EUROPEAN PARLIAMENT

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Committee on the Environment, Public Health and Food Safety

2012/0266(COD)

12.4.2013

***I
DRAFT REPORT

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))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Dagmar Roth-Behrendt

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Symbols for procedures

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

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

Amendments to a draft act

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

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

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council on 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))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2012)0542),

– having regard to Article 294(2) and Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0318/2012),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 14 February 2013[1],

– after consulting the Committee of the Regions ,

– having regard to Rule 55 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Employment and Social Affairs and the Committee on the Internal Market and Consumer Protection (A7-0000/2013),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) Key elements of the existing regulatory	(3) Key elements of the existing regulatory

[1] OJ C 0, 0.0.0000, p. 0. .

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.	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 ***relating to the marketing authorisation procedure*** ensuring transparency and traceability regarding devices should be introduced, to improve health and safety.

Or. en

Amendment 2

Proposal for a regulation
Recital 7

Text proposed by the Commission	*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.***	(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. ***Since in some cases it is difficult to distinguish between medical devices and cosmetic, medicinal or food products, the possibility to take an EU-wide decision regarding the regulatory status of a product should be introduced in Regulation (EC) No 1223/2009 on cosmetic products, Directive 2004/27/EC on medicinal products for human use,*** Regulation (EC) No 178/2002 ***on*** food law ***and*** food safety ***and Directive 2002/46/EC on food supplements. Those Union acts*** should ***therefore*** be amended.

Or. en

Amendment 3

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*** to decide on a case-by-case basis whether or not a product ***or groups of products fall*** within the scope of this Regulation.

Or. en

Justification

In order to have clarity and consistency across all Member States that same products are classified in the same way, the Commission and not the Member States should establish if a product/s fall within the scope of this regulation.

Amendment 4

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) A multidisciplinary advisory committee of experts and representatives of stakeholder and civil society organisations 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, classification and other aspects of implementation of this Regulation as necessary.

Or. en

Justification

An advisory committee should be established to provide narrow specialist advice where needed

Amendment 5

Proposal for a regulation
Recital 12

Text proposed by the Commission	*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 are also not covered by this Regulation.	(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.

Or. en

Justification

Currently, medical devices consisting of viable biological substances are covered by Directive 93/42/EEC. A general exclusion of biological substances would result in a loss of safe and efficient medical devices existing on the market at present which will not be approved as medicinal products as they have no pharmacological, immunological or metabolic mode of action

Amendment 6

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(31) The findings of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), established by Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC[1], in its scientific opinion of 15 April 2010 on the safety of reprocessed medical devices marketed for single-use, and of the Commission in its report of 27 August 2010 to the European Parliament and the Council on the issue of reprocessing of medical devices in the European Union, in accordance with Article 12a of Directive 93/42/EEC[2], call for regulation of the reprocessing of single-use devices in order to ensure a high level of protection of health and safety whilst allowing this practice to further develop under clear conditions. By reprocessing a single-use device its intended purpose is modified and the reprocessor should therefore be considered the manufacturer of the reprocessed device.	***deleted***

Or. en

Amendment 7

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 both logical and legal points of view. Only devices labelled as reusable should therefore be reprocessed. Consequently, devices labelled as single-use should be real single-use and there should be only two possible situations for devices: single-use or reusable. In recent past, manufacturers have started to label their devices as single-use too systematically. In order to avoid this, all devices should be reusable as a rule and it should be for the manufacturer to provide justification based on sufficient scientific evidence as derogation to that rule and enter that justification in the electronic system for the registration of devices. For class III devices, this derogation should be subject to a positive opinion from the Scientific Committee on Emerging and Newly Risks (SCENIHR). The reprocessing of devices encompasses a lot of various activities to ensure that a medical device can be safely reused, ranging from decontamination, sterilization, cleaning, disassembly, repair, component replacement and packaging. These activities should be subject to comparable and transparent standards.

Or. en

Amendment 8

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(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	(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

system.

basis for regulatory decision-making and to build confidence in the regulatory system.

Or. en

Amendment 9

Proposal for a regulation
Recital 36

Text proposed by the Commission	*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, to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) set up by Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices .	(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, ***marketing authorizations,*** certificates, clinical investigations, vigilance and market surveillance. The objectives of the database are to enhance overall transparency ***via better access to information for the public and healthcare professionals***, to streamline and facilitate the flow of information between economic operators, ***the Agency,*** 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 .

Or. en

Amendment 10

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(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.	(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 existing information for 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.

Or. en

Justification

It is in the public interest in matters of health and safety for public access to information to be extended or made possible upon request, where it is limited.

Amendment 11

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(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.	(39) For high-risk medical devices, manufacturers should ***provide the national authority or the Agency, as relevant, involved in the marketing authorisation procedure, with a full report on the*** safety and ***clinical*** performance of ***that*** device. ***A summary of that report*** should be publicly available ***via Eudamed***.

Or. en

Amendment 12

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	***deleted***

medical device before submitting the application to the notified body.

Or. en

Amendment 13

Proposal for a regulation
Recital 42 a (new)

Text proposed by the Commission	*Amendment*
	(42a) The conformity assessment procedure should not be applicable for all types of devices. A swift centralized marketing authorization procedure should be introduced for innovative implantable devices, for innovative devices which incorporate, as an integral part, a substance which, if used separately, would be considered to be a medicinal product, with action ancillary to that of the device, for innovative devices intended to administer a medicinal product, and for innovative devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable. A swift decentralized marketing authorization procedure should be introduced for all devices of class III, for non-innovative implantable devices, for non-innovative devices, which incorporate, as an integral part, a substance which, if used separately, would be considered to be a medicinal product, with action ancillary to that of the device, and for non-innovative devices intended to administer a medicinal product, and for innovative devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable.

Or. en

Amendment 14

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) The conformity assessment procedure for class I devices should be carried out, as a general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products. For medical devices in classes IIa, IIb ***and III***, an appropriate level of involvement of a notified body should be compulsory, ***with medical devices in class III requiring*** explicit prior approval of their design and manufacture before they can be placed on the market.	(44) The conformity assessment procedure for class I devices should be carried out, as a general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products. For medical devices in classes IIa ***and*** IIb***, an appropriate level of involvement of a notified body should be compulsory. For class III devices, the involvement of the Agency or of the Member States*** should be compulsory, ***together*** with ***the*** explicit prior approval of their design and manufacture before they can be placed on the market.

Or. en

Amendment 15

Proposal for a regulation
Recital 48 a (new)

Text proposed by the Commission	*Amendment*
	(48a) A clinical investigation should only start after being granted a positive evaluation by an independent ethics committee. Member States should take the necessary measures to establish Ethics Committees where such committees do not exist.

Or. en

Amendment 16

Proposal for a regulation
Recital 49

Text proposed by the Commission	*Amendment*
(49) Sponsors of clinical investigations to be conducted in more than one Member State should be given the possibility to submit a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety related aspects of the investigational device and of the scientific design of the clinical investigation to be conducted in several Member Stats, such single application should facilitate the coordination between the Member States under the direction of a coordinating Member State. ***The coordinated assessment should not include the assessment of intrinsically national, local and ethical aspects of a clinical investigation, including informed consent.*** Each Member State should retain the ultimate responsibility for deciding whether the clinical investigation may be conducted on its territory.	(49) Sponsors of clinical investigations to be conducted in more than one Member State should be given the possibility to submit a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety related aspects of the investigational device and of the scientific design of the clinical investigation to be conducted in several Member Stats, such single application should facilitate the coordination between the Member States under the direction of a coordinating Member State. Each Member State should retain the ultimate responsibility for deciding whether the clinical investigation may be conducted on its territory.

Or. en

Amendment 17

Proposal for a regulation
Recital 53

Text proposed by the Commission	*Amendment*
(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	(53) ***Member States should take all necessary measures to raise awareness among healthcare professionals, users and patients about the importance of reporting suspected serious incidents.*** Healthcare professionals, ***users*** and

with their peers when they confirm that a serious incident has occurred in order to minimise recurrence of those incidents.	patients should be empowered ***and enabled*** to report such incidents at national level using harmonised formats. ***In order to minimise the recurrence of such incidents, the*** national competent authorities should inform manufacturers and report the information ***via the respective electronic system in Eudamed*** when they confirm that a serious incident has occurred.

Or. en

Amendment 18

Proposal for a regulation
Recital 57

Text proposed by the Commission	*Amendment*
(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.	(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.***

Or. en

Amendment 19

Proposal for a regulation
Recital 58

Text proposed by the Commission	*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 the level and structure of the fees to ensure	(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

transparency.

fees to ensure transparency.

Or. en

Amendment 20

Proposal for a regulation
Recital 58 a (new)

Text proposed by the Commission	*Amendment*
	(58a) Member States should adopt regulations 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.

Or. en

Amendment 21

Proposal for a regulation
Recital 59

Text proposed by the Commission	*Amendment*
(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 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	(59) ***A*** 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 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

Commission and the Member States in ensuring a harmonised implementation of this Regulation.	States in ensuring a harmonised implementation of this Regulation.

Or. en

Justification

The MDCG is not an expert committee per se but an EU Level coordination group and as it lacks all the expertise that would be needed to decide on specific topics that will come up, the MDCG would need to be assisted by advisory committee which will provide the narrow expertise as per the needs of a given case etc.

Amendment 22

Proposal for a regulation
Article 1 – paragraph 2 – point f

Text proposed by the Commission	*Amendment*
(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;	(f) 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;

Or. en

Justification

Currently, medical devices consisting of viable biological substances are covered by Directive 93/42/EEC. A general exclusion of biological substances would result in a loss of safe and efficient medical devices existing on the market at present which will not be approved as medicinal products as they have no pharmacological, immunological or metabolic mode of action

Amendment 23

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 intended to be used on multiple patients or during multiple procedures.

Or. en

Amendment 24

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 used for surgically invasive medical procedures;	***deleted***

Or. en

Amendment 25

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;

Or. en

Amendment 26

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;

Or. en

Amendment 27

Proposal for a regulation
Article 2 – paragraph 1 – point 31 c (new)

Text proposed by the Commission	*Amendment*
	(31c) "safety" means the avoidance of risk or harm caused by the medical device or associated with its use;

Or. en

Amendment 28

Proposal for a regulation
Article 2 – paragraph 1 – point 33 – subparagraph 2 (new)

Text proposed by the Commission	*Amendment*
(33) 'clinical investigation' means any systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a device;	(33) 'clinical investigation' means any systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a device; ***Clinical investigations for medical devices, where made compulsory in accordance with this Regulation, shall include randomized clinical investigations in the appropriate target population and well-controlled investigations.***

Or. en

Amendment 29

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:

Or. en

Amendment 30

Proposal for a regulation
Article 2 – paragraph 1 – point 40

Text proposed by the Commission	*Amendment*
(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;	(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, use errors or inadequacy in the information supplied by the manufacturer;

Or. en

Justification

Correction of an error in referencing.

Amendment 31

Proposal for a regulation
Article 3

Text proposed by the Commission	*Amendment*
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).	The Commission may, at the request of a Member State or on its own initiative, by means of implementing acts ***and on the basis of the opinion of the advisory committee referred to in Article 78a***, 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' ***and if so, it shall determine the risk classification on the basis of the actual risk and scientific evidence.*** 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.	

Or. en

Amendment 32

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.

Or. en

Amendment 33

Proposal for a regulation
Article 15 a (new)

Text proposed by the Commission	*Amendment*
	Article 15a
	General principles on labelling of single-use devices and reprocessing of reusable devices
	1. All medical devices shall be treated as reusable devices unless otherwise labelled by the manufacturer.
	2. Only reusable devices labelled as such 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.
	"Single-use" devices shall not be reprocessed.
	3. Where a device is labelled as "single-use", it is the responsibility of the manufacturer to provide a justification based on sufficient scientific evidence that the device cannot be reprocessed safely.

Or. en

Amendment 34

Proposal for a regulation
Article 15 b (new)

Text proposed by the Commission	*Amendment*
	Article 15b
	Procedure for the labelling of class III devices as single use
	1. By way of derogation from Article 15a(3), when the manufacturer intends to label a class III device as "single-use", he shall, before doing so, conduct tests in order to gather sufficient scientific evidence, or refer to the latest scientific evidence, proving that the reprocessing of this device is not considered safe.
	2. Once gathered, the scientific evidence shall be provided by the manufacturer to the Commission, which shall immediately consult the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in this respect.
	The SCENIHR shall adopt an opinion within 90 days and inform the Commission and the manufacturer accordingly.
	In the event that the SCENIHR concludes that the scientific evidence provided by the manufacturer is not sufficient to prove that the device is not able to be reprocessed safely, it shall ask the manufacturer to conduct further tests to provide more convincing evidence.
	Upon receipt of the additional requested evidence by the manufacturer, the SCENIHR shall adopt a final opinion within 30 days and inform the Commission and the manufacturer accordingly.

The manufacturer shall label a class III device as "single-use" only once the SCENIHR has concluded that there is sufficient scientific evidence that the reprocessing of this device is not considered safe.

Or. en

Amendment 35

Proposal for a regulation
Article 15 c (new)

Text proposed by the Commission	*Amendment*
	Article 15c
	Procedure for the requalification of single-use devices as reusable devices
	1. Any natural or legal person who wishes to reprocess a device labelled as "single-use" and who has evidence that this device could be safely reprocessed shall inform the Commission of its intention to do so and submit this evidence to it.
	The Commission shall then immediately consult the SCENIHR in this respect.
	The SCENIHR shall adopt an opinion within 90 days and inform the Commission, the manufacturer and the natural or legal person accordingly.
	2. In the event the SCENIHR agrees with the natural or legal person that the device can be reprocessed, the manufacturer shall as soon as possible and, in any case, within 90 days following the adoption of the opinion of the SCENIHR, re-label the medical device as "reusable".
	3. In the event that the SCENIHR issues a negative opinion and that the natural or legal person disagrees with it, it may, within 60 days following the adoption of the opinion, provide the Commission with

further evidence that reprocessing the device will not put patient safety at risk.

The Commission shall then immediately request the SCENIHR to duly consider that further evidence and to adopt a final opinion within 90 days.

In the event that the SCENIHR confirms its first opinion disapproving the re-labelling of the concerned device as reusable, the natural or legal person, having requested the reprocessing of the concerned single-use device, shall not do so.

Or. en

Amendment 36

Proposal for a regulation
Article 15 d (new)

Text proposed by the Commission	*Amendment*
	Article 15d
	Reprocessing of medical devices labelled as reusable
	1. Any natural or legal person who reprocesses a device labelled as "reusable" 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. The Commission, by means of implementing acts, shall establish EU standards to ensure the safe reprocessing of medical devices labelled as "reusable".
	In doing so, the Commission shall ensure that these standards are consistent with the latest scientific evidence, the relevant ISO standards, or other international technical standards adopted by recognised

international standard-setting organisations, with the understanding that those international standards are able to guarantee, at the very least, a higher level of safety and performance than ISO standards.

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

Or. en

Amendment 37

Proposal for a regulation
Article 26

Text proposed by the Commission	*Amendment*
Summary of safety *and clinical performance*	***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 summary of*** safety and clinical performance. ***It*** shall be written in a way that is ***clear to the 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.***	1. In the case of devices ***submitted for marketing authorisation procedure***, 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 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***. The draft of this ***report*** shall be part of the documentation to be submitted ***to and validated by*** the ***national authority or the Agency, as relevant,*** involved in the ***marketing authorisation procedure***. .
	1a. The summary referred to in paragraph 1 shall be made available to the public via Eudamed in accordance with provisions under Article 27(2)(b) and Annex V, Part A, point 18.
2. The Commission may, by means of implementing acts, set out the form and the	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).	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).

Or. en

Justification

A proper report with full information from clinical investigation should be submitted to the notified bodies, while a user-friendly summary of that report should be made available to the public via Eudamed.

Amendment 38

Proposal for a regulation
Article 27 – paragraph 2 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) the electronic system on marketing authorisations referred to in Article 41b.

Or. en

Amendment 39

Proposal for a regulation
Article 27 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	3. The data shall be entered into Eudamed by the ***Agency, 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.

Or. en

Justification

The various electronic systems under Eudamed give differentiated access to the public. In order to ensure the usefulness of that data to the public, it is important that all sections accessible to it are presented in a user-friendly manner, which is to be established by the Commission in consultation with the relevant organisation best positioned to provide the best advice on those modalities.

Amendment 40

Proposal for a regulation
Article 27 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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 ***the Agency,*** notified bodies, economic operators, sponsors, ***healthcare professionals*** and the public to the extent defined in the provisions referred to in paragraph 2.

Or. en

Justification

The various electronic systems under Eudamed give differentiated access to the public. In order to ensure the usefulness of that data to the public, it is important that all sections accessible to it are presented in a user-friendly manner, which is to be established by the Commission in consultation with the relevant organisation best positioned to provide the best advice on those modalities.

Amendment 41

Proposal for a regulation
Article 27 – paragraph 6

Text proposed by the Commission	*Amendment*
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	6. The Commission, ***the Agency*** and the Member States shall ensure that the data subjects may effectively exercise their rights to information, to access, to rectify

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.	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.

Or. en

Justification

The various electronic systems under Eudamed give differentiated access to the public. In order to ensure the usefulness of that data to the public, it is important that all sections accessible to it are presented in a user-friendly manner, which is to be established by the Commission in consultation with the relevant organisation best positioned to provide the best advice on those modalities.

Amendment 42

Proposal for a regulation
Article 27 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7a. When developing and managing Eudamed, the Commission shall, in consultation with relevant partners including patient and consumer organisations, ensure that all publicly accessible parts of Eudamed are presented in a user-friendly format.

Or. en

Justification

The various electronic systems under Eudamed give differentiated access to the public. In order to ensure the usefulness of that data to the public, it is important that all sections accessible to it are presented in a user-friendly manner, which is to be established by the Commission in consultation with the relevant organisation best positioned to provide the best advice on those modalities.

Amendment 43

Proposal for a regulation
Article 28 – paragraph 6

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

Or. en

Amendment 44

Proposal for a regulation
Article 28 – paragraph 7

Text proposed by the Commission	*Amendment*
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.	7. 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.

Or. en

Amendment 45

Proposal for a regulation
Article 28 – paragraph 8 – subparagraph 2

Text proposed by the Commission	*Amendment*
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.	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 to the Commission and a summary of the outcome shall be made publicly available.

Or. en

Amendment 46

Proposal for a regulation
Article 29 – paragraph 1

Text proposed by the Commission	*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. Minimum requirements to be met by notified bodies are set out in Annex VI.	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 pharmacological, medical and technical knowledge is crucial.*** 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.***

Or. en

Amendment 47

Proposal for a regulation
Article 30 – paragraph -1 (new)

Text proposed by the Commission	*Amendment*
	-1. Notified body 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.
	Subcontracting shall be awarded to public entities. Contracts can also be awarded to external experts for the assessment of

innovative medical devices or technologies where clinical expertise is limited.

Or. en

Amendment 48

Proposal for a regulation
Article 30 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Notified bodies shall make publicly available the list of subcontractors or subsidiaries, as well as the specific tasks for which they are responsible.

Or. en

Amendment 49

Proposal for a regulation
Article 30 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	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.

Or. en

Amendment 50

Proposal for a regulation
Article 30 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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.

Or. en

Amendment 51

Proposal for a regulation
Article 32 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
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.***	Findings regarding non-compliance of a***n 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 it will take to ensure compliance of that applicant conformity assessment body with the requirements set out in Annex VI.***

Or. en

Amendment 52

Proposal for a regulation
Article 32 – paragraph 6

Text proposed by the Commission	*Amendment*
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.	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***. The*** relevant national authority shall ***base*** its decision on the designation of the notified body ***on this recommendation by the MDCG. In case where its decision differs from that recommendation, the national authority shall provide the MDCG with all necessary justifications***.

Or. en

Amendment 53

Proposal for a regulation
Article 33 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States ***may*** notify only conformity assessment bodies which satisfy the requirements set out in Annex VI.	2. Member States ***shall*** notify only conformity assessment bodies which satisfy the requirements set out in Annex VI.

Or. en

Amendment 54

Proposal for a regulation
Article 33 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. en

Amendment 55

Proposal for a regulation
Article 33 – paragraph 8

Text proposed by the Commission	*Amendment*
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.	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.

Or. en

Amendment 56

Proposal for a regulation
Article 34 – paragraph 2

Text proposed by the Commission	*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, accessible to the public. The Commission shall ensure that the list is kept up to date.	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

Or. en

Amendment 57

Proposal for a regulation
Article 35 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
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.	Notified bodies shall, without delay, ***and at least within 15 days***, 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.

Or. en

Amendment 58

Proposal for a regulation
Article 35 – paragraph 2

Text proposed by the Commission	*Amendment*
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.***	2. Notified bodies shall respond without delay, ***and at least within 15 days*** 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 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.***

Or. en

Amendment 59

Proposal for a regulation
Article 36 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
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.	The national authority responsible for notified bodies shall immediately ***and at least within 10 days***, inform the Commission and the other Member States of any suspension, restriction or withdrawal of a notification.

Or. en

Amendment 60

Proposal for a regulation
Article 36 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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, ***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.

Or. en

Amendment 61

Proposal for a regulation
Article 36 – paragraph 5 – subparagraph 2

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

Or. en

Amendment 62

Proposal for a regulation
Article 39 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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. ***This group shall meet on a regular basis and at least twice a year.***

Or. en

Amendment 63

Proposal for a regulation
Article 40 – title

Text proposed by the Commission	*Amendment*
Fees	Fees ***for the activities of national authorities***

Or. en

Amendment 64

Proposal for a regulation
Article 40 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on	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.	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. ***These fees shall be comparable across Member States and the level of the fees shall be made public.***

Or. en

Amendment 65

Proposal for a regulation
Article 40 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 setting out the structure and the ***comparable*** 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.

Or. en

Amendment 66

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 regulations 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.

Or. en

Amendment 67

Proposal for a regulation
Chapter V – Section 1 a (new)

Text proposed by the Commission	*Amendment*
	Section 1a - Marketing authorisation

Or. en

Amendment 68

Proposal for a regulation
Article 41 a (new)

Text proposed by the Commission	*Amendment*
	Article 41a
	General principles regarding the marketing authorisation
	1. None of the following devices may be placed on the market within the Union unless a Union marketing authorisation has been granted through the centralised procedure referred to in Article 41c, and in accordance with the provisions of this Regulation:
	- innovative implantable devices,
	- innovative devices referred to in Article 1(4),
	- innovative devices referred to in Article 1(5) and point 5.3. of Annex VII (Rule 11), or
	- innovative devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable.
	2. None of the following devices may be placed on the market of a Member State unless a national marketing authorisation has been granted by the competent authority of that Member State through the decentralised procedure referred to in Article 41d, and in accordance with the provisions of this Regulation:
	- class III devices,
	- non-innovative implantable devices,
	- non-innovative devices referred to in Article 1(4),
	- non-innovative devices referred to in Article 1(5) and point 5.3. of Annex VII

(Rule 11), or

- non-innovative devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable.

3. By way of derogation from paragraph 2, the manufacturer may decide to apply for a marketing authorisation under the centralised procedure for the devices included in paragraph 2.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 to amend the list set out in paragraph 1, in the light of technical progress.

5. Devices referred to in paragraphs 1 and 2, and which are already on the Union market at the date of entry into force of this Regulation, shall be required to have a marketing authorisation, in accordance with the procedures set out in this Section, as from the expiry date of the validity of their certificate.

6. A marketing authorisation granted under this Section shall be valid for five years.

The marketing authorisation may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the Agency.

7. All applications for marketing authorisation and granted marketing authorisations under the provisions of Articles 41c, 41d, 41e and 41f as well as the information referred to in Article 41b shall be entered either by the Commission or the Member States, as relevant, in the electronic system referred to in Article 41b(1), without delay and at the latest 15 days after receipt.

Before commencing the review of an application for a medical device, the Committee for the Authorisation of

Medical Devices, as referred to in Article 41c, or the competent authority of the relevant Member State shall verify that no other application has been introduced for the same medical device.

Or. en

Amendment 69

Proposal for a regulation
Article 41 b (new)

Text proposed by the Commission	*Amendment*
	Article 41b
	Electronic system on marketing authorisations
	1. The Commission shall, in collaboration with the Member States, set up and manage an electronic registration system for the applications for marketing authorisations and granted marketing authorisations under this Section and to collate and process the following information:
	- the name of the manufacturer,
	- the name and the risk-class of the medical device,
	- the applicable procedure,
	- in the case of a decentralised procedure, the Member State in which the manufacturer has applied,
	- the documentation accompanying the application for a marketing authorisation,
	- the assessment report for the medical device issued during the marketing authorisation procedure,
	- the date of the marketing authorisation approval and, where different, the date on which the device is placed on the market,

- any information regarding the suspension or withdrawal of the marketing authorisation.

2. The information collated and processed in the electronic system which relates to the centralised procedure as referred to in Article 41c shall be entered into the electronic registration system by the European Medicines Agency

The information collated and processed in the electronic system which relates to the decentralised procedure as referred to in Article 41d shall be entered into the electronic registration system by the Member States.

3. In case where this information needs to be updated, with regards to placing of the device on the market, the suspension or withdrawal of the device from the market, the manufacturer shall immediately inform the Agency or the national competent authority, as relevant, who shall immediately update the information in the electronic system.

4. The information collated and processed in the electronic system which relates to applications for marketing authorisations shall be accessible only to the Member States, the Agency and the Commission.

The information collated and processed in the electronic system and which relates to granted marketing authorisations shall be accessible to the public.

Or. en

Amendment 70

Proposal for a regulation
Article 41 c (new)

Text proposed by the Commission	*Amendment*
	Article 41c
	Centralised procedure
	1. A Committee for the Authorisation of Medical Devices is hereby established in accordance with the provisions of Article 41d. The Committee shall be part of the European Medicines Agency.
	2. The Committee for the Authorisation of Medical Devices shall be responsible for drawing up the opinion of the Agency on any matter concerning the admissibility of applications submitted in accordance with the centralised procedure, the granting, variation, suspension or revocation of an authorisation to place implantable devices and devices which include or dispense active substances on the market.
	3. Each application for the devices referred to in Article 41a (1) shall include the particulars and documents as referred to in Annexes VII, IX and X, as relevant.
	4. The application shall be accompanied by the fee payable to the Agency for examining the application.
	5. The Agency shall ensure that the opinion of the Committee for the Authorisation of Medical Devices is issued within 210 days from receipt of a valid application.
	The Committee for the Authorisation of Medical Devices shall be given at least 80 days from receipt of an application for analysing the scientific data in the documentation accompanying an application for a marketing authorisation. On the basis of a duly reasoned request, from the Committee for the Authorisation of Medical Devices, the Agency may

extend that period.

6. The Committee may only once request the manufacturer to submit additional information that for scientifically valid grounds is necessary for the assessment of the application for marketing authorisation. This may include a request for samples or an on-site visit to the manufacturer's premises. Where such a request has been made, the period referred to in paragraph 5 shall be suspended until the additional information requested has been supplied.

7. The Commission shall, in consultation with the Agency, the Member States and interested parties, draw up a detailed guide concerning the form in which applications for authorisation are to be presented.

8. Where the Committee for the Authorisation of Medical Devices considers it necessary in order to complete its examination of an application, it may require the applicant to undergo a specific inspection of the manufacturing site of the medical device concerned. Such inspections shall be made unannounced.

The inspection shall be carried out within the time-limit laid down in paragraph 5 by inspectors from the Member State holding the appropriate qualifications. Those inspectors may be accompanied by a rapporteur or an expert appointed by the Committee for the Authorisation of Medical Devices.

9. The Agency shall forthwith inform the applicant if the opinion of the Committee for the Authorisation of Medical Devices is that:

(a) the application does not satisfy the criteria for authorisation set out in this Regulation;

(b) the documentation accompanying the application is not in compliance with the provisions of this Regulation or needs to

be amended or supplemented;

(c) the marketing authorisation needs to be granted subject to certain conditions.

(d) the marketing authorisation for the medical device concerned needs to be refused on grounds that the device does not comply with this Regulation.

10. Within 15 days of receipt of the opinion referred to in paragraph 9, the applicant may notify the Agency in writing of his intention to request a re-examination of the opinion. In such a case, the applicant shall transmit to the Agency the detailed grounds for such a request within 60 days of receipt of the opinion.

Within 60 days following receipt of the grounds for the request, the Committee for the Authorisation of Medical Devices shall re-examine its opinion in accordance with the conditions laid down in the fourth subparagraph of Article 62(1) of Regulation (EC) 726/2004. The reasons for the conclusion reached shall be annexed to the final opinion.

11. Within 15 days from its adoption, the Agency shall send the final opinion of the Committee for the Authorisation of Medical Devices to the Commission, the Member States and the applicant, together with a report describing the assessment of the medical device by the Committee for the Authorisation of Medical Devices and stating the reasons for its conclusions.

12. If an applicant withdraws an application for a marketing authorisation submitted to the Agency before an opinion has been issued concerning that application, the applicant shall communicate its reasons for withdrawal to the Agency. The Agency shall make this information publicly available and shall publish the assessment report, if available, after deleting all information of a commercially confidential nature.

13. Within 15 days of receipt of the opinion referred to in paragraph 11, the Commission shall prepare a draft of the decision to be taken in respect of the application.

Where the draft decision diverges from the opinion of the Agency, the Commission shall annex a detailed explanation of the reasons for the differences.

The draft decision shall be transmitted to the Member States and the applicant.

Member States shall have 22 days to submit their written observations on the draft decision to the Commission. However, if a decision has to be taken urgently, a shorter time-limit may be set by the Chairperson of the Committee on Medical Devices according to the degree of urgency involved. This time-limit shall not, otherwise than in exceptional circumstances, be shorter than 5 days;

14. Member States may request in writing that the draft decision referred to in paragraph 13 be discussed by a plenary meeting of the Committee on Medical Devices, stating their reasons in detail.

Where, in the opinion of the Commission, a Member State's written observations raise important new questions of a scientific or technical nature which the opinion delivered by the Agency has not addressed, the Chairperson of the Committee on Medical Devices shall suspend the procedure and refer the application back to the Agency for further consideration.

15. The Commission shall take a final decision within 30 days from the end of the examination procedure referred to in Article 88(3).

16. The refusal of a marketing authorisation shall constitute a prohibition on the placing on the market of the devices referred to in Article 41a(1)

throughout the Union.

17. After a marketing authorisation has been granted, the marketing authorisation holder shall inform the Agency of the dates of actual placing on the market of the medical device in the Member States, taking into account the various presentations authorised.

18. The marketing authorisation holder shall also notify the Agency if the product ceases to be placed on the market, either temporarily or permanently, and it shall provide a justification on medical and/or economic grounds in this respect.

Or. en

Amendment 71

Proposal for a regulation
Article 41 d (new)

Text proposed by the Commission	*Amendment*
	Article 41d
	Committee for the Authorisation of Medical Devices
	1. The Committee for the Authorisation of Medical Devices shall be composed of the following:
	(a) one member and one alternate member appointed by each Member State, in accordance with paragraph 3 of this Article;
	(b) six members appointed by the Commission, with a view to ensuring that the relevant expertise in the field of medical devices is available within the Committee, on the basis of a public call for expressions of interest;
	(c) one member and one alternate member appointed by the Commission, on the basis of a public call for expressions

of interest, after consulting the European Parliament, in order to represent healthcare professionals;

(d) one member and one alternate member appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent patient organisations.

The alternate members shall represent and vote for the members in their absence. The alternate members referred to in point (a) may be appointed to act as rapporteurs in accordance with Article 62 of Regulation (EC) 726/2004.

2. A Member State may delegate its tasks in the Committee for the Authorisation of Medical Devices to another Member State. Each Member State may represent no more than one other Member State.

3. The members and alternate members of the Committee for the Authorisation of Medical Devices shall be appointed on the basis of their relevant expertise in the field of medical devices, in order to guarantee the highest levels of specialist qualifications and a broad spectrum of relevant expertise. For this purpose, Member States shall liaise with the Management Board of the Agency and the Commission in order to ensure that the final composition of the Committee for the Authorisation of Medical Devices covers the scientific areas relevant to its tasks.

4. The members and alternate members of the Committee for the Authorisation of Medical Devices shall be appointed for a term of three years, which may be prolonged once and thereafter renewed following the procedures referred to in paragraph 1. The Committee shall elect its Chairperson from among its full members for a term of three years, which may be prolonged once.

5. Paragraphs 3, 4, 5, 6, 7 and 8 of Article 61 of Regulation (EC) 726/2004 shall apply to the Committee for the Authorisation of Medical Devices.

6. The mandate of the Committee for the Authorisation of Medical Devices shall cover all aspects of the evaluation of medical devices in the scope of the procedures under Articles 41c and 41f ;

Or. en

Amendment 72

Proposal for a regulation
Article 41 e (new)

Text proposed by the Commission	*Amendment*
	Article 41e
	Decentralised procedure
	1. Member States shall verify through the electronic system on marketing authorisations referred to in Article 41b that no other application is currently being reviewed, and that no other marketing authorisation has been granted for the same medical device.
	2. Where a Member State notes that another application for a marketing authorisation for the same medical device is being examined in another Member State, the Member State concerned shall decline to assess the application and immediately inform the applicant.
	3. Where a Member State has authorised a medical device which is the subject of an application for a marketing authorisation in another Member State, the latter shall reject the application and immediately inform the applicant.
	4. Member States shall take all appropriate measures to ensure that the

procedure for granting a marketing authorisation for devices referred to in Article 41a (2) is completed within a maximum of 210 days after the submission of a valid application.

5. The competent national authority of a Member State may only once request to the manufacturer to submit additional information that, for scientifically valid grounds, is necessary for the assessment of the application for marketing authorisation. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, and within 60 days maximum, the period referred to in paragraph 4 shall be suspended.

6. If an applicant withdraws an application for a marketing authorisation submitted to the competent authority of a Member States before an opinion on the application has been given, the applicant shall communicate its reasons for doing so to the competent authority of that Member State. The national competent authority shall make this information publicly accessible and shall publish the assessment report, if available, after deletion of all information of a commercially confidential nature.

7. As soon as the marketing authorization is issued, the applicant shall be informed by the competent authority of the Member State concerned.

8. The national competent authority shall, without delay, and within 15 days, make publicly available the marketing authorisation.

9. The national competent authority shall draw up an assessment report and make comments on the file, notably as regards the result of the clinical investigations and the risk management system.

10. The national competent authority,

after deletion of all information of a commercially confidential nature, shall make the assessment report publicly accessible without delay, and at the latest within 15 days, together with the reasons for its opinion.

11. Member States shall inform the Agency of any marketing authorisation that they have granted.

12. After a marketing authorisation has been granted, the marketing authorisation holder shall inform the competent authority of the authorising Member State of the date of the actual placing on the market of the medical device in that Member State.

13. The marketing authorisation holder shall also notify the competent authority if the medical device ceases to be placed on the market of the Member State, either temporarily or permanently, and it shall provide a justification in this respect on medical and/or economic grounds.

Or. en

Amendment 73

Proposal for a regulation
Article 41 f (new)

Text proposed by the Commission	*Amendment*
	Article 41f
	Mutual recognition of decentralised marketing authorisation
	1. The MDCG as established by Article 78 shall be responsible for the examination of any question relating to a marketing authorisation in more than one Member State of a medical device eligible for authorisation in accordance with the procedure laid down in Article 41e.

2. With a view to the granting of a marketing authorisation for such a medical device in more than one Member State, an applicant shall submit an application based on an identical dossier to the competent authority in these Member States. The dossier shall contain the information and documents referred to in Annexes VIII, IX and X of this Regulation. The documents submitted shall include a list of the Member States concerned by the application. The applicant shall request one Member State to act as 'reference Member State' and to prepare an assessment report on the medical device in accordance with paragraphs 3 or 4.

3. Where the medical device has already been granted a marketing authorisation at the time of application, the concerned Member States shall recognise the marketing authorisation granted by the reference Member State which shall be the Member State that has first issued the marketing authorisation. To this end, the marketing authorisation holder shall request the reference Member State to update the existing assessment report of the authorised medical device. The reference Member State shall update the assessment report within 90 days of receipt of a valid application. The assessment report together with other relevant information and documents shall be sent to the concerned Member States and to the applicant.

4. In cases where the medical device has not received a marketing authorisation at the time of application, the applicant shall request the reference Member State to prepare a draft assessment report. The reference Member State shall prepare the report within 120 days after receipt of a valid application and it shall send them to the Member States concerned and to the applicant.

5. Within 90 days of receipt of the documents referred to in paragraphs 3 and 4, the Member States concerned shall approve the assessment report and shall inform the reference Member State accordingly. The reference Member State shall record the agreement of all parties, close the procedure and inform the applicant accordingly.

6. Each Member State in which an application has been submitted in accordance with paragraph 2 shall adopt a decision in conformity with the assessment report as approved, within 30 days after acknowledgement of the agreement.

7. If, within the period laid down in paragraph 5, a Member State concerned cannot approve the assessment report on the ground of a potential serious risk to public health, it shall give a detailed description of the reasons for its position to the reference Member State, to the other Member States concerned and to the applicant. The points of disagreement shall be forthwith referred to the MDCG.

8. Within the MDCG, all Member States referred to in paragraph 7 shall endeavour to reach agreement on the action to be taken. They shall concede the applicant the opportunity to make his point of view known orally or in writing. If, within 60 days of the communication of the points of disagreement, the Member States reach an agreement, the reference Member State shall record the agreement, close the procedure and inform the applicant accordingly. Paragraph 6 shall apply.

9. If the Member States fail to reach an agreement within the 60-day period laid down in paragraph 7, the Agency shall be informed immediately, with a view to the application of the procedure under Article 41g. The Agency shall be provided with a detailed statement of the matters on which

the Member States have been unable to reach agreement and the reasons for their disagreement. A copy shall be transmitted to the applicant.

10. As soon as the applicant is informed that the matter has been referred to the Agency, he shall forthwith forward to the Agency a copy of the information and documents referred to in paragraph 2.

11. In the circumstances referred to in paragraph 9, Member States that have approved the assessment report of the reference Member State may, at the request of the applicant, authorise the medical device without waiting for the outcome of the procedure laid down in Article 41g. In that event, the authorisation granted shall be without prejudice to the outcome of that procedure.

Or. en

Amendment 74

Proposal for a regulation
Article 41 g (new)

Text proposed by the Commission	*Amendment*
	Article 41g
	Arbitration procedure in the event of disagreement over mutual recognition of decentralised marketing authorisation
	1. Where reference is made to the procedure laid down in this Article, the Committee on Medical Devices shall consider the matter concerned and shall issue a reasoned opinion within 60 days of the date on which the matter was referred to it.
	In urgent cases, and on a proposal from its Chairperson, the Committee may agree

to a shorter deadline.

2. In order to consider the matter, the Committee on Medical Devices shall appoint one of its members to act as rapporteur. The Committee may also appoint individual experts to advise it on specific questions. When appointing experts, the Committee shall define their tasks and specify the time-limit for the completion of these tasks.

3. Before issuing its opinion, the Committee on Medical Devices shall provide the applicant or the marketing authorisation holder with an opportunity to present written or oral explanations within a time limit which it shall specify.

The Committee may suspend the time limits referred to in paragraph 1 in order to allow the applicant or the marketing authorisation holder to prepare explanations.

4. The Agency shall forthwith inform the applicant or the marketing authorisation holder of the opinion of the Committee on the marketing authorisation of the medical device concerned.

Within 15 days after receipt of the opinion of the Committee on Medical Devices,, the applicant or the marketing authorisation holder may notify the Agency in writing of his intention to request a re-examination of the opinion. In that case, he shall forward to the Agency the detailed grounds for the request within 60 days after receipt of the opinion.

Within 60 days following receipt of the grounds for the request, the Committee shall re-examine its opinion. It shall appoint a different rapporteur and, where necessary, a different co-rapporteur from the rapporteur and co-rapporteur appointed for the initial opinion. The re-examination procedure shall deal only with the points of the opinion identified by the applicant or the marketing

authorisation holder and shall be based only on the scientific data available when the Committee adopted the initial opinion. The applicant or the marketing authorisation holder may request that the Committee consult the advisory committee as established by Article 78a in connection with the re-examination.

The reasons for the conclusion reached in the re-examination shall be annexed to the assessment report referred to in paragraph 5 of this Article.

5. Within 15 days after its adoption, the Agency shall transmit the final opinion of the Committee on Medical Devices to the Member States, to the Commission and to the applicant or the marketing authorisation holder, together with the assessment report of the medical device and stating the reasons for its conclusions.

In the event of a favourable opinion concerning the application for a mutual recognition of decentralised marketing authorisation for a medical device as referred to in Article 41f, the following documents shall be annexed to the opinion:

(a) the dossier documents, as referred to in Article 41f (2);

(b) any conditions that might be affecting the authorisation;

(c) details of any recommended conditions or restrictions with regard to the safe and effective use of the medical device;

(d) the proposed text of the labelling and leaflet for the medical device.

6. Within 15 days of the receipt of the opinion referred to in paragraph 5, the Commission shall prepare a draft of the decision to be taken in respect of the application, taking into account Union law.

In the event of a draft decision which envisages the granting of a marketing authorization, the documents referred to in paragraph 5 shall be annexed.

Where the draft decision is not in accordance with the opinion of the Agency, the Commission shall also annex a detailed explanation of the reasons for the differences.

The draft decision shall be transmitted to the Member States and the applicant or the marketing authorisation holder.

Member States shall have 22 days to submit their written observations on the draft decision to the Commission. However, if a decision has to be taken urgently, a shorter time-limit may be set by the Chairperson of the Committee on Medical Devices according to the degree of urgency involved. That time limit shall not, other than under exceptional circumstances, be shorter than 5 days.

7. Member States may request in writing that the draft decision referred to in paragraph 6 be discussed by a plenary meeting of the Committee on Medical Devices, as referred to in Article 88(1), stating their reasons in detail.

Where, in the opinion of the Commission, a Member State's written observations raise important new questions of a scientific or technical nature which the opinion delivered by the Agency has not addressed, the Chairperson of the Committee on Medical Devices shall suspend the procedure and refer the application back to the Agency for further consideration.

8. The Commission shall take a final decision in accordance with, and within 30 days after the end of, the procedure referred to in Article 88(3). The Commission shall update the information on the concerned device in the electronic system referred to in Article 41b.

9. A refusal of a marketing authorisation shall constitute a prohibition on the placing on the market of the concerned device throughout the Union.

10. The decision as referred to in paragraph 8 shall be addressed to all Member States and transmitted to the marketing authorisation holder or the applicant. The concerned Member States and the reference Member State shall either grant or revoke the marketing authorisation, or vary its terms as necessary to comply with the decision within 30 days following its notification. They shall inform the Commission and the Agency accordingly.

Or. en

Amendment 75

Proposal for a regulation
Article 41 h (new)

Text proposed by the Commission	*Amendment*
	Article 41h
	Variation to a marketing authorisation
	1. Any application by the marketing authorization holder to vary a marketing authorization which has been granted in accordance with the provisions of Articles 41c, 41e and 41f shall be submitted to all the Member States which have previously authorized the medical device concerned.
	The Commission shall, in consultation with the Agency, be empowered to adopt delegated acts in accordance with Article 89 of this Regulation in order to adopt the appropriate arrangements for the examination of variations to the terms of a marketing authorization.
	2. In case of arbitration submitted to the

Commission, the procedure laid down in Article 41g shall apply by analogy to variations made to marketing authorizations.

3. Where a Member State considers that the variation of a marketing authorization which has been granted in accordance with the provisions of this Chapter or its suspension or withdrawal is necessary for the protection of public health, the Member State concerned shall forthwith refer the matter to the Agency for the application of the procedure laid down in Article 41g.

In exceptional cases, where urgent action is essential to protect public health, until a definitive decision is adopted, a Member State may suspend the marketing and the use of the medical device concerned on its territory. It shall inform the Commission, the Agency and the other Member States no later than the following working day of the reasons for this measure.

Or. en

Amendment 76

Proposal for a regulation
Article 42 – paragraph 2

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

verification as specified in Annex X.	conformity verification as specified in Annex X.
In the case of devices referred to in the first subparagraph of Article 1(4), ***the notified body*** shall follow the consultation procedure as specified in Section 6.1 of Chapter II of Annex VIII or Section 6 of Annex IX, as applicable.	In the case of devices referred to in the first subparagraph of Article 1(4), the ***Committee for the Authorisation of Medical Devices referred to in Article 41c, or the national authority,*** shall follow the consultation procedure as specified in Section 6.1 of Chapter II of Annex VIII or Section 6 of Annex IX, as applicable.
In the case of devices that are covered by this Regulation in accordance with point (e) of Article 1(2), the ***notified body*** shall follow the consultation procedure as specified in Section 6.2 of Chapter II of Annex VIII or Section 6 of Annex IX, as applicable.	In the case of devices that are covered by this Regulation in accordance with point (e) of Article 1(2), the ***marketing authorisation*** shall follow the consultation procedure as specified in Section 6.2 of Chapter II of Annex VIII or Section 6 of Annex IX, as applicable.

Or. en

Amendment 77

Proposal for a regulation
Article 42 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Manufacturers of devices classified as class IIb, other than custom-made or investigational devices, shall be subject to a conformity assessment based on full quality assurance as specified in Annex VIII, except for its Chapter II, with assessment of the design documentation within the technical documentation on a representative basis. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX coupled with a conformity assessment based on product conformity verification as specified in Annex X.	3. ***By way of derogation from Article 41a,*** manufacturers of devices classified as class IIb, other than custom-made or investigational devices, shall be subject to a conformity assessment based on full quality assurance as specified in Annex VIII, except for its Chapter II, with assessment of the design documentation within the technical documentation on a representative basis. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX coupled with a conformity assessment based on product conformity verification as specified in Annex X.

Or. en

Amendment 78

Proposal for a regulation
Article 42 – paragraph 4

Text proposed by the Commission	*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 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.	4. ***By way of derogation from Article 41a,*** 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.

Or. en

Amendment 79

Proposal for a regulation
Article 43 – title

Text proposed by the Commission	*Amendment*
Involvement of notified bodies	Involvement of notified bodies ***in the conformity assessment procedure***

Or. en

Amendment 80

Proposal for a regulation
Article 43 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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. ***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.

Or. en

Amendment 81

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).

Or. en

Amendment 82

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***;

Or. en

Amendment 83

Proposal for a regulation
Article 50 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Clinical investigations shall be designed and conducted in a way that the rights, safety and well-being of the subjects participating in a clinical investigation are protected and that the clinical data generated in the clinical investigation are going to be reliable and robust.	3. Clinical investigations shall be designed and conducted in a way that the rights, safety and well-being of the subjects participating in a clinical investigation are protected, ***in accordance with Article 50a (3),*** and that the clinical data generated in the clinical investigation are going to be reliable and robust.

Or. en

Amendment 84

Proposal for a regulation
Article 50 a (new)

Text proposed by the Commission	*Amendment*
	Article 50a
	Involvement of Ethics Committee
	1. Authorisation to conduct a clinical investigation may only be granted if an independent ethics committee has previously submitted a positive evaluation of that investigation.
	2. The statement of the Ethics Committee shall cover in particular the medical justification, 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.

3. The Ethics Committee shall ensure that the rights, safety and well-being of subjects participating in a clinical investigation are protected.

4. It shall be independent of the researcher, independent of the sponsor, and free of any other undue influence. It shall act in accordance with the laws and regulations of the country or countries in which the research is to be conducted and must abide by all relevant international norms and standards.

5. The Ethics Committee shall consist of a clearly defined number of members and substitutes which include healthcare professionals, laypersons and at least one well-experienced, knowledgeable patient or patient representative, who collectively possess the relevant qualifications and experience to be able to review and evaluate the scientific, medical and ethical aspects of the proposed clinical investigation.

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

Members States shall publish the number, the names and the professions of the members and substitutes of the Ethics Committees and inform the Commission about the composition of the Ethics Committees and the date on which they become operational.

Or. en

Amendment 85

Proposal for a regulation
Article 51 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
2. 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.	2. 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 ***ten*** 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.

Or. en

Amendment 86

Proposal for a regulation
Article 51 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
3. Where the Member State finds that the clinical investigation applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a maximum of ***six*** days for the sponsor to comment or to complete the application.	3. Where the Member State finds that the clinical investigation applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a maximum of ***ten*** days for the sponsor to comment or to complete the application.

Or. en

Amendment 87

Proposal for a regulation
Article 51 – paragraph 3 – subparagraph 3

Text proposed by the Commission	*Amendment*
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.	Where the Member State has not notified the sponsor according to paragraph 2 within ***five*** 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.

Or. en

Amendment 88

Proposal for a regulation
Article 51 – paragraph 5 – point c

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

Or. en

Amendment 89

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.

Or. en

Amendment 90

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 53 a summary of its results drawn up in a way that is easy for a lay person to understand.

Or. en

Amendment 91

Proposal for a regulation
Article 53 – paragraph 2

Text proposed by the Commission	*Amendment*
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 […/…]. 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.	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 […/…]. With the exception of the information referred to in Article 52, the information collated and processed in the electronic system shall be accessible to the Member States and to the Commission. ***The Commission shall also ensure that healthcare professionals have access to the electronic system.***

Or. en

Amendment 92

Proposal for a regulation
Article 53 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	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 on any of the following grounds:
	(a) protection of personal data in accordance with Regulation (EC) No 45/2001;
	(b) protection of commercially sensitive information;
	(c) effective supervision of the conduct of the clinical investigation by the Member State(s) concerned.

Or. en

Justification

It is important that healthcare professionals also have appropriate access to the electronic system on clinical investigations since it contains reports on serious adverse events and device deficiencies. It is also important to ensure that where it is in the public interest, there is a way to request existing information which is otherwise not readily accessible without a special request.

Amendment 93

Proposal for a regulation
Article 56 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where a Member State has refused, suspended or terminated a clinical investigation, or has called for a substantial	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.	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 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.

Or. en

Amendment 94

Proposal for a regulation
Article 57 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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.

Or. en

Amendment 95

Proposal for a regulation
Article 57 – paragraph 2

Text proposed by the Commission	*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. That notification shall be made within 15 days from the end of the clinical investigation in relation to that Member State.	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 overall end of the clinical investigation. That notification shall be made within 15 days from the overall end of the clinical investigation.	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. ***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 overall end of the clinical investigation.

Or. en

Amendment 96

Proposal for a regulation
Article 58 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. In the single application, the sponsor shall propose one of the Member States concerned as coordinating Member State. ***The reporting Member State shall be chosen from among the Member States concerned in which most of the subjects participating in the clinical investigation in question live.*** 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.

Or. en

Amendment 97

Proposal for a regulation
Article 61 – paragraph 1 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) any serious incident in respect of devices made available on the Union market;	(a) any serious incident, ***including date and place of incident,*** 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;***

Or. en

Amendment 98

Proposal for a regulation
Article 61 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	3. The Member States shall take all appropriate measures, ***including targeted information campaigns***, to encourage ***and enable*** healthcare professionals, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1. They ***shall inform the Commission of those measures.***
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	***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.	manufacturer shall ensure the appropriate follow-up. ***Where a competent authority of a member State ascertains that the reports received pursuant to the first subparagraph relate to a serious incident it shall notify those reports to the electronic system referred to in Article 62 without delay, unless the same incident has already been reported by the manufacturer***.
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.	The ***Commission, in cooperation with the*** Member States ***and in consultation with relevant partners including patient and consumer organisations,*** shall ***develop*** standard forms for ***electronic and non-electronic*** reporting of serious incidents by healthcare professionals, users and patients.

Or. en

Justification

Issues related to reporting by healthcare professionals, users and patients should be strengthened. The standard forms should be developed by the Commission with input by patient and consumer organisations in both electronic and non-electronic format, for users without internet access or computer literacy.

Amendment 99

Proposal for a regulation
Article 62 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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 Agency***, to the notified bodies ***and healthcare professionals***.

Or. en

Justification

If there is a legitimate interest in gaining knowledge of serious incidents concerning certain medical devices at an early stage, a comprehensive right to information must therefore be created.

Amendment 100

Proposal for a regulation
Article 62 – paragraph 3

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

Or. en

Justification

If there is a legitimate interest in gaining knowledge of serious incidents concerning certain medical devices at an early stage, a comprehensive right to information must therefore be created

Amendment 101

Proposal for a regulation
Article 63 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. en

Justification

Relates to inclusion of this provision under Article 61(3).

Amendment 102

Proposal for a regulation
Article 68 – paragraph 2

Text proposed by 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 ***and*** to 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, to the Commission, ***to the Agency 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.***

Or. en

Justification

It is important that the Agency and healthcare professionals also have full access to the electronic system for market surveillance since it contains important information on devices presenting risk to health. While the public might have more differentiated access, if there is a legitimate interest in gaining knowledge of serious incidents concerning certain medical devices at an early stage, a comprehensive right to information must therefore be created.

Amendment 103

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	***deleted***

contributions.

Or. en

Justification

Rather than on a case by case basis, an advisory committee providing directly specialist advice and expertise should be established to support the work of the Commission, the MDCG and Member States.

Amendment 104

Proposal for a regulation
Article 78 – paragraph 8 – subparagraph 1 – indent 3 a (new)

Text proposed by the Commission	*Amendment*
	- the examination of questions related to the mutual recognition procedure in accordance with provisions under Article 41e.

Or. en

Amendment 105

Proposal for a regulation
Article 78 a (new)

Text proposed by the Commission	*Amendment*
	Article 78a
	Advisory Committee
	1. A multidisciplinary advisory committee composed of experts and representatives of stakeholder and civil society organisations shall be established to provide support, scientific advice and expertise to the MDCG, the Commission and Member States on various aspects of medical technology in relation to medical devices and in vitro diagnostic medical devices, 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. The advisory committee shall consult the EMA and the European Food Safety Authority when deliberating borderline cases involving medicinal and food products.

3. The Commission shall provide the logistic support to the operations of the advisory committee.

Or. en

Justification

Rather than on a case by case basis, an advisory committee providing directly specialist advice and expertise should be established to support the work of the Commission, the MDCG and Member States

Amendment 106

Proposal for a regulation
Article 80 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) to examine questions related to the mutual recognition procedure in accordance with provisions under Article 41e.

Or. en

Amendment 107

Proposal for a regulation
Article 82 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Members of the MDCG and staff of the	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.***	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.

Or. en

Amendment 108

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.

Or. en

Amendment 109

Proposal for a regulation
Article 83 – paragraph 1

Text proposed by the Commission	*Amendment*
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	The Commission and the Member States shall take all appropriate measures to ***ensure*** the establishment of registers for ***medical*** devices to gather post-market experience related to the use of such

such devices. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices.	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.

Or. en

Amendment 110

Proposal for a regulation
Chapter II - title

Text proposed by the Commission	*Amendment*
Chapter ***II***	Chapter ***VI***
Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement	Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement
	Articles under this Chapter: 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 20, 21, 22

Or. en

Amendment 111

Proposal for a regulation
Chapter VI b (new)

Text proposed by the Commission	*Amendment*
	Chapter VII
	Reprocessing of medical devices
	Articles under this Chapter: 15a, 15b, 15c, 15d

Or. en

Amendment 112

Proposal for a regulation
Chapter III - title

Text proposed by the Commission	*Amendment*
Chapter ***III***	Chapter ***VIII***
Identification and traceability of devices, registration of devices and of economic operators, ***summary of safety and clinical performance,*** European databank on medical devices	Identification and traceability of devices, registration of devices and of economic operators, European databank on medical devices
	Articles under this Chapter: 23, 24, 25, 27

Or. en

Amendment 113

Proposal for a regulation
Chapter IV - title

Text proposed by the Commission	*Amendment*
Chapter IV	Chapter IV
Notified bodies	Notified bodies
	Articles under this Chapter: 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 40a, 43

Or. en

Amendment 114

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***
	Articles under this Chapter: 41

Or. en

Amendment 115

Proposal for a regulation
Chapter II a (new)

Text proposed by the Commission	*Amendment*
	Chapter III
	Marketing authorisation and conformity assessment
	Articles under this Chapter: 26, 41a, 41b, 41c, 41d, 41e, 41f, 41g, 41h, 42, 44, 45, 46, 47, 48,

Or. en

Amendment 116

Proposal for a regulation
Chapter VI - title

Text proposed by the Commission	*Amendment*
Chapter ***VI***	Chapter ***V***
Clinical evaluation and clinical investigations	Clinical evaluation and clinical investigations
	Articles under this Chapter: 49, 50, 50a, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60

Or. en

Amendment 117

Proposal for a regulation
Chapter VII - title

Text proposed by the Commission	*Amendment*
Chapter ***VII***	Chapter ***IX***
Vigilance and market surveillance	Vigilance and market surveillance
	Articles under this Chapter: 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75

Or. en

Amendment 118

Proposal for a regulation
Chapter VIII - title

Text proposed by the Commission	*Amendment*
Chapter ***VIII***	Chapter ***X***
Cooperation between Member States, Medical Device Coordination Group, EU reference laboratories, device registers	Cooperation between Member States, Medical Device Coordination Group, EU reference laboratories, device registers
	Articles under this Chapter: 76, 77, 78, 78a, 79, 80, 81, 82, 83

Or. en

Amendment 119

Proposal for a regulation
Chapter IX - title

Text proposed by the Commission	*Amendment*
Chapter ***IX***	Chapter ***XI***
Confidentiality, data protection, funding,	Confidentiality, data protection, funding,

penalties	penalties
	Articles under this Chapter: 84, 85, 86, 87

Or. en

Amendment 120

Proposal for a regulation
Annex I – PART III – point 19.2 – point n

Text proposed by the Commission	*Amendment*
(n) If the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union.	(n) If the device is intended for single use, an indication of that fact. ***The manufacturer shall provide sufficient evidence that the device cannot be reprocessed safely.*** A manufacturer's indication of single use shall be consistent across the Union.

Or. en

Amendment 121

Proposal for a regulation
Annex I – PART III – 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***

Or. en

Amendment 122

Proposal for a regulation
Annex I – PART III – 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, 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.***	(k) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, 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.

Or. en

Amendment 123

Proposal for a regulation
Annex I – PART III – point 19.3 – point l

Text proposed by the Commission	*Amendment*
(l) 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.	(l) ***With the exception of devices referred to in Article 15b, i***f the device bears an indication that the device is for single use, ***all*** 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.

Or. en

Amendment 124

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.

Or. en

Justification

In order to promote transparency, there is a need for an additional review by an independent scientific body of the manufacturer's PMCF evaluation report for the highest risk devices. ...

Amendment 125

Proposal for a regulation
Annex V - Part A - point 10

Text proposed by the Commission	*Amendment*
10. reprocessed single-use device ***(y/n),***	***10. in case of*** single-use device***, the justification as referred to in Article 15a(3).***

Or. en

Amendment 126

Proposal for a regulation
Annex VI – paragraph 1 – point 1.1 – point 1.1.4

Text proposed by the Commission	*Amendment*
1.1.4. The organisational structure, distribution of responsibilities and	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.	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.	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.***

Or. en

Amendment 127

Proposal for a regulation
Annex VI – paragraph 1 – point 1.2 – point 1.2.3

Text proposed by the Commission	*Amendment*
1.2.3. The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not:	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 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	- 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;	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.	- 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 provide evidence to the national authority that there are no conflicts of interest in compliance with this point. The national authority shall to the Commission twice a year in full transparency.

Or. en

Amendment 128

Proposal for a regulation
Annex VI – paragraph 1 – point 1.2 – point 1.2.6

Text proposed by the Commission	*Amendment*
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.	1.2.6. 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.***

Or. en

Amendment 129

Proposal for a regulation
Annex VI – paragraph 1 – point 1.3

Text proposed by the Commission	*Amendment*
1.3. Confidentiality	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 authorities or the Commission. Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.	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 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 by the public or healthcare professionals, the notified body shall make publicly available the reasons for such information being subject to non-disclosure.***

Or. en

Amendment 130

Proposal for a regulation
Annex VI – paragraph 1 – point 1.6 – point 1.6.1

Text proposed by the Commission	*Amendment*
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.	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. ***The notified body shall keep a record of the actions it takes to inform its***

personnel.

Or. en

Amendment 131

Proposal for a regulation
Annex VI – paragraph 3 – point 3.1.

Text proposed by the Commission	*Amendment*
3.1. General	3.1. General
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.	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.	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.	This presupposes the ***permanent*** 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.
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	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 ***pharmacological, medical and*** technical knowledge and sufficient and

relating to medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data.	appropriate experience relating to medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data.
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 involved in conformity assessment activities and inform the personnel concerned about it. ***3.1.3a. The notified body shall make available the list of its personnel and their expertise to the Commission and, upon request, to other parties. That list shall be kept up to date.***

Or. en

Amendment 132

Proposal for a regulation
Annex VI – paragraph 3 – point 3.2. – point 3.2.3.

Text proposed by the Commission	*Amendment*
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:	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;	**-** Union medical devices legislation and relevant guidance documents;
- the conformity assessment procedures in accordance with this Regulation;	**-** 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	- a broad base of medical device technologies, the medical device industry and the design and manufacture of medical

devices;	devices;
- the notified body's quality management system and related procedures;	**-** 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;	- 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;	**-** 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.	**-** 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,

Or. en

Amendment 133

Proposal for a regulation
Annex VI – paragraph 3 – point 3.2. – point 3.2.4.

Text proposed by the Commission	*Amendment*
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:	3.2.4. ***Clinical experts: n***otified bodies shall have available***, on a permanent basis,*** personnel with expertise ***in clinical investigation design, medical statistics, clinical patient management, Good Clinical Practice in the field of clinical investigations and pharmacology.*** 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 evaluation conducted by the manufacturer and identify appropriately qualified experts;	- 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;	- 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 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 data presented, and the results of the external clinical experts' assessment of the manufacturer's 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 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.	- 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.
	- provide an understanding of active substances.

Or. en

Amendment 134

Proposal for a regulation
Annex VI – paragraph 3 – point 3.2. – point 3.2.5. – introductory part

Text proposed by the Commission	*Amendment*
3.2.5. The personnel responsible for	3.2.5. ***Product assessors: t***he personnel

carrying out product related review (e.g. design dossier review, technical documentation review or type examination including aspects such as clinical evaluation, biological safety, sterilisation, software validation) shall have the following proven qualification:	responsible for carrying out product related review (e.g. design dossier review, technical documentation review or type examination including aspects such as clinical evaluation, biological safety, sterilisation, software validation) shall have the following proven qualification:

Or. en

Amendment 135

Proposal for a regulation
Annex VI – paragraph 3 – point 3.2. – point 3.2.6. – introductory part

Text proposed by the Commission	*Amendment*
3.2.6. The personnel responsible for carrying out audits of the manufacturer's quality management system shall have the following proven qualification:	3.2.6. ***Auditors: t***he personnel responsible for carrying out audits of the manufacturer's quality management system shall have the following proven qualification:

Or. en

Amendment 136

Proposal for a regulation
Annex VI – paragraph 3 – point 3.3. – point 3.3.1

Text proposed by the Commission	*Amendment*
3.3.1. The notified body shall have a process in place to fully document the qualification of each personnel involved in conformity assessment activities and the satisfaction of the qualification criteria referred to in Section 3.2. ***Where in exceptional circumstances the fulfilment of the qualification criteria set out in Section 3.2 cannot be fully demonstrated, the notified body shall appropriately justify the authorisation of these personnel to carry out specific conformity***	3.3.1. The notified body shall have a process in place to fully document the qualification of each personnel involved in conformity assessment activities and the satisfaction of the qualification criteria referred to in Section 3.2.

assessment activities.

Or. en

Amendment 137

Proposal for a regulation
Annex VI – paragraph 3 – point 3.4.

Text proposed by the Commission	*Amendment*
3.4. Subcontractors and external experts	3.4. Subcontractors and external experts
	3.4.-1 Notified body shall have permanent "in house" competent personnel and expertise, not only in technical fields linked with the assessment of the performance of the devices, but also in the medical sector. They shall have the capacity to evaluate "in house" the quality of subcontractors. By derogation, the following paragraphs apply.
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.	3.4.1. Without prejudice to the limitations emanating from Section 3.2., notified bodies may subcontract clearly defined parts of the conformity assessment activities ***to public entities. Contracts can also be awarded to external experts for the assessment of innovative medical devices or technologies 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 and be subject to a written agreement covering, among others, confidentiality and conflict of interests.	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 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.	3.4.3. Where subcontractors or external experts are used in the context of the conformity assessment, in particular regarding novel invasive and ***novel*** 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.
3.4.4. The notified body shall establish procedures for assessing and monitoring the competence of all subcontractors and external experts used.	3.4.4. The notified body shall establish procedures for assessing and monitoring the competence of all subcontractors and external experts used. ***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.***

Or. en

Amendment 138

Proposal for a regulation
Annex VI – paragraph 3 – point 3.5. – point 3.5.2.

Text proposed by the Commission	*Amendment*
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.	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.

Or. en

Amendment 139

Proposal for a regulation
Annex VI – paragraph 4 – point 4.3

Text proposed by the Commission	*Amendment*
4.3. The notified body shall have in place documented procedures covering at least:	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 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,	- 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 minimum time for its audit assessments,***
- the language of the application, of the correspondence and of the documentation to be submitted,	- the language of the application, of the correspondence and of the documentation to be submitted,
- the terms of the agreement with the manufacturer or authorised representative,	- the terms of the agreement with the manufacturer or authorised representative,
- the fees to be charged for conformity assessment activities,	- the fees to be charged for conformity assessment activities,
- the assessment of relevant changes to be submitted for prior approval,	- the assessment of relevant changes to be submitted for prior approval,
- the planning of surveillance,	- the planning of surveillance,
- the renewal of certificates.	- the renewal of certificates.

Or. en

Amendment 140

Proposal for a regulation
Annex VII – point 6.9 – rule 21

Text proposed by the Commission	*Amendment*
Devices that are composed of substances	***deleted***

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.

Or. en

Amendment 141

Proposal for a regulation
Annex XIII – Part B – paragraph 3

Text proposed by the Commission	*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***.***	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. ***For class III medical devices, the manufacturer's PMCF evaluation report shall be reviewed by an independent scientific body, such as an academic institution or a medical society. In order to conduct its review, the manufacturer shall provide the relevant data to the independent scientific body. Both the manufacturer's PMCF evaluation report and its review by an independent scientific body shall be part of the technical documentation for class III medical devices.***

Or. en

Justification

In order to promote transparency, there is a need for an additional review by an independent scientific body of the manufacturer's PMCF evaluation report for the highest risk devices.

Amendment 142

Proposal for a regulation
Annex XIII – Part B – paragraph 4

Text proposed by the Commission	*Amendment*
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.	4. The conclusions of the PMCF evaluation report, ***and where applicable its review by an independent scientific body 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.

Or. en

Justification

In order to promote transparency, there is a need for an additional review by an independent scientific body of the manufacturer's PMCF evaluation report for the highest risk devices.

Amendment 143

Proposal for a regulation
Annex XIV – Part I – paragraph 2 – point 2.1.

Text proposed by the Commission	*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 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.	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.

Or. en

Amendment 144

Proposal for a regulation
Annex XIV – Part I – paragraph 2 – point 2.3.

Text proposed by the Commission	*Amendment*
2.3. Clinical investigations shall be performed in circumstances similar to the normal conditions of use of the device.	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***.

Or. en

Amendment 145

Proposal for a regulation
Annex VI – Part II – paragraph 1 – point 1.11

Text proposed by the Commission	*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).	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 randomized 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.

Or. en

EXPLANATORY STATEMENT

Your rapporteur welcomes the Commission proposal to revise the existing regulatory framework on medical devices. Such revision of this twenty years-old framework was particularly needed and many improvements have been brought to the current legislation. However, your rapporteur still believes that many other changes, which you will find described below, should still be introduced in the text.

Order of the text

The Commission proposes a structure for the text which is not entirely satisfactory as it does not mirror the sequence of activities that need to be performed before a medical device can be safely used. The second chapter is already referring to making devices available, free movement, or even reprocessing, before any mention of the classification of the devices or of the selection of the approval procedure. The order used also puts the emphasis on placing the device on the market and on its free movement within the EU, while leaving considerations of patient safety and public health (classification, procedure for approval and clinical investigations) at a second stage.

Your rapporteur believes that the logical sequence of the lifecycle of a device should be better reflected in the structure of the text and therefore proposes to change the chapter sequence of the proposal as follows: section 1 of chapter V on the classification of a device should be taken out and be dealt with in a new chapter II; chapter III should outline the various approval procedures of devices; chapter IV on notified bodies would remain in its place as it is linked with the conformity assessment procedure which is described in the previous chapter; chapter V sets out the provisions on clinical evaluations and clinical investigations which are required to demonstrate conformity with general safety and performance requirements based on clinical data and, consequently, for the approval of a device; following the decision regarding the approval of a device, the placing on the market and free movement of devices are treated in the proposed chapter VI; a separate chapter VII on the labelling of devices as single-use or reusable, and on reprocessing in the case of the latter is established; provisions on the identification and traceability of devices, on the registration of devices and economic operators, as well as the European databank on medical devices are set out in chapter VIII. The last four chapters of the Commission proposal remain at the end of the text.

Classification of devices

Your rapporteur generally agrees with the improvements brought about in the Commission proposal in terms of the classification of medical devices into four classes according to the level of risk they post onto patients. However, rule 21 in annex VII on classification, which stipulates that all devices composed of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body are classified in class III is disproportionate. It would affect a very high number of medical devices on the market which already fall under rule 5. Your rapporteur suggests the deletion of this new rule.

The approval system of medical devices

The conformity assessment procedure has shown substantial weaknesses over the past years, such as the lack of transparency, swift approval and placing on the market of medical devices despite insufficient investigations on patients and therefore insufficient clinical data, consequently putting patients at risk.

Your rapporteur believes that medical devices presenting the highest potential risks for patients should be subject to a more stringent procedure than a conformity assessment. This category should include medical devices listed in class III, those implanted into the body, incorporating a substance considered to be a medicinal product, intended to administer a medicinal product, or utilising non-viable tissues or cells of human or animal origin, or their derivatives. For such devices, your rapporteur proposes to introduce a new marketing authorisation procedure, at centralised level for devices of an innovative nature and at decentralised level for the other devices mentioned above.

A Committee for the Authorisation of Medical Devices is created within the European Medicines Agency (EMA), which will be involved in the centralised procedure. Your rapporteur also proposes to include the possibility for manufacturers required to use the decentralised procedure, to apply for the centralised procedure. In the case of the decentralised procedure, the mutual recognition principle applies and the Medical Devices Coordination Group (MDCG) is assigned a facilitation role where disagreements arise over marketing authorisations between Member States. Where disagreements persist, the Committee for the Authorisation of Medical Devices is requested to provide an opinion. The final decision is taken by the Commission.

In order to increase the transparency related to the approval of devices, an electronic system for the registration of applications, the granting, the suspension and the revocation of marketing authorisations is also created and made publicly accessible. The EMA and the Member States, as relevant, will be responsible for entering the relevant information into the system. Moreover, where the decentralised procedure applies, the Member States shall inform the Agency of any marketing authorisation that they have granted. Manufacturers are obliged to inform the competent authority and provide justification where a medical device ceases to be placed on market. For both the centralised and the decentralised procedure, strict deadlines apply. The Committee is granted the possibility to request additional information from the manufacturer only once. These provisions have been introduced to ensure swift procedures and quick decisions for the benefit of manufacturers and patients.

Notified bodies

Both the functioning of notified bodies and their monitoring by national authorities have shown huge weaknesses over the past years. The issues which were raised notably include: the very large and imprecise number of notified bodies within the EU; substantial disparities concerning the quality of the conformity assessments conducted; the lack of transparency surrounding their organisation, the data used, their activities, and the results of their assessments; the question whether they have personnel available with the required scientific expertise in order to perform assessments of the manufacturers' clinical evaluations appropriately; and the lack of proper and strict monitoring the work of the notified bodies by some national authorities. The proposal of the Commission has addressed some of these

weaknesses. This constitutes a substantial improvement as compared to the existing legislation. However, many points in relation to the abovementioned issues still need to be addressed.

Your rapporteur is of the view that the provisions related to the personnel in the national authorities responsible for the designation and monitoring of notified bodies should be reinforced as well to ensure that sufficient qualifications to audit the notified bodies for which they are responsible are available.

Moreover, it should be ensured that notified bodies have permanent "in house" competent personnel and that subcontracting is limited to public entities, or to external experts in cases where clinical expertise is rare, for instance in the event of innovative devices or technologies. Where subcontracting is applied, notified bodies should make publicly available the names of subcontractors and the precise tasks for which they have been awarded a contract. Once a year, notified bodies should be required to send documents to the relevant national authority to enable the verification of the subcontractors' qualifications.

During the designation process of a notify body, the relevant national authority should provide justifications where its decision is not in accordance with the recommendation of the MDCG. The reason why such justifications are needed is that the recommendation will already be based on an opinion of the joint assessment team: this process is consequently providing a series of checks before the recommendation is issued.

As a consequence of the internal market, manufacturers are allowed to apply with a notified body established in another Member State than the one where the manufacturer is registered. However, in the view of improving transparency, if a manufacturer chooses to do so, it should inform the national authority of the Member State where it is registered of such an application.

Your rapporteur supports the Commission proposal to establish a coordination group, which would include all notified bodies. However, in order to guarantee satisfactory coordination and cooperation among notified bodies, and with the overall aim to increase convergence in the quality of the work of notified bodies, it should be ensured that this group meets at least twice a year.

Your rapporteur welcomes the Commission introduction of fees charged by national authorities for their activities related to the designation and monitoring of notified bodies. However, it is important that those fees are made public and comparable across Member States.

Your rapporteur believes that the Commission proposal does not offer sufficient guarantees that the competition among notified bodies on the basis of the fees to perform their conformity assessment activities is not done to the expense of patient safety. Therefore, provisions are included to require Member States to adopt national legislation in this respect, in order to ensure transparency of fees and to facilitate their comparability.

Labelling of devices as single-use (or reusable) and reprocessing of devices

Reuse of medical devices was very common until the 1980s, when manufacturers started

more systematically to label their devices as single-use. The current situation is that there are too many devices labelled as single-use while they could be reprocessed, as manufacturers want to avoid bearing the responsibility in case the reprocessing of a device would pose a danger to a patient. Sometimes, improper labelling is the result of economic considerations. The Commission has decided to maintain the possibility to reprocess single-use devices. This is not satisfactory from a logical point of view. Your rapporteur is of the view that devices labelled as single-use should be real single-use and that there should be only two options: single-use and reusable. Your rapporteur also strongly believes that activities encompassed in the reprocessing of devices should be subject to stricter and more transparent standards.

As a result, only devices labelled as reusable should be reprocessed. All devices should be labelled as reusable as a rule and, by derogation, manufacturers of class I, IIa and IIb devices should still be granted the possibility to label them as single-use if they provide justification based on sufficient scientific evidence. They also have to be entered in the electronic system for the registration of devices. By derogation to this rule, manufacturers of class III devices should still have the possibility to label them as single-use if the Scientific Committee on Emerging and Newly Identified Health Risks gives a positive opinion. These derogations would enable devices to still be labelled as single-use when they are clearly single-use, provided that the manufacturer can give evidence of that fact. Moreover, a swift procedure should be introduced for cases where a company specialised in reprocessing, or a hospital or a clinic which already reprocess specific devices, wants to challenge the single-use label of a manufacturer by providing evidence that the medical device can be reprocessed safely. It should also be made clear that the reprocessing of a device entails an automatic shift of responsibility from the manufacturer to the re-processor. Finally, the Commission should adopt implementing acts to set up the highest and most coherent standards for the reprocessing of reusable devices within the EU.

Clinical investigations

The Commission has introduced important provisions on clinical investigations and yet some terms such as "performance" or "safety" are not defined although manufacturers should collate data to prove that their devices meet performance and safety requirements.

Performance should notably be understood broadly so as to encompass efficacy and benefit to the patient, which shall be checked in cases where clinical investigations apply. This is crucial to ensure that devices are technically achieving the aim for which they were designed and produced, but also bring benefit to the patient and are efficient when used in real-life. It should also be ensured that, where clinical investigations apply, they shall be designed in a way that the best methodology available is used and randomized controlled clinical investigations are included. The Commission proposal also mirrors the provisions of the proposed regulation on clinical trials in which the reference to ethics committees has disappeared. However, your rapporteur believes that clinical investigations should only start after having been granted a positive evaluation result by an independent ethics committee. Member States should take the necessary measures to establish ethics committees where such committees do not exist. Lastly, it should also be ensured that , in case of an early termination of a clinical investigation, information on the reasons for this is provided to all Member States, so that they can inform sponsors conducting similar clinical investigations of the results of that clinical investigation at the same time throughout the EU . This will enable to

bring more transparency and to avoid having several studies being run in parallel and successively providing clinical evidence concluding that a device may pose a risk to the patient.

European databank on medical devices (EUDAMED)

The use of Eudamed has been obligatory since May 2011, but there has been a lot of criticism regarding its functioning. The Commission has proposed some improvements, but your rapporteur is of the view that some provisions on the transparency of information are still missing.

Consequently, 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 should be ensured.

Vigilance and market surveillance

The Commission has introduced important provisions on the reporting of incidents and field safety corrective actions. Some elements are nevertheless still missing to ensure a swift tracing back of all aspects surrounding the incidents. This should help determine whether the incident is linked with the device itself or the way it was used.

Consequently, it should be ensured that the reporting through the electronic system includes date and place of incidents, and where available, information on the patient or user and healthcare professional, in full respect of privacy.

Coordination between Member States and MDCG

The Commission has proposed the creation of the MDCG, but it is not sure whether this group will have sufficient expertise to perform its tasks.

Your rapporteur proposes to set up a multidisciplinary advisory committee of experts and representatives of stakeholders and civil society organisations in order to provide scientific advice to the MDCG, but also to the Commission, and the Member States. This group will provide expertise on issues of classification, borderline cases and other aspects of the Regulation's implementation, as necessary.