by the Commission

If in the case of reports received in accordance with Article 61(3) the competent authority ascertains that the reports relate to a serious incident it shall notify without delay those reports to the electronic system referred to in Article 62, unless the same incident has already been reported by the manufacturer.

Amendment

deleted

Amendment 202

Proposal for a regulation

Article 63 – paragraph 2

Text proposed by the Commission

2. The national competent authorities shall

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 incident.

carry out a risk assessment with regard to reported 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, *as well as they shall take into account patients' opinions.*

Amendment 203

Proposal for a regulation

Article 63 – paragraph 3 – subparagraph 1

Text proposed by the Commission

In the case of devices referred to in the first subparagraph of Article 1(4) and where the *serious* incident or field safety corrective action may be related to a substance which, if used separately, would be considered to be a medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 6 shall inform the relevant competent authority for medicinal products, or the European Medicines Agency (EMA), that was consulted by the notified body in accordance with the second subparagraph of Article 42(2).

Amendment

In the case of devices referred to in the first subparagraph of Article 1(4) and where the incident or field safety corrective action may be related to a substance which, if used separately, would be considered to be a medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 6 shall inform the relevant competent authority for medicinal products, or the EMA, that was consulted by the notified body in accordance with the second subparagraph of Article 42(2).

Amendment 204

Proposal for a regulation

Article 63 – paragraph 3 – subparagraph 2

Text proposed by the Commission

In the case of devices covered by this Regulation in accordance with point (e) of

Amendment

In the case of devices covered by this Regulation in accordance with point (e) of

Article 1(2) and where the *serious* incident or field safety corrective action may be related to the tissues or cells of human origin utilised for the manufacture of the device, the competent authority or the coordinating competent authority referred to in paragraph 6 shall inform the relevant competent authority for human tissues and cells that was consulted by the notified body in accordance with the third subparagraph of Article 42(2).

Article 1(2) and where the incident or field safety corrective action may be related to the tissues or cells of human origin utilised for the manufacture of the device, the competent authority or the coordinating competent authority referred to in paragraph 6 shall inform the relevant competent authority for human tissues and cells that was consulted by the notified body in accordance with the third subparagraph of Article 42(2).

Amendment 205

Proposal for a regulation Article 63 – paragraph 4

Text proposed by the Commission

4. After carrying out the assessment, the evaluating competent authority shall, through the electronic system referred to in Article 62, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or imposed on him to minimise the risk of recurrence *of a serious incident*, including information on the underlying events and the outcome of its assessment.

Amendment

4. After carrying out the assessment, the evaluating competent authority shall, through the electronic system referred to in Article 62, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or imposed on him to minimise the risk of recurrence, including information on the underlying events and the outcome of its assessment.

Amendment 206

Proposal for a regulation Article 63 – paragraph 6 – subparagraph 1 – point a

Text proposed by the Commission

(a) where similar *serious* incidents related to the same device or type of device of the same manufacturer occur in more than one Member State;

Amendment

(a) where similar incidents related to the same device or type of device of the same manufacturer occur in more than one Member State;

Amendment 207

Proposal for a regulation Article 63 – paragraph 7 – subparagraph 1 – point a

Text proposed by the Commission

Amendment

(a) to monitor the investigation of the *serious* incident by the manufacturer and the corrective action to be taken;

(a) to monitor the investigation of the incident by the manufacturer and the corrective action to be taken;

Amendment 208

Proposal for a regulation

Article 63 – paragraph 7 – subparagraph 1 – point b

Text proposed by the Commission

Amendment

(b) to consult with the notified body that issued a certificate in accordance with Article 45 for the device in question regarding the impact of the *serious* incident on the certificate;

(b) to consult with the notified body that issued a certificate in accordance with Article 45 for the device in question regarding the impact of the incident on the certificate;

Amendment 209

Proposal for a regulation

Article 63 a (new)

Text proposed by the Commission

Amendment

Article 63 a

Periodic safety update reports

1. Manufacturers of medical devices classified as class III shall report to the electronic system referred to in Article 62:

(a) summaries of data relevant to the benefits and risks of the medical devices, including results of all studies with a consideration of their potential impact on the certification;

(b) a scientific evaluation of the risk-benefit ratio of the medical device;

(c) all data relating to the volume of sales of the medical devices including an estimate of the population exposed to the medical device.

2. Manufacturers shall submit periodic safety update reports to the competent authorities immediately upon request or at

least once a year during the first 2 years following initial placing on the market of that medical device.

3. The MDCG shall assess the periodic safety update reports to determine whether there are new risks or whether risks have changed, or whether there are changes to the risk-benefit ratio of the medical device.

4. Following the assessment of the periodic safety update reports, the MDCG shall consider whether any action regarding the medical device concerned is necessary. The MDCG shall inform the notified body in case of unfavourable scientific assessment. In this case, the notified body shall maintain, vary, suspend or revoke the authorisation as appropriate.

Amendment 210

Proposal for a regulation Article 64 – paragraph 1

Text proposed by the Commission

Manufacturers of devices classified in class IIb and III shall report to the electronic system referred to in Article 62 any statistically significant increase in the frequency or severity of ***incidents that are not serious*** incidents or of expected undesirable side-effects that have a significant impact on the risk-benefit analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents or expected undesirable side-effects in respect of the device, or category or group of devices, in question during a specific time period as established in the manufacturer's conformity assessment. Article 63 shall

Amendment

Manufacturers of devices classified in class IIb and III shall report to the electronic system referred to in Article 62 any statistically significant increase in the frequency or severity of ***all*** incidents or of expected undesirable side-effects that have a significant impact on the risk-benefit analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents or expected undesirable side-effects in respect of the device, or category or group of devices, in question during a specific time period as established in the manufacturer's conformity assessment. Article 63 shall apply.

apply.

Amendment 211

Proposal for a regulation Article 64 a (new)

Text proposed by the Commission

Amendment

Article 64a

Medical devices which fall under legal acts of the European Union concerning the quality and safety of blood

1. This Regulation is without prejudice to existing and implemented provisions at European level relating to the collection, testing, processing, storage and distribution of blood and blood components.

2. This Regulation is without prejudice to national laws and Union legislation in the field of traceability and vigilance in the field of blood and blood components which have a higher standard than this Regulation. They should be retained in the interests of patients.

Amendment 212

Proposal for a regulation Article 66 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) typology of *serious* incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;

(a) typology of incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;

Amendment 213

Proposal for a regulation Article 66 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) harmonised forms for the reporting of *serious* incidents and field safety corrective actions, periodic summary reports and trend reports by manufacturers as referred to in Articles 61 and 64;

(b) harmonised forms for the reporting of incidents and field safety corrective actions, periodic summary reports and trend reports by manufacturers as referred to in Articles 61 and 64;

Amendment 214

Proposal for a regulation

Article 66 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) timelines for the reporting of *serious* incidents and field safety corrective actions, periodic summary reports and trend reports by manufacturers, taking into account the severity of the event to be reported as referred to in Articles 61 and 64;

(c) timelines for the reporting of incidents and field safety corrective actions, periodic summary reports and trend reports by manufacturers, taking into account the severity of the event to be reported as referred to in Articles 61 and 64;

Amendment 215

Proposal for a regulation

Article 66 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

In drafting the implementing acts, the Commission shall seek the prior advice of the MDAC

Amendment 216

Proposal for a regulation

Article 67 – paragraphs 1 to 2

Text proposed by the Commission

Amendment

1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples.

1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples.

They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and, **where necessary and justified**, enter the premises of economic operators and take the necessary samples of devices. They may destroy or otherwise render inoperable devices presenting a **serious** risk where they deem it necessary.

They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and enter **and inspect** the premises of economic operators and take the necessary samples of devices **for analysis by an official laboratory**. They may destroy or otherwise render inoperable devices presenting a risk where they deem it necessary.

1 a. The competent authorities shall designate inspectors who shall be empowered to carry out the checks referred to in paragraph 1. The checks shall be carried out by the inspectors of the Member State in which the economic operator is located. These inspectors may be assisted by experts appointed by the competent authorities.

1b. Unannounced inspections may also be carried out. The organisation and implementation of such inspections shall always take account of the principle of proportionality, particularly with reference to the hazard potential of a particular product.

1c. Following each inspection carried out under paragraph 1, the competent authority shall draw up a report on compliance by the economic operator inspected with the legal and technical requirements applicable under this Regulation and any corrective actions needed.

1d. The competent authority which carried out the inspection shall communicate the content of this report to the inspected economic operator. Before adopting the report, the competent authority shall give the inspected economic operator the opportunity to submit comments. The final inspection report as referred to in paragraph 1b shall be entered into the electronic system provided for in Article 68.

1e. Without prejudice to any international agreements concluded between the Union and third countries, checks as referred in paragraph 1 may also take place in the premises of an economic operator located in a third country, if the device is intended to be made available on the Union market.

2. The Member States shall periodically review and assess the **functioning** of their surveillance **activities**. Such reviews and assessments shall be carried out at least every **four** years and the results thereof shall be communicated to the other Member States and the Commission. The Member **State concerned** shall make a summary of the results accessible to the public.

2. The Member States shall **draw up strategic surveillance plans covering their planned surveillance activities, as well as the human and material resources needed to carry these activities out. Member States shall** periodically review and assess the **implementaion** of their surveillance **plans**. Such reviews and assessments shall be carried out at least every **two** years and the results thereof shall be communicated to the other Member States and the Commission. **The Commission may make recommendations for adjustments to the surveillance plans.** The Member States shall make a summary of the results **and of the Commission's recommendations** accessible to the public.

Amendment 217

Proposal for a regulation Article 68 – paragraph 2

Text proposed by the Commission

2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States **and to the Commission**.

Amendment

2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States, **to the Commission, to the notified bodies, to the EMA and to healthcare professionals. The Commission shall also ensure that the public has an appropriate level of access to the electronic system. In particular, it shall ensure that, in case information is requested on a specific medical device, it is made available without delay and within 15 days. The Commission, in consultation with the Medical Devices Coordination Group, shall provide an**

overview of this information, every 6 months, for the public and healthcare professionals. This information shall be accessible through the European databank in Article 27

Amendment 218

Proposal for a regulation

Article 68 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

The information in to relation to Article 68 paragraph 1, points a, b, c and d shall be made available to the MDCG who shall communicate it at the first meeting of the MDAC after the information becomes available.

Amendment 219

Proposal for a regulation

Article 69 – paragraph 1

Text proposed by the Commission

Amendment

Where the competent authorities of a Member State, based on vigilance data or other information, have sufficient reason to believe that a device presents a risk to the health or safety of patients, users or other persons, they shall carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by the device. The relevant economic operators shall cooperate as necessary with the competent authorities.

Where the competent authorities of a Member State, based on vigilance data or other information, have sufficient reason to believe that a device presents a risk to the health or safety of patients, users or other persons, they shall carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by the device. The relevant economic operators shall cooperate as necessary with the competent authorities. ***In connection with that evaluation, the competent authorities shall inform the notified assessment bodies, in the case of class IIa, IIb and III devices, and the other competent authorities of the findings of the evaluation and the measures that are to be taken on the basis of those findings.***

Amendment 220

Proposal for a regulation

Article 69 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Where the competent authorities of a Member State, based on vigilance data or other information, have reason to believe that a device presents a risk to the health or safety of patients, users or other persons, they may carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by the device. The relevant economic operators shall cooperate as necessary with the competent authorities.

Amendment 221

Proposal for a regulation

Article 70 – paragraph 1

Text proposed by the Commission

Amendment

1. Where, having performed an evaluation pursuant to Article 69, the competent authorities find that the device, which presents a risk to the health or safety of patients, users or other persons, does not comply with the requirements laid down in this Regulation, they shall ***without delay*** require the relevant economic operator to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to prohibit or restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it within a reasonable period, proportionate to the nature of the risk.

1. Where, having performed an evaluation pursuant to Article 69, the competent authorities find that the device, which presents a risk to the health or safety of patients, users or other persons, does not comply with the requirements laid down in this Regulation, they shall ***immediately*** require the relevant economic operator to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to prohibit or restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it within a reasonable period ***that is clearly defined and communicated to the relevant economic operator***, proportionate to the nature of the risk.

Amendment 222

Proposal for a regulation

Article 70 – paragraph 2

Text proposed by the Commission

2. Where the competent authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 68.

Amendment

2. Where the competent authorities consider that non-compliance is not restricted to their national territory, they shall ***immediately*** inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 68.

Amendment 223

Proposal for a regulation

Article 70 – paragraph 3

Text proposed by the Commission

3. The economic operators shall ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.

Amendment

3. The economic operators shall ***without delay*** ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.

Amendment 224

Proposal for a regulation

Article 70 – paragraph 3 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

Where the concerned devices are to be recalled, the economic operator shall make all reasonable efforts to complete the recall before the end of clearly defined period communicated to it by the competent authority as referred to in paragraph 1,

Amendment 225

Proposal for a regulation

Article 70 – paragraph 4 – subparagraph 2

Text proposed by the Commission

They shall notify the Commission and the other Member States, ***without delay***, of those measures, by means of the electronic system referred to in Article 68.

Amendment

They shall notify the Commission and the other Member States, ***immediately***, of those measures, by means of the electronic system referred to in Article 68.

Amendment 226

Proposal for a regulation

Article 70 – paragraph 6

Text proposed by the Commission

6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any additional information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned. In the event of disagreement with the notified national measure, they shall ***without delay*** inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 68.

Amendment

6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any additional information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned. In the event of disagreement with the notified national measure, they shall ***immediately*** inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 68.

Amendment 227

Proposal for a regulation

Article 70 – paragraph 7

Text proposed by the Commission

7. Where, within ***two months*** of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

Amendment

7. Where, within ***one month*** of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

Amendment 228

Proposal for a regulation

Article 70 – paragraph 8

Text proposed by the Commission

8. All Member States shall ensure that appropriate restrictive measures are taken *without delay* in respect of the device concerned.

Amendment

8. All Member States shall ensure that appropriate restrictive measures are taken *immediately* in respect of the device concerned.

Amendment 229

Proposal for a regulation

Article 71 – paragraph 1

Text proposed by the Commission

1. Where, within *two months* of receipt of the notification referred to in Article 70(4), objections are raised by a Member State against a provisional measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Amendment

1. Where, within *one month* of receipt of the notification referred to in Article 70(4), objections are raised by a Member State against a provisional measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Amendment 230

Proposal for a regulation

Article 72 – paragraph 1

Text proposed by the Commission

1. Where, having performed an evaluation pursuant to Article 69, a Member State finds that although a device has been legally placed on the market or put into service, it presents a risk to the health or safety of patients, users or other persons or to other aspects of the protection of public

Amendment

1. Where, having performed an evaluation pursuant to Article 69, a Member State finds that although a device has been legally placed on the market or put into service, it presents a risk to the health or safety of patients, users or other persons or to other aspects of the protection of public

health, it shall require the relevant economic operator or operators to take all appropriate provisional measures to ensure that the device concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the device from the market or to recall it within a reasonable period, proportionate to the nature of the risk.

health, it shall ***immediately*** require the relevant economic operator or operators to take all appropriate provisional measures to ensure that the device concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the device from the market or to recall it within a reasonable period, proportionate to the nature of the risk.

Amendment 231

Proposal for a regulation

Article 73 – paragraph 1 – introductory part

Text proposed by the Commission

1. Without prejudice to Article 70, a Member State shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is proportionate to the non-compliance where it makes one of the following findings:

Amendment

1. Without prejudice to Article 70, a Member State shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is ***clearly defined and communicated and that is*** proportionate to the non-compliance where it makes one of the following findings:

Amendment 232

Proposal for a regulation

Article 73 – paragraph 2

Text proposed by the Commission

2. Where the economic operator does not put an end to the non-compliance within the period referred to in paragraph 1, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States ***without delay*** of those measures, by means of the electronic system referred to in Article 68.

Amendment

2. Where the economic operator does not put an end to the non-compliance within the period referred to in paragraph 1, the Member State concerned shall ***immediately*** take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States ***immediately*** of those measures, by means of the electronic system referred to in Article 68.

Amendment 233

Proposal for a regulation

Article 74 – paragraph 1

Text proposed by the Commission

1. Where a Member State, after having performed an evaluation which indicates a potential risk related to a device or a specific category or group of devices considers that the making available on the market or putting into service of such device or specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in order to protect the health and safety of patients, users or other persons or other aspects of public health, it **may** take any necessary and justified provisional measures.

Amendment

1. Where a Member State, after having performed an evaluation which indicates a potential risk related to a device or a specific category or group of devices considers that the making available on the market or putting into service of such device or specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in order to protect the health and safety of patients, users or other persons or other aspects of public health, it **shall** take any necessary and justified provisional measures.

Amendment 234

Proposal for a regulation

Article 75 – paragraph 2

Text proposed by the Commission

2. Except in cases where immediate action is necessary for reasons of serious risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time before any measure is adopted. If action has been taken without the economic operator being heard, he shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.

Amendment

2. Except in cases where immediate action is necessary for reasons of serious risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time **that is clearly determined** before any measure is adopted. If action has been taken without the economic operator being heard, he shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.

Amendment 235

Proposal for a regulation

Article 75 – paragraph 3

Text proposed by the Commission

3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that he has taken effective corrective action.

Amendment

3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator's **satisfactorily** demonstrating that he has taken effective corrective action.

Amendment 264

Proposal for a regulation
Chapter VIII - title

Text proposed by the Commission

Chapter VIII

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

Amendment

Chapter X*

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

** As a consequence of this amendment, this Chapter will cover Articles 76 to 83*

Amendment 236

Proposal for a regulation
Article 76 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Amendment 237

Proposal for a regulation

Article 77 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Amendment 238

Proposal for a regulation

Article 78 – paragraph 2 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

The Commission shall verify the competence of the members of the MDCG. The Commission shall make public the results of its verification in each instance and provide information about the competence of the members of the MDCG.

Amendment 239

Proposal for a regulation

Article 78 – paragraph 6

Text proposed by the Commission

Amendment

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

deleted

Amendment 240

Proposal for a regulation

Article 78 a (new)

Text proposed by the Commission

Amendment

Article 78a

Medical Device Advisory Committee

1. The Commission shall establish a multidisciplinary MDAC composed of experts and representatives of the relevant stakeholders in order to provide support, advice and expertise to the MDCG, the Commission and Member States on technical, scientific, social and economic aspects of regulating medical devices and in vitro diagnostic medical devices, such as in the field of medical technology, borderline cases involving medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products, as well as further aspects of the implementation of this Regulation.

2. When establishing the MDAC, the Commission shall ensure a broad, appropriate and balanced representation of the disciplines relevant for medical devices. The MDAC may establish under its responsibility expert panels for specific medical disciplines.

3. The MDAC shall be chaired by a representative of the Commission. The Commission shall provide the logistic support to its operations.

4. The MDAC shall establish its rules of procedure which shall enter into force after receiving a favourable opinion from the Commission.

5. The MDAC shall ensure an appropriate level of consultation of the EMA and the EFSA when deliberating borderline cases involving medicinal and food products.

6. The MDAC shall disclose the declarations of interest of its members.

Amendment 367

**Proposal for a regulation
Article 78 b (new)**

Article 78b

**Assessment Committee for Medical
Devices**

1. An Assessment Committee for Medical Devices (ACMD) is hereby established, under the principles of the highest scientific competences, impartiality, and transparency and to avoid potential conflicts of interest.

2. The ACMD shall be composed of:

- at least one member representing each of the medical fields referred to in paragraph 3. This member shall be a recognised expert in his/her field and be able to draw on additional expertise where necessary. These experts shall be appointed by way of a Commission call for interest, for a 3 year term that maybe renewed once;

- one representative of the EMA;

- one representative of the European Commission;

- three representatives of patients 'organizations appointed by the European Commission by way of a Commission call for interest.

The ACMD shall meet on request from the MDCG and the Commission, and its meetings shall be chaired by a Commission representative.

The Commission shall ensure that the composition of the ACMD corresponds to the expertise needed for the purpose of the assessment procedure in specific cases.

The Commission shall ensure the secretariat of this Committee.

3. The members of the ACMD shall be chosen for their competence and

experience in the corresponding field.

- *Anaesthesiology;*
- *Blood grouping or tissue typing;*
- *Blood transfusion and transplantation;*
- *Cardiology;*
- *Communicable diseases;*
- *Dentistry;*
- *Dermatology;*
- *Ear / Nose / Throat (ENT);*
- *Endocrinology;*
- *Gastroenterology;*
- *General/Plastic surgery;*
- *Medical genetics;*
- *Nephrology / Urology;*
- *Neurology;*
- *Obstetrics/Gynaecology;*
- *Oncology;*
- *Ophthalmology;*
- *Orthopaedics;*
- *Physical medicine;*
- *Pulmonology / Pneumology;*
- *Radiology.*

The Members of the ACMD shall perform their tasks with impartiality and objectivity. They shall be completely independent and shall neither seek nor take instructions from any government, notified body or manufacturer. Each member shall draw up a declaration of interests which shall be made publicly available.

In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending, deleting or supplementing the fields referred to in point a of this paragraph.

4. The ACMD shall fulfil the tasks

defined in Article 44a. When adopting a clinical assessment, the members of the ACMD shall use their best endeavours to reach consensus. If consensus cannot be reached, the ACMD shall decide by the majority of their members. In the case of the Coordination Group, the European Commission shall not take part in votes. Diverging opinion shall be annexed to the ACMD opinion.

5. The ACMD shall establish its rules of procedure which shall, in particular lay down procedures for the following:

- the adoption of the clinical assessments including in case of urgency;*
- the delegation of tasks to members.*

Amendment 366 and 368

Proposal for a regulation Article 80 – points a and b

Text proposed by the Commission

Amendment

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

(-a) to provide regulatory opinions on the basis of a clinical assessment delivered in accordance with Art 44a) (assessment procedure in specific cases);

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

(aa) to establish and document the high level principles of competence and qualification and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing). The qualification criteria shall address the

various functions within the conformity assessment process as well as the devices, technologies and areas covered by the scope of designation;

(ab) to review and approve the criteria of the competent authorities of Member States in respect of point (aa) of this Article;

(ac) to oversee the coordination group of Notified Bodies as specified in Article 39;

(ad) to support the Commission in providing an overview of vigilance data and market surveillance activities, including any preventive health protection measures taken, on a 6-monthly basis. This information shall be accessible through the European databank in Article 27;

(b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 44;

Amendment 243

Proposal for a regulation

Article 81 – paragraph 2 – point b

Text proposed by the Commission

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

Amendment

(b) to provide scientific advice **and technical assistance** regarding **the definition of** the state of the art in relation to specific devices, or a category or group of devices;

Amendment 244

Proposal for a regulation

Article 81 – paragraph 2 – point f

Text proposed by the Commission

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

Amendment

(f) to contribute to the development of **CTS as well as of international standards**

Amendment 245

Proposal for a regulation

Article 81 – paragraph 2 – point g a (new)

Text proposed by the Commission

Amendment

(ga) to provide scientific opinions and technical assistance to the Commission in relation to the requalification of single-use devices as reusable devices.

Amendment 246

Proposal for a regulation

Article 82 – paragraph 1

Text proposed by the Commission

Amendment

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

1. Members of the MDCG, *of the advisory panels to the MDCG* and staff of the EU reference laboratories shall not have financial or other interests in the medical device industry *or in the supply chain* which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. They shall declare any direct and indirect interests they may have in the medical device industry *or in the supply chain* and update this declaration whenever a relevant change occurs. The declaration of interests shall be *made publicly available on the Commission website*.

Amendment 247

Proposal for a regulation

Article 82 – paragraph 2

Text proposed by the Commission

Amendment

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

2. Experts *participating in the advisory committee referred to in Article 78a* shall be requested to declare their interests in the issue in question.

Amendment 248

Proposal for a regulation Article 83 – paragraph 1

Text proposed by the Commission

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

Amendment

The Commission and the Member States shall take all appropriate measures to **ensure** the establishment of **coordinated and harmonised** registers for **medical devices** to gather post-market experience related to the use of such devices. **Registers for medical devices in classes IIb and III shall be systematically established.** Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices.

Amendment 265

Proposal for a regulation Chapter IX - title

Text proposed by the Commission

Chapter IX

Confidentiality, data protection, funding, penalties

Amendment

Chapter XI*

Confidentiality, data protection, funding, penalties

** As a consequence of this amendment, this Chapter will cover Articles 84 to 87*

Amendment 249

Proposal for a regulation Article 86

Text proposed by the Commission

This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles. They shall inform the Commission and the other Member States at least three months before

Amendment

This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles. They shall inform the Commission and the other Member States at least three months before

the structure and level of fees is to be adopted.

the structure and level of fees is to be adopted. ***The structure and level of fees shall be publicly available on request.***

Amendment 250

Proposal for a regulation Article 87

Text proposed by the Commission

The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. The Member States shall notify those provisions to the Commission by [3 months prior to the date of application of the Regulation] and shall notify it without delay of any subsequent amendment affecting them.

Amendment

The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. ***The dissuasive nature of the penalty shall be determined in relation to the financial benefit obtained as a result of the infringement.*** The Member States shall notify those provisions to the Commission by [3 months prior to the date of application of the Regulation] and shall notify it without delay of any subsequent amendment affecting them.

Amendment 251

Proposal for a regulation Article 89 – paragraph 1

Text proposed by the Commission

1. The power to adopt the delegated acts referred to in Articles 2(2) and (3), **4(5)**, **8(2)**, 17(4), 24(7), 25(7), 29(2), 40(2), 41(4), **42(11)**, 45(5), 51(7), 53(3), 74(4) and 81(6) is conferred on the Commission subject to the conditions laid down in this Article.

Amendment

1. The power to adopt the delegated acts referred to in Articles 2(2) and (3), **15b (1)**, **16 (1)**, 17(4), 24(7), 25(7), 29(2), 40(2), 41(4), **44a (2)**, **44a(9)**, 45(5), 51(7), 53(3), **57(3a)**, 74(4), **78b(3)** and 81(6) is conferred on the Commission subject to the conditions laid down in this Article.

Amendment 252

Proposal for a regulation Article 89 – paragraph 2

Text proposed by the Commission

2. The delegation of power referred to in Articles 2(2) and (3), **4(5)**, **8(2)**, 17(4), 24(7), 25(7), 29(2), 40(2), 41(4), **42(11)**, 45(5), 51(7), 53(3), 74(4) and 81(6) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

Amendment

2. The delegation of power referred to in Articles 2(2) and (3), **15b (1)**, **16 (1)**, 17(4), 24(7), 25(7), 29(2), 40(2), 41(4), **44a (2)**, **44a(9)**, 45(5), 51(7), 53(3), **57(3a)**, 74(4), **78b(3)** and 81(6) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

Amendment 253

Proposal for a regulation
Article 89 – paragraph 3

Text proposed by the Commission

3. The delegation of power referred to in Articles 2(2) and (3), **4(5)**, **8(2)**, 17(4), 24(7), 25(7), 29(2), 40(2), 41(4), **42(11)**, 45(5), 51(7), 53(3), 74(4) and 81(6) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment

3. The delegation of power referred to in Articles 2(2) and (3), **15b (1)**, **16 (1)**, 17(4), 24(7), 25(7), 29(2), 40(2), 41(4) **44a (2)**, **44a(9)**, 45(5), 51(7), 53(3), **57(3a)**, 74(4), **78b(3)** and 81(6) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment 254

Proposal for a regulation
Article 89 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

The Commission shall, in drafting delegated acts, seek the advice of the MDCG.

Amendment 255

Proposal for a regulation

Article 94 – paragraph 4

Text proposed by the Commission

4. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.

Amendment

4. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application ***if the relevant delegated acts and implementing acts have been implemented.***

Amendment 266

Proposal for a regulation

Annex I – part I – point 2 – point c

Text proposed by the Commission

(c) reduce as far as possible the remaining risks by taking adequate protection measures, including alarms; and

Amendment

(c) reduce as far as possible the remaining risks by taking adequate protection measures, including alarms; ***hence, it should take into consideration the latest tools and concepts developed in hazard and risk assessment based on human-relevant models, pathways of toxicity, adverse outcome pathways and evidence-based toxicology;*** and

Amendment 267

Proposal for a regulation

Annex I – part I – point 2 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

Points (a), (b), (c) and (d) of this point shall not reduce the necessity for clinical investigation and post-market clinical

follow up to adequately address the risks, hazards and performance of devices.

Amendment 378

Proposal for a regulation Annex I – Part I – point 6 a (new)

Text proposed by the Commission

Amendment

6a. This Regulation now combines active implantable medical devices covered by Directive 90/385/EEC, and implantable medical devices covered by Directive 93/42/EEC, and places all active implantable medical devices and implantable devices of public health concern in the highest risk class III category attracting the strictest controls, and as the vast majority of class IIb implantable medical devices such as pins, bone-screws, plates, staples etc., have a long history of safe implantation within the human body, and as special notified bodies will be specifically designated for such class IIb implantable devices, class IIb implantable devices need not be subjected to the scrutiny procedure.

Amendment 268

Proposal for a regulation Annex I – part II – point 7 – point 7.1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) the physical compatibility between the different manufacturers' parts of the devices which consist of more than one implantable part;

Amendment 355

Proposal for a regulation Annex I – part II – point 7 – point 7.4

Text proposed by the Commission

Amendment

7.4. The devices shall be designed and

7.4. The devices shall be designed and

manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. ***Special attention shall be given to*** substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006⁵⁷, ***and to*** substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health ***and*** which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)⁵⁸.

manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. ***Medical devices or parts thereof that are invasive or come into contact with the body of patients, or (re)administer medicines, body liquids or other substances, including gases, to/from the body, or transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body, shall not contain, in concentrations above 0,1% by weight in homogeneous materials, substances*** which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006⁵⁷, ***or*** substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health ***or*** which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)⁵⁸, ***or are endocrine disrupters pursuant to Commission Recommendation (.../.../EU) on criteria for the identification of endocrine disrupters.***

The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to allow the use of such substances for a period not exceeding four years where any of the following conditions is fulfilled:

- their elimination or substitution via design changes or materials and components which do not require any of these substances is technically impracticable,

- the reliability of substitutes is not ensured,

- the combined negative health or patient safety impact caused by substitution is likely to outweigh the combined health or patient safety benefits thereof.

The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to renew the derogation if the criteria of the second subparagraph continue to be fulfilled.

Manufacturers wishing to apply for a derogation, a renewal of a derogation or the revoking of a derogation shall submit the following information to the Commission:

(a) the name, address and contact details of the applicant;

(b) information on the medical device and the specific uses of the substance in the material and components of the medical device for which an exemption, or its revocation, is requested and its particular characteristics;

(c) verifiable and referenced justification for an exemption, or its revocation, in line with the conditions established in the second subparagraph;

(d) an analysis of possible alternative substances, materials or designs, including, when available, information about independent research, peer-review studies and development activities by the applicant and an analysis of the availability of such alternatives;

(e) other relevant information;

(f) the proposed actions to develop, request the development and/or to apply possible alternatives including a timetable for such actions by the applicant;

(g) where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification.

If devices , or parts thereof, *that are intended*

If devices or parts thereof, *as referred to in the first subparagraph,*

– *to be invasive devices and to come into contact with the body of the patient for short- or long-term, or*

– *to (re)administer medicines, body liquids or other substances, including gases, to/from the body, or*

– *to transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body*

contain, in a concentration of 0.1% by mass *of the plasticised material or above, phthalates* which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008, *these* devices shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as devices containing *phthalates*. *If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women*, the manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.

⁵⁷ OJ L 353, 31.12.2008, p. 1.

⁵⁸ OJ L 136, 29.5.2007, p.3.

contain, in a concentration of 0.1% by mass *or above, in a homogeneous material, substances* which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008, *or substances identified as endocrine disrupters pursuant to the first subparagraph, and were granted a derogation pursuant to the second or third subparagraph*, the devices shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as devices containing *such substances*. The manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.

⁵⁷ OJ L 353, 31.12.2008, p. 1

⁵⁸ OJ L 136, 29.5.2007, p.3.

Amendment 271

Proposal for a regulation

Annex I – part II – point 8 – point 8.1 – point a a (new)

Text proposed by the Commission

Amendment

(aa) fully comply with the requirements of applicable Union Directives concerning occupational safety, such as Directive 2010/32/EU,

Amendment 272

Proposal for a regulation

Annex I – part II – point 8 – point 8.1 – point a – paragraph 2

Text proposed by the Commission

Amendment

and, where necessary,

deleted

Amendment 273

Proposal for a regulation

Annex I – part II – point 8 – point 8.7 a (new)

Text proposed by the Commission

Amendment

8.7a. Medical device manufacturers shall notify their users of the levels of disinfection required to ensure patient safety and of all available methods for achieving those levels of disinfection. Manufacturers shall be required to test their devices using all methods designed to ensure patient safety and to substantiate any decision to reject a solution, either by demonstrating that it is ineffective or by demonstrating that it will cause damage impairing the medical usefulness of their devices to a significantly greater degree than other solutions that they themselves recommend.

Amendment 274

Proposal for a regulation

Annex I – part II – point 9 – title

Text proposed by the Commission

Amendment

9. Devices incorporating a substance considered to be a medicinal product **and devices composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally.**

9. Devices incorporating a substance considered to be a medicinal product

Amendment 275

Proposal for a regulation

Annex I – part II – point 9 – point 9.2

Text proposed by the Commission

Amendment

9.2. Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body shall comply, by analogy, with the relevant requirements laid down in Annex I to Directive 2001/83/EC.

deleted

Amendment 276

Proposal for a regulation

Annex I – part II – point 10 – point 10.2 – point a a (new)

Text proposed by the Commission

Amendment

(aa) The use of non-animal methods should be promoted. Animal use should be minimised and tests on vertebrates should be undertaken as a last resort. In accordance with Directive 2010/63/EU, tests on vertebrate animals must be replaced, restricted or refined. Therefore, we call on the Commission to lay down rules to avoid duplicative testing and duplication of tests and studies on vertebrates should be prohibited.

Amendment 277

Proposal for a regulation

Annex I – part II – point 10 – point 10.3

Text proposed by the Commission

10.3. For devices manufactured utilising other non-viable biological substances the following applies:

In the case of biological substances other than those referred to in Sections 10.1. and 10.2., the processing, preservation, testing and handling of those substances shall be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

Amendment

10.3. For devices manufactured utilising other non-viable biological substances the following applies:

In the case of biological substances other than those referred to in Sections 10.1. and 10.2., the processing, preservation, testing and handling of those substances shall be carried out so as to provide optimal safety for patients, users and, where applicable, other persons, ***including in the waste disposal chain***. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

Amendment 278

Proposal for a regulation

Annex I – part II – point 11 – point 11.2 a (new)

Text proposed by the Commission

Amendment

11.2a. Devices which can transfer potentially fatal blood-borne infections to healthcare staff, patients or other persons, by unintended cuts and pricks such as needle stick injuries, shall incorporate appropriate safety-engineered protection mechanisms in accordance with Directive 2010/32/EU. However the specificities relating to the dental profession must be respected.

Amendment 279

Proposal for a regulation

Annex I – part II – point 11 – point 11.7

Text proposed by the Commission

Amendment

11.7. Devices shall be designed and manufactured in such a way as to facilitate

11.7. Devices shall be designed and manufactured in such a way as to facilitate

the safe disposal of the device and/or of any waste substances by the user, patient or other person.

the safe disposal of the device and *the substances with which the device has been exposed to* and/or of any waste substances by the user, patient or other person *and, where possible and appropriate, replace with the use of devices and methods with improved safety features and characteristics to reduce as far as possible the exposure of patients, users and other persons to potentially harmful substances, such as chemical or nuclear material.*

Amendment 280

Proposal for a regulation

Annex I – part II – point 13 – point 13.1 – point a

Text proposed by the Commission

(a) Devices shall be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation shall be reduced as far as possible and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

Amendment

(a) Devices shall be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation shall be reduced as far as possible and appropriate, compatible with the intended purpose, *and if possible these applications shall be replaced with applications with a higher safety standard*, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

Amendment 281

Proposal for a regulation

Annex I – part II – point 13 – point 13.3 – paragraph 1

Text proposed by the Commission

Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible and appropriate.

Amendment

Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible and appropriate: *where possible, methods should be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.*

Amendment 282

Proposal for a regulation

Annex I – part II – point 13 – point 13.4 – point a

Text proposed by the Commission

(a) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.

Amendment

(a) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use, ***and if possible, devices should be used that can at any time during and after treatment monitor the emission of radiation.***

Amendment 283

Proposal for a regulation

Annex I – part II – point 18 – point 18.2 – indent 1 a (new)

Text proposed by the Commission

Amendment

– as laid out in Directive 2010/32/EU, reduce as far as possible the risk of injury and infection to other persons by incorporating safety-engineered protection mechanisms designed to prevent needle stick and other sharp injuries, and

Amendment 284

Proposal for a regulation

Annex I – part III – point 19 – point 19.1 – point d

Text proposed by the Commission

(d) Labels shall be provided in a human-readable format ***but may*** be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.

Amendment

(d) Labels shall be provided in a human-readable format ***and shall*** be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.

Amendment 285

Proposal for a regulation

Annex I – part III – point 19 – point 19.2 – point a a (new)

Text proposed by the Commission

Amendment

(aa) The mention ‘This product is a medical device’.

Amendment 286

Proposal for a regulation

Annex I – section 19.2 – point b

Text proposed by the Commission

Amendment

(b) The details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device.

(b) The details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device and *where applicable that the device is only to be used during a single procedure.*

Amendment 287

Proposal for a regulation

Annex I – part III – point 19 – point 19.2 – point o

Text proposed by the Commission

Amendment

(o) If the device is a single use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles.

deleted

Amendment 288

Proposal for a regulation

Annex I – part III – – point 19 – point 19.3 – point k

Text proposed by the Commission

Amendment

(k) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection,

(k) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection,

decontamination, packaging and, where appropriate, the validated method of re-sterilisation. Information should be provided to identify when the device should no longer be reused, e.g. signs of material degradation **or the maximum number of allowable reuses.**

decontamination, packaging, **the maximum number of allowable reuses** and, where appropriate, the validated method of re-sterilisation. Information should be provided to identify when the device should no longer be reused, e.g. signs of material degradation.

Amendment 289

Proposal for a regulation

Annex I – part III – paragraph 19 – point 19.3 – point 1

Text proposed by the Commission

(1) If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with point c) of Section 19.1 no instructions for use are needed, the information shall be made available to the user upon request.

Amendment

(1) **With the exception of devices referred to in Article 15b, if the device bears an indication that it is for single use, the evidence justifying that the device cannot be reprocessed safely referred to in Article 15c(1), and which includes all** information on characteristics and technical factors that could pose a risk if the device were to be re-used. If in accordance with point c) of Section 19.1 no instructions for use are needed, the information shall be made available to the user upon request.

Amendment 290

Proposal for a regulation

Annex I – part III – point 19 – point 19.3 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The instructions for use shall be lay-friendly and reviewed by the representatives of relevant stakeholders, including patient and healthcare professionals' organisations.

Amendment 291

Proposal for a regulation

Annex II – point 5 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

The documentation shall contain *a summary of*

The documentation shall contain ***all available information concerning:***

Amendment 292

**Proposal for a regulation
Annex II - point 6.1 - point d**

Text proposed by the Commission

Amendment

(d) the PMCF plan and PMCF evaluation report in accordance with Part B of Annex XIII or any justification why a PMCF is not deemed necessary or appropriate.

(d) the PMCF plan and PMCF evaluation report, ***including a review of the PMCF evaluation report by an independent scientific body for class III medical devices***, in accordance with Part B of Annex XIII or any justification why a PMCF is not deemed necessary or appropriate.

Amendment 293

**Proposal for a regulation
Annex IV – point 1 – introductory part**

Text proposed by the Commission

Amendment

1. The CE marking shall consist of the initials '***CE***' taking the following form:

1. The CE marking shall consist of the initials '***CE***' ***accompanied by the term "Medical Device"*** taking the following form:

Amendment 294

**Proposal for a regulation
Annex VI – points 1 and 2**

Text proposed by the Commission

Amendment

1.1. Legal status and organisational structure

1.1.4. The organisational structure, distribution of responsibilities and operation of the notified body shall be such that it assures confidence in the

1.1. Legal status and organisational structure

1.1.4. The organisational structure, distribution of responsibilities and operation of the notified body shall be such that it assures confidence in the

performance and results of the conformity assessment activities conducted.

The organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel with influence upon the performance and results of the conformity assessment activities shall be clearly documented.

1.2. Independence and impartiality

1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer.

1.2.3. The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not:

- be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products, nor the authorised representative of any of those parties. This shall not preclude the purchase and use of assessed products that are necessary for the operations of the notified body (e.g. measuring equipment), the conduct of the conformity assessment or the use of such products for personal purposes;
- be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the products which they assess, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities

performance and results of the conformity assessment activities conducted.

The organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel with influence upon the performance and results of the conformity assessment activities shall be clearly documented. ***This information shall be made publicly available.***

1.2. Independence and impartiality

1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer. ***This does not preclude the notified body to perform conformity assessment activities for different economic operators producing different or similar products.***

1.2.3. The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not:

- be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products, nor the authorised representative of any of those parties. This shall not preclude the purchase and use of assessed products that are necessary for the operations of the notified body (e.g. measuring equipment), the conduct of the conformity assessment or the use of such products for personal purposes;
- be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the products which they assess, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities

for which they are notified;

- offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of the products or processes under assessment. This does not preclude general training activities relating to medical device regulations or related standards that are not client specific.

1.2.4. The impartiality of the notified bodies, of their top level management **and** of the assessment personnel shall be guaranteed. The remuneration of the top level management **and** assessment personnel of a notified body shall not depend on the results of the assessments.

1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity of its conformity assessment activities.

1.3. Confidentiality

The personnel of a notified body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the national authorities responsible for notified bodies, competent

for which they are notified;

- offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of the products or processes under assessment. This does not preclude general training activities relating to medical device regulations or related standards that are not client specific.

The notified body shall make publicly available the declarations of interest of its top-level management and the personnel responsible for carrying out the conformity assessment tasks. The national authority shall verify the compliance of the notified body with the provisions under this point and shall report to the Commission twice a year in full transparency.

1.2.4. The impartiality of the notified bodies, of their top level management, of the assessment personnel **and subcontractors** shall be guaranteed. The remuneration of the top level management, assessment personnel **and subcontractors** of a notified body shall not depend on the results of the assessments.

1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity of its conformity assessment activities. ***The notified body shall provide evidence to the national authority of compliance with this point.***

1.3. Confidentiality

The personnel of a notified body shall observe professional secrecy with regard to information obtained in carrying out their tasks under this Regulation, ***only in justified cases and*** except in relation to the national authorities responsible for notified

authorities or the Commission. Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.

1.5. Financial requirements

The notified body shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking into account specific circumstances during an initial start-up phase.

1.6. Participation in coordination activities

1.6.1. The notified body shall participate in, or ensure that its assessment personnel is informed of the relevant standardisation activities and the activities of the notified body coordination group and that its assessment and decision making personnel are informed of all relevant legislation, guidance and best practice documents adopted in the framework of this Regulation.

2. QUALITY MANAGEMENT REQUIREMENTS

2.2. The quality management system of the notified body shall at least address the following:

- policies for assignment of personnel to activities and their responsibilities;
- decision-making process in accordance with the tasks, responsibilities and role of the top-level management and other

bodies, competent authorities or the Commission. Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.

Where information and data are requested from the notified body by the public or healthcare professionals and where such request is declined, the notified body shall justify the reasons for non-disclosure and shall make publicly available its justification.

1.5. Financial requirements

The notified body, ***including its subsidiaries***, shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking into account specific circumstances during an initial start-up phase.

1.6. Participation in coordination activities

1.6.1. The notified body shall participate in, or ensure that its assessment personnel ***including subcontractors***, is informed of ***and trained on*** the relevant standardisation activities and the activities of the notified body coordination group and that its assessment and decision making personnel are informed of all relevant legislation, ***standards***, guidance and best practice documents adopted in the framework of this Regulation. ***The notified body shall keep a record of the actions it takes to inform its personnel.***

2. QUALITY MANAGEMENT REQUIREMENTS

2.2. The quality management system of the notified body ***and its subcontractors*** shall at least address the following:

- policies for assignment of personnel to activities and their responsibilities;
- decision-making process in accordance with the tasks, responsibilities and role of the top-level management and other

- notified body personnel;
- control of documents;
- control of records;
- management review;
- internal audits;
- corrective and preventive actions;
- complaints and appeals.

- notified body personnel;
- control of documents;
- control of records;
- management review;
- internal audits;
- corrective and preventive actions;
- complaints and appeals;
- *continuous training*.

Amendment 295

Proposal for a regulation Annex VI – point 3.1

Text proposed by the Commission

3.1.1. A notified body shall be capable of carrying out all the tasks assigned to it by this Regulation with the highest degree of professional integrity and the requisite technical competence in the specific field, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility.

In particular, it shall have the necessary personnel and shall possess or have access to all equipment and facilities needed to perform properly the technical and administrative tasks entailed in the conformity assessment activities in relation to which it has been notified.

This presupposes the availability within its organisation of sufficient scientific personnel who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Regulation and, in particular, those set out in Annex I.

Amendment

3.1.1. A notified body **and its subcontractors** shall be capable of carrying out all the tasks assigned to it by this Regulation with the highest degree of professional integrity and the requisite technical competence in the specific field, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility. ***In accordance with Article 35, this requirement shall be monitored to ensure that it is of the requisite quality.***

In particular, it shall have the necessary personnel and shall possess or have access to all equipment and facilities needed to perform properly the technical, ***scientific*** and administrative tasks entailed in the conformity assessment activities in relation to which it has been notified.

This presupposes the ***permanent*** availability within its organisation of sufficient scientific personnel who possess experience, ***a university degree*** and ***the*** knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Regulation and, in particular, those set out in Annex I.

Permanent in-house staff shall be used. However, in accordance with Article 30, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of these experts, as well as their declarations of interest and the specific tasks for which they are responsible.

Notified bodies shall conduct unannounced inspections at least once a year of all premises at which the medical devices coming within their remit are manufactured.

The notified body responsible for carrying out the assessment tasks shall notify the other Member States of the findings of the annual inspections carried out. Those findings shall be set out in a report.

It shall also forward a record of the annual inspections carried out to the relevant national authority responsible.

3.1.2. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with technical knowledge and sufficient and appropriate experience relating to medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data.

3.1.2. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with *medical, technical and where needed pharmacological* knowledge and sufficient and appropriate experience relating to medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data *or the evaluation of an assessment made by a subcontractor.*

3.1.3. The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation of the personnel involved in conformity assessment activities and inform the personnel concerned about it.

3.1.3. The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation of the personnel, *including any subcontractors, subsidiaries and external experts*, involved in conformity assessment activities and inform the personnel concerned about it.

3.1.3.a The notified body shall make available the list of its personnel involved in conformity assessment activities and their expertise to the Commission and,

upon request, to other parties. That list shall be kept up to date.

Amendment 296

Proposal for a regulation Annex VI – point 3.2.

Text proposed by the Commission

3.2.1. The Notified Body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas (e.g. biocompatibility, sterilisation, tissues and cells of human and animal origin, clinical evaluation) covered by the scope of designation.

3.2.2. The qualification criteria shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 33, providing sufficient level of detail for the required qualification within the subdivisions of the scope description.

Specific qualification criteria shall be defined for the assessment of biocompatibility aspects, clinical evaluation and the different types of sterilisation processes.

3.2.3. The personnel responsible for authorising other personnel to perform specific conformity assessment activities and the personnel with overall responsibility for the final review and decision-making on certification shall be employed by the notified body itself and

Amendment

3.2.1. The **MDCG** shall establish and document ***the principles of high level competence and*** qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas (e.g. biocompatibility, sterilisation, tissues and cells of human and animal origin, clinical evaluation, ***risk management***) covered by the scope of designation.

3.2.2. The qualification criteria shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 33, providing sufficient level of detail for the required qualification within the subdivisions of the scope description.

Specific qualification criteria shall be defined for the assessment of biocompatibility aspects, ***safety***, clinical evaluation and the different types of sterilisation processes.

3.2.3. The personnel responsible for authorising other personnel to perform specific conformity assessment activities and the personnel with overall responsibility for the final review and decision-making on certification shall be employed by the notified body itself and

shall not be subcontracted. These personnel altogether shall have proven knowledge and experience in the following:

- Union medical devices legislation and relevant guidance documents;
- the conformity assessment procedures in accordance with this Regulation;
- a broad base of medical device technologies, the medical device industry and the design and manufacture of medical devices;
- the notified body's quality management system and related procedures;
- the types of qualifications (knowledge, experience and other competence) required for carrying out conformity assessments in relation to medical devices as well as the relevant qualification criteria;
- training relevant to personnel involved in conformity assessment activities in relation to medical devices;
- the ability to draw up certificates, records and reports demonstrating that the conformity assessments have been appropriately carried out.

3.2.4. Notified bodies shall have available personnel with **clinical** expertise. This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:

shall not be subcontracted. These personnel altogether shall have proven knowledge and experience in the following:

- Union medical devices legislation and relevant guidance documents;
- the conformity assessment procedures in accordance with this Regulation;
- a broad base of medical device technologies, the medical device industry and the design and manufacture of medical devices;
- the notified body's quality management system and related procedures;
- the types of qualifications (knowledge, experience and other competence) required for carrying out conformity assessments in relation to medical devices as well as the relevant qualification criteria;
- training relevant to personnel involved in conformity assessment activities in relation to medical devices;
- the ability to draw up certificates, records and reports demonstrating that the conformity assessments have been appropriately carried out.

- at least three years' appropriate experience in the field of conformity assessments within a notified body,

- adequate seniority / experience in conformity assessments under this Regulation or previously applicable directives during a period of at least three years within a notified body. The notified body staff involved in certification decisions shall not have been involved in the conformity assessment on which a certification decision needs to be taken.

3.2.4. ***Clinical experts:*** notified bodies shall have available personnel with expertise ***in clinical investigation design, medical statistics, clinical patient management, Good Clinical Practice in the field of clinical investigations. Permanent "in-house" staff shall be used. However, in accordance with Article 30, notified bodies may hire external experts***

- identify when specialist input is required for the assessment of the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;

- appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;

- be able to discuss *the clinical data contained within the manufacturer's clinical evaluation* with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;

- be able to scientifically challenge the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;

- be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;

- be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker.

3.2.5. The personnel responsible for carrying out product related review (e.g. design dossier review, technical

on an ad hoc and temporary basis provided they can make publicly available the list of these experts, as well as the specific tasks for which they are responsible. This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:

- identify when specialist input is required for the assessment of *the clinical investigation plans and* the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;

- appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;

- be able to discuss *the rationale of the planned study design, the clinical investigation plans and the selection of the control intervention* with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;

- be able to scientifically challenge *the clinical investigation plans and* the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;

- be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;

- be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker.

- ensure independence and objectivity and disclose potential conflicts of interest.

3.2.5. *Product assessors:* the personnel responsible for carrying out product related *reviews* (e.g. design dossier review,

documentation review or type examination including aspects such as clinical evaluation, biological safety, sterilisation, software validation) shall have the following proven qualification:

– successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering;

- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device or technology to be assessed or related to the scientific aspects to be assessed;

- appropriate knowledge of the general safety and performance requirements laid down in Annex I as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;

- appropriate knowledge and experience of risk management and related medical device standards and guidance documents;

3.2.6. The personnel responsible for carrying out audits of the manufacturer's quality **management** system shall have the following proven qualification:

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering

four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare,

technical documentation review or type examination including aspects such as clinical evaluation, biological safety, sterilisation, software validation) shall have the **specialist qualifications, which should include:**

– successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering;

- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device (**as defined within a generic device group**) or technology to be assessed or related to the scientific aspects to be assessed;

- appropriate knowledge of the general safety and performance requirements laid down in Annex I as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;

- **qualification based on technical or scientific fields (e.g. sterilization, biocompatibility, animal tissue, human tissue, software, functional safety, clinical evaluation, electrical safety, packaging);**

- appropriate knowledge and experience of risk management and related medical device standards and guidance documents;

- **appropriate knowledge and experience of clinical evaluation;**

3.2.6. **Auditor:** The personnel responsible for carrying out audits of the manufacturer's quality **assurance** system shall have **specialist qualifications, which should include:**

- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering;

four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare,

research experience) whilst two years of this experience shall be in the area of quality management

research experience) whilst two years of this experience shall be in the area of quality management;

- appropriate knowledge of technologies such as those defined by IAF/EAC coding or equivalent.

Amendment 297

Proposal for a regulation Annex VI – point 3.4.

Text proposed by the Commission

3.4. Subcontractors and external experts

3.4.1. Without prejudice to the limitations emanating from Section 3.2., notified bodies may subcontract clearly defined parts of the conformity assessment activities. The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed.

3.4.2. Where a notified body subcontracts conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place. Any subcontracting or consultation of external experts shall be properly documented and be subject to a written agreement covering, among others, confidentiality and conflict of interests.

3.4.3. Where subcontractors or external experts are used in the context of the conformity assessment, in particular regarding novel, invasive and implantable medical devices or technologies, the notified body shall have adequate own competence in each product area for which it is designated to lead the conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification.

Amendment

3.4. Subcontractors and external experts

3.4.1. Without prejudice to the limitations emanating from Section 3.2., notified bodies may subcontract clearly defined parts of the conformity assessment activities ***in particular where clinical expertise is limited.*** The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed.

3.4.2. Where a notified body subcontracts conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place. Any subcontracting or consultation of external experts shall be properly documented, ***be publicly available and*** be subject to a written agreement covering, among others, confidentiality and conflict of interests.

3.4.3. Where subcontractors or external experts are used in the context of the conformity assessment, in particular regarding novel, invasive and implantable medical devices or technologies, the notified body shall have adequate own competence in each product area, ***each treatment or medical speciality*** for which it is designated to lead the conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification.

3.4.4a. The policy and procedures under points 3.4.2 and 3.4.4 shall be communicated to the national authority before any subcontracting takes place.

Amendment 298

Proposal for a regulation

Annex VI – paragraph 3 – point 3.5. – point 3.5.2.

Text proposed by the Commission

3.5.2. It shall review the competence of its personnel and identify training needs in order to maintain the required level of qualification and knowledge.

Amendment

3.5.2. It shall review the competence of its personnel and identify training needs **and ensure that necessary measures are taken accordingly**, in order to maintain the required level of qualification and knowledge.

Amendment 299

Proposal for a regulation

Annex VI – 3.5 a (new)

Text proposed by the Commission

Amendment

3.5.a Additional requirements for special notified bodies

3.5 a 1. Clinical experts for special notified bodies

Special notified bodies shall have available personnel with expertise in clinical investigation design, medical statistics, clinical patient management, good clinical practice in the field of clinical investigations and pharmacology. Permanent in-house staff shall be used. However, in accordance with Article 30, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of these experts, as well as the specific tasks for which they are responsible. This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:

- identify when specialist input is required for the assessment of the clinical investigation plans and the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;

- appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;

- be able to discuss the rationale of the planned study design, the clinical investigation plans and the selection of the control intervention with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;

- be able to scientifically challenge the clinical investigation plans and the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;

- be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;

- be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker.

- have an understanding of active substances.

- ensure independence and objectivity and disclose potential conflicts of interest.

3.5 a 2. Product specialists for special notified bodies

The personnel responsible for carrying out product related reviews (for example design dossier review, technical documentation review or type examination) for devices referred to in Article 43a shall have the following

proven product specialist qualification:

- ***Meet the requirement as stipulated above for product assessors;***
- ***Have an advanced academic degree in field relevant to medical devices, or alternative have six years of relevant experience in medical devices or related sectors;***
- ***Have an ability to identify key risks of products within the specialist's product categories without prior reference to manufacturer's specifications or risk analyses;***
- ***Have an ability to assess against the essential requirements in the absence of harmonised or established national standards;***
- ***The professional experience should be gained in the first product category their qualification is based on, relevant to the product category of designation of the notified body, providing sufficient knowledge and experience to thoroughly analyse the design, the validation and verification testing and the clinical use with a sound understanding of the design, manufacture, testing, clinical use and risks associated with such a device;***
- ***Missing professional experience for further product categories closely related to the first product category, may be substituted by internal product specific training programmes;***
- ***For product specialist with qualification in specific technology such as sterilisation, tissues and cells of human and animal origin, combination products, professional experience should be gained in the specific technology area, relevant to the scope of designation of the notified body.***

For each designated product category, the Special notify body shall have a minimum of two product specialists of which at least one in house, to review devices referred to in Art. 43 a (new), first paragraph. For those devices, product specialists shall be

available in house for the designated technology fields (for example combination products, sterilisation, tissues and cells of human or animal origin) covered by the scope of notification.

3.5 a 3. Training for product specialists

Product specialists shall receive at minimum 36 hours of training in medical devices, the Medical Device Regulations, and assessment and certification principles, including training in the verification of manufactured product.

The notified body shall ensure that a product specialist to be qualified obtains adequate training in the relevant procedures of the notified body's quality management system and is taken through a training plan consisting of sufficient design dossier reviews witnessed, performed under supervision and peer reviewed before doing a qualifying full independent review.

For each product category for which qualification is sought, the notified body must show evidence of appropriate knowledge in the product category. A minimum of five design dossiers (at least two of them initial applications or significant extensions of certification) shall be conducted for the first product category. For subsequent qualification in additional product categories evidence of adequate product knowledge and experience needs to be demonstrated.

3.5 a 4. Maintenance qualification for product specialists

Qualifications of product specialists shall be reviewed on an annual basis; a minimum of four design dossier reviews, independent of the number of product categories qualified for shall be demonstrated as a four-year rolling average. Reviews of significant changes to the approved design (not full design examinations) count for 50%, as do reviews supervised.

On an ongoing basis, the product Specialist needs to show evidence of state-of-art product knowledge, review experience in each product category for which qualification exists. Annual training with regard to latest status of Regulations, harmonised standards, relevant guidance documents, clinical evaluation, performance evaluation, CTS requirements needs to be demonstrated.

If the requirements for renewal of qualification are not met, the qualification shall be suspended. Then the first upcoming design dossier review shall be done under supervision, and re-qualification confirmed based on the outcome of this review.

Amendment 300

Proposal for a regulation Annex VI – point 4.1

Text proposed by the Commission

4.1. The notified body's decision-making process shall be clearly documented, including the *process for the* issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.

Amendment

4.1. The notified body's decision-making process shall be **transparent and** clearly documented **and its outcome publicly available**, including the issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.

Amendment 301

Proposal for a regulation Annex VI – point 4.3

Text proposed by the Commission

4.3. The notified body shall have in place documented procedures covering at least:

- the application for conformity assessment by a manufacturer or by an authorised

Amendment

4.3. The notified body shall have in place documented procedures **that are publicly available** covering at least:

- the application for conformity assessment by a manufacturer or by an authorised

representative,
- the processing of the application, including the verification of the completeness of the documentation, the qualification of the product as device and its classification,

representative,
- the processing of the application, including the verification of the completeness of the documentation, the qualification of the product as device and its classification, *as well as the recommended duration for conducting its conformity assessment,*

Amendment 302

Proposal for a regulation Annex VI – point 4 a (new)

Text proposed by the Commission

Amendment

4a. Recommended duration for conformity assessments conducted by notified bodies

4.1. Notified bodies shall identify the audit duration for the stage 1 and stage 2 initial audits, and surveillance audits for each applicant and certified client

4.2. An audit duration shall be based, inter alia, on the effective number of personnel of the organization, the complexity of the processes within the organization, the nature and the characteristics of the medical devices included in the scope of the audit and the different technologies that are employed to manufacture and control the medical devices. The audit duration may be adjusted based on any significant factors that uniquely apply to the organization to be audited. The notified body shall ensure that any variation in audit duration does not compromise the effectiveness of audits

4.3. The duration of any scheduled on site audit shall not be less than one auditor/day.

4.4. Certification of multiple sites under one quality assurance system shall not be based on a sampling system.

Amendment 303

Proposal for a regulation

Annex VII – part III – point 4 – point 4.4 – paragraph 1 – indent 2

Text proposed by the Commission

– are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in class III,

Amendment

– are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in class III, ***with the exception of sutures and staples.***

Amendment 304

Proposal for a regulation

Annex VII – part III – point 6 – point 6.7 – paragraph 1

Text proposed by the Commission

All devices incorporating or consisting of nanomaterial ***are in class III unless the nanomaterial is encapsulated or bound in such a manner that it cannot*** be released into the *patient's or user's* body ***when the device is used within its intended purpose.***

Amendment

All devices incorporating or consisting of nanomaterial ***deliberately intended to*** be released into the ***human*** body ***are in class III.***

Amendment 305

Proposal for a regulation

Annex VII – part III – point 6 – point 6.8

Text proposed by the Commission

6.8. Rule 20

All devices intended to be used for aphaeresis, such as aphaeresis machines, sets, connectors and solutions, are in class III.

Amendment

deleted

Amendment 306

Proposal for a regulation

Annex VII – part III – point 6 – point 6.9

Text proposed by the Commission

Amendment

6.9. Rule 21

deleted

Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body are in class III.

Amendment 307

Proposal for a regulation

Annex VIII – point 3 – point 3.2 – paragraph 1

Text proposed by the Commission

Amendment

3.2. Application of the quality management system shall ensure that the devices conform to the provisions of this Regulation which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

3.2. Application of the quality management system shall ensure that the devices conform to the provisions of this Regulation which apply to them at every stage, from design to final inspection **and delivery**. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

Amendment 308

Proposal for a regulation

Annex VIII – point 3 – point 3.2 – paragraph 2 – point d – indent 2

Text proposed by the Commission

Amendment

– the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

– the product identification **and traceability** procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

Amendment 309

Proposal for a regulation Annex VIII – point 4 – point 4.1

Text proposed by the Commission

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality management system.

Amendment

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils **all** the obligations imposed by the approved quality management system.

Amendment 310

Proposal for a regulation Annex VIII – point 4.4 – paragraph 1

Text proposed by the Commission

The notified body shall randomly perform unannounced **factory** inspections **to the manufacturer** and, if appropriate, **at** 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 must not be disclosed to the manufacturer.

Amendment

The notified body shall randomly perform **at least once every five years and for each manufacturer and generic device group** unannounced inspections **at the relevant manufacturing sites** and, if appropriate, at the manufacturer's suppliers and/or subcontractors, The notified body shall establish a plan for the unannounced inspections which **shall not take a periodicity lower than one inspection per year and** must not be disclosed to the manufacturer. **At the time of such inspections, the notified body shall carry out the tests or ask to carry them in order to check that the quality management system is working properly. It shall provide the manufacturer with an inspection report and with a test report.**

Amendment 311

Proposal for a regulation Annex VIII – point 4 – point 4.4 – paragraph 3

Text proposed by the Commission

The notified body shall provide the manufacturer with an inspection report

Amendment

The notified body shall provide the manufacturer with an inspection report

which shall include, if applicable, the result of the sample check.

which shall include, if applicable, the result of the sample check. ***This report shall be made public.***

Amendment 312

Proposal for a regulation

Annex VIII – point 4 – point 4.5 – paragraph 1

Text proposed by the Commission

Amendment

In the case of devices classified as class III, the surveillance assessment shall also include a check of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, the coherence between the quantities of produced or purchased parts and/or materials and the quantities of finished products.

deleted

Amendment 313

Proposal for a regulation

Annex VIII – point 5.3 – paragraph 1

Text proposed by the Commission

Amendment

The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned. The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the requirements of the Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned. ***The notified body shall ensure that the manufacturer's application adequately describes the design, manufacture and performance of the device, allowing assessment of whether the product conforms with the requirements set out in this Regulation. The notified bodies shall comment on the conformity of the following:***

- general description of the product,***
- design specifications, including a description of the solutions adopted to fulfil the essential requirements,***
- systematic procedures used for the design process and techniques used to control, monitor and verify the design of***

the device.

The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the requirements of the Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

Amendment 314

Proposal for a regulation Annex VIII – point 5 – point 5.3 a (new)

Text proposed by the Commission

Amendment

5.3 a. For devices in class III the clinical part of the dossier shall be evaluated by an appropriate clinical expert among those contained in the list developed by the MDCG according to Art. 80 g)

Amendment 315

Proposal for a regulation Annex VIII – point 8 – introductory part

Text proposed by the Commission

Amendment

8. The manufacturer or his authorised representative shall, for a period ***ending*** at least ***five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market,*** keep at the disposal of the competent authorities:

8. The manufacturer or his authorised representative shall, for a period at least ***equivalent to the lifetime of the medical device as defined by the manufacturer, but not less than 10 years from the date of product release by the manufacturer,*** keep at the disposal of the competent authorities:

Amendment 316

Proposal for a regulation Annex IX – point 7 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

The manufacturer or his authorised representative shall, for a period ***ending*** at

The manufacturer or his authorised representative shall, for a period at least

least *five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market*, keep at the disposal of the competent authorities:

equivalent to the lifetime of the medical device as defined by the manufacturer, but not less than 10 years from the date of product release by the manufacturer, keep at the disposal of the competent authorities:

Amendment 317

Proposal for a regulation Annex X – part A – point 4 – paragraph 2

Text proposed by the Commission

Amendment

In the case of devices classified as class III, the surveillance shall also include a check of the coherence between the quantity of produced or purchased raw material or crucial components approved for the type and the quantity of finished products.

deleted

Amendment 318

Proposal for a regulation Annex X – part A – point 6 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

The manufacturer or his authorised representative shall, for a period *ending* at least *five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market*, keep at the disposal of the competent authorities:

The manufacturer or his authorised representative shall, for a period at least *equivalent to the lifetime of the medical device as defined by the manufacturer, but not less than 10 years from the date of product release by the manufacturer*, keep at the disposal of the competent authorities:

Amendment 319

Proposal for a regulation Annex X – part A – point 7 – point 7.5 – introductory part

Text proposed by the Commission

Amendment

7.5. By way of derogation from Section 6, the manufacturer or his authorised representative shall, for a period *ending* at least *five years after the last device has been placed on the market*, keep at the

7.5. By way of derogation from Section 6, the manufacturer or his authorised representative shall, for a period at least *equivalent to the lifetime of the medical device as defined by the manufacturer*,

disposal of the competent authorities:

but not less than 10 years from the date of product release by the manufacturer, keep at the disposal of the competent authorities:

Amendment 320

Proposal for a regulation

Annex X – Part B – point 4 – paragraph 1

Text proposed by the Commission

4. The notified body shall carry out the appropriate examinations and tests in order to **verify** the conformity of the device with the requirements of the Regulation by examining and testing every product as specified in Section 5.

Amendment

4. The notified body shall carry out the appropriate examinations and tests in order to **assess** the conformity of the device with the requirements of the Regulation by examining and testing every product as specified in Section 5 **or by examination and testing of the products on a statistical basis as specified in section 6.**

Amendment 321

Proposal for a regulation

Annex X – Part B – point 5 a (new) – title

Text proposed by the Commission

Amendment

5 a. Statistical verification of conformity

Amendment 322

Proposal for a regulation

Annex X – Part B – point 5 a – part 5.1 (new)

Text proposed by the Commission

Amendment

5.1. The manufacturer shall present the manufactured products in the form of homogeneous batches. The proof of homogeneity for the presented products shall be part of the batch documentation.

Amendment 323

Proposal for a regulation

Annex X – Part B – point 5 a - part 5.2 (new)

Text proposed by the Commission

Amendment

5.2. A random sample is taken from each batch. The products which make up the sample shall be examined individually and the appropriate physical or laboratory tests defined in the relevant standard(s) referred to in Article 6 or equivalent tests shall be carried out in order to verify the conformity of the devices with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them.

Amendment 324

Proposal for a regulation

Annex X – Part B – point 5 a – part 5.3 (new)

Text proposed by the Commission

Amendment

5.3. Statistical control of products shall be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the harmonised standards or equivalent tests referred to in Article 6, taking account of the specific nature of the product categories in question.

Amendment 325

Proposal for a regulation

Annex X – Part B – point 5 a – part 5.4 (new)

Text proposed by the Commission

Amendment

5.4. The notified body shall affix, or have affixed, its identification number to each approved device and shall draw up an EU product verification certificate relating to the tests carried out.

All products in the batch may be put on the market except any in the sample

which failed to conform.

If a batch is rejected, the competent notified body must take appropriate measures to prevent the batch from being placed on the market.

In the event of frequent rejection of batches, the notified body may suspend the statistical verification.

Amendment 326

Proposal for a regulation

Annex X – Part B – point 7 – paragraph 1 – introductory part

Text proposed by the Commission

The manufacturer or his authorised representative shall, for a period *ending* at least *five years*, *and in the case of implantable devices at least 15 years*, *after the last device has been placed on the market*, keep at the disposal of the competent authorities:

Amendment

The manufacturer or his authorised representative shall, for a period at least *equivalent to the lifetime of the medical device as defined by the manufacturer*, *but not less than 10 years from the date of product release by the manufacturer*, keep at the disposal of the competent authorities:

Amendment 327

Proposal for a regulation

Annex X – Part B – point 8 – point 8.4 – introductory part

Text proposed by the Commission

8.4. By way of derogation from Section 7, the manufacturer or his authorised representative shall, for a period *ending* at least *five years after the last device has been placed on the market*, keep at the disposal of the competent authorities:

Amendment

8.4. By way of derogation from Section 7, the manufacturer or his authorised representative shall, for a period at least *equivalent to the lifetime of the medical device as defined by the manufacturer*, *but not less than 10 years from the date of product release by the manufacturer*, keep at the disposal of the competent authorities:

Amendment 328

Proposal for a regulation

Annex XIII – part A – point 2

Text proposed by the Commission

2. Confirmation of conformity with the requirements concerning the characteristics and performances referred to in Section 1 of Annex I, under the normal conditions of use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, shall be based on clinical data.

Amendment

2. Confirmation of conformity with the requirements concerning the characteristics and performances referred to in Section 1 of Annex I, under the normal conditions of use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, shall be based on clinical data.

Data from independent scientific institutions or medical societies based on their own collections of clinical data shall also be taken into account.

Amendment 329

**Proposal for a regulation
Annex XIII - Part A - point 5**

Text proposed by the Commission

5. In the case of ***implantable devices and*** devices falling within ***class III***, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone. Demonstration of equivalence in accordance with Section 4 shall generally not be considered as sufficient justification within the meaning of the first sentence of this paragraph.

Amendment

5. In the case of devices falling within ***Article 43a(1)***, ***with the exception of those used for a short term***, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone. Demonstration of equivalence in accordance with Section 4 shall generally not be considered as sufficient justification within the meaning of the first sentence of this paragraph.

Amendment 330

**Proposal for a regulation
Annex XIII – point 5 a (new)**

Text proposed by the Commission

Amendment

5a. All clinical data collected by the manufacturer as part of a PMCF should be made accessible to health professionals.

Amendment 331

Proposal for a regulation Annex XIII – part B – point 1

Text proposed by the Commission

1. Post-market clinical follow-up, hereinafter: PMCF, is a continuous process to update the clinical evaluation referred to in Article 49 and Part A of this Annex and shall be part of the manufacturer's post-market surveillance plan. To this end, the manufacturer shall proactively collect and evaluate clinical data from the use in or on humans of a device which is authorised to bear the CE marking, within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety and performance throughout the expected lifetime of the device, the continued acceptability of identified risks and to detect emerging risks on the basis of factual evidence.

Amendment

1. Post-market clinical follow-up, hereinafter: PMCF, is a continuous process to update the clinical evaluation referred to in Article 49 and Part A of this Annex and shall be part of the manufacturer's post-market surveillance plan. To this end, the manufacturer shall proactively collect, ***register in the electronic system on vigilance referred to in Article 62*** and evaluate clinical data from the use in or on humans of a device which is authorised to bear the CE marking, within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety and performance throughout the expected lifetime of the device, the continued acceptability of identified risks and to detect emerging risks on the basis of factual evidence.

Amendment 332

Proposal for a regulation Annex XIII – part B – point 3

Text proposed by the Commission

3. The manufacturer shall analyse the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the technical documentation.

Amendment

3. The manufacturer shall analyse the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the technical documentation ***and be sent periodically to the concerned Member States.***

For class III medical devices, the manufacturer's PMCF evaluation report shall be reviewed by a third party or external expert under the principles of highest scientific competence and impartiality. In order to conduct its review, the manufacturer shall provide the relevant data to the third party or external expert. Both the manufacturer's

PMCF evaluation report and its review by an independent body shall be part of the technical documentation for class III medical devices.

Amendment 333

Proposal for a regulation Annex XIII – part B – point 4

Text proposed by the Commission

4. The conclusions of the PMCF evaluation report shall be taken into account for the clinical evaluation referred to in Article 49 and Part A of this Annex and in the risk management referred to in Section 2 of Annex I. If through the PMCF the need for corrective measures has been identified, the manufacturer shall implement them.

Amendment

4. The conclusions of the PMCF evaluation report, ***and where applicable its review by a third party or external experts as referred to in paragraph 3***, shall be taken into account for the clinical evaluation referred to in Article 49 and Part A of this Annex and in the risk management referred to in Section 2 of Annex I. If through the PMCF the need for corrective measures has been identified, the manufacturer shall implement them ***and inform the concerned Member States***.

Amendment 334

Proposal for a regulation Annex XIV – part I – point 1 – paragraph 1

Text proposed by the Commission

Every step in the clinical investigation, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example 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 Association General Assembly in Helsinki, Finland, in 1964, and last amended by the 59th World Medical Association General Assembly in Seoul, Korea, in 2008.

Amendment

Every step in the clinical investigation, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example 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 Association General Assembly in Helsinki, Finland, in 1964, and last amended by the 59th World Medical Association General Assembly in Seoul, Korea, in 2008. ***Conformity with the above principles shall be granted after an examination by the concerned Ethics***

Committee. Regulation of the detailed requirements relating to the participation of subjects in clinical trials shall be the responsibility of the Member States.

Amendment 335

Proposal for a regulation

Annex XIV – Part I – paragraph 2 – point 2.1.

Text proposed by the Commission

2.1. Clinical investigations shall be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims for the device as well as the safety, performance and benefit/risk related aspects referred to in Article 50(1); these investigations shall include an adequate number of observations to guarantee the scientific validity of the conclusions.

Amendment

2.1. Clinical investigations shall be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute ***the technical performance of the device, the clinical safety and efficacy of the device when used for the intended purpose in the target population and in accordance with the instructions of use,*** and the manufacturer's claims for the device as well as the safety, performance and benefit/risk related aspects referred to in Article 50(1); these investigations shall include an adequate number of observations to guarantee the scientific validity of the conclusions.

Amendment 336

Proposal for a regulation

Annex XIV – Part I – paragraph 2 – point 2.3.

Text proposed by the Commission

2.3. Clinical investigations shall be performed in circumstances similar to the normal conditions of use of the device.

Amendment

2.3. Clinical investigations shall be performed in circumstances similar to the normal conditions of use of the device ***for the intended purpose in the target population.***

Amendment 337

Proposal for a regulation

Annex XIV – part I – point 2 – point 2.7

Text proposed by the Commission

2.7. The clinical investigation report, signed by the medical practitioner or other authorised person responsible, shall contain ***a critical evaluation of all the*** data collected during the clinical investigation, including negative findings.

Amendment

2.7. The clinical investigation report, signed by the medical practitioner or other authorised person responsible, shall contain ***all clinical*** data collected during the clinical investigation ***and a critical evaluation of such data***, including negative findings.

Amendment 338

Proposal for a regulation

Annex XIV – Part I a (new) – point 1

Text proposed by the Commission

Amendment

1. 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 investigations 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; consent shall represent 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 his or her capacity for understanding regarding the clinical investigation and its risks and benefits from the investigator or his/her representative, in accordance with the national law of the Member State concerned;***
- 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 investigation at any time without giving a reason and with no liability or prejudice whatsoever being incurred by the subject or their legal representative as a result shall be followed***

by the investigator;

- no incentives or financial inducements are given except compensation for participation in the clinical investigation;*
- such research is essential to validate data obtained in a clinical investigation on persons able to give informed consent or by other research methods;*
- such research relates directly to medical condition from which the person concerned suffers;*
- the clinical investigation 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;*
- the research is necessary to promote the health of the population concerned by the clinical performance study and cannot instead be performed on capacitated subject;*
- there are grounds for expecting that participation in the clinical investigation will produce a benefit to the incapacitated subject outweighing the risks or will produce only a minimal risk;*
- 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.

Amendment 339

Proposal for a regulation Annex XIV – Part I a (new) - point 2

Text proposed by the Commission

Amendment

2. Minors

A clinical investigation may be conducted only where, in addition to the general conditions, all of the following conditions are met:

– the written informed consent of the legal representative or representatives has been obtained, whereby consent shall represent the minor’s presumed will;

- the informed and express consent of the minor has been obtained, where they are able to give consent according to national law,

– the minor has received all relevant information in a way adapted to his or her 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 study, the risks and the benefits;

– without prejudice to second indent, the explicit wish of a minor who is capable of forming an opinion and assessing this information to refuse participation in, or to be withdrawn from the clinical investigation at any time, is duly taken into consideration by the investigator;

– no incentives or financial inducements are given except compensation for participation in the clinical investigation;

– 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 investigation 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 to expect that some direct benefit for the category of patients concerned by the study may be obtained from the clinical investigation;

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

- the interest of the patient shall always prevail over those of science and society;

- the clinical investigation does not replicate other studies based on the same hypothesis and age-appropriate technology are used;

– 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. Minors who are able to give consent according to national law shall also give their informed and express consent to participate in the study.

If during a clinical investigation the minor reaches the age of majority as defined in the national law of the Member State concerned, his/her express informed consent shall be obtained before the clinical investigation may continue.

Amendment 340

Proposal for a regulation

Annex XIV – Part II – point 1 – point 1.11

Text proposed by the Commission

1.11. Summary of the clinical investigation plan (objective(s) of the clinical investigation, number and gender of subjects, criteria for subject selection, subjects under 18 years of age, design of the investigation such as controlled and/or randomised studies, planned dates of commencement and of completion of the clinical investigation).

Amendment

1.11. Summary of the clinical investigation plan (objective(s) of the clinical investigation, number and gender of subjects, criteria for subject selection, subjects under 18 years of age, design of the investigation such as controlled and/or randomised studies, planned dates of commencement and of completion of the clinical investigation). *As randomised controlled investigations usually generate a higher level of evidence for clinical efficacy and safety, the use of any other design or study has to be justified. Also the choice of the control intervention shall be justified. Both justifications shall be provided by independent experts with the necessary qualifications and expertise.*

Amendment 343

Proposal for a regulation

Annex XIV – part II – point 3 – point 3.1 – point 3.1.3

Text proposed by the Commission

3.1.3. Information on the principal investigator, coordinating investigator, including their qualifications, and on the investigation site(s).

Amendment

3.1.3. Information on the principal investigator, coordinating investigator, including their qualifications, and on the investigation site(s), ***as well as information about the contract between the sponsor and the investigating establishment, together with details of the funding.***

Amendment 344

Proposal for a regulation

Annex XIV – part II – point 3 – point 3.1 – point 3.1.4

Text proposed by the Commission

3.1.4. Overall synopsis of the clinical investigation.

Amendment

3.1.4. Overall synopsis of the clinical investigation ***in the national language of the country concerned.***

Amendment 347

Proposal for a regulation

Annex XIV – part II – point 3 – point 3.15 a (new)

Text proposed by the Commission

Amendment

3.15a. A plan for the further treatment of subjects after the clinical investigation.