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Committee on the Environment, Public Health and Food Safety

2012/0266(COD)

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AMENDMENTS
599 - 907

Draft report
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(PE507.972v02-00)

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

Proposal for a regulation
(COM(2012)0542 – C7-0318/2012 – 2012/0266(COD))

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Amendment 599
Milan Cabrnoch

Proposal for a regulation
Article 45 – paragraph 1

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

Or. cs

Amendment 600
Philippe Juvin

Proposal for a regulation
Article 45 – paragraph 1

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

Or. fr

Amendment 601
Philippe Juvin

Proposal for a regulation
Article 45 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. During the certificate of conformity's period of validity, the relevant notified body shall conduct, at least once a year, unannounced inspections at the place of manufacture of the medical device it is responsible for assessing. An unannounced inspection is one is which the manufacturer is given no advance notice of possible inspection dates and times.

Or. fr

Amendment 602
Philippe Juvin

Proposal for a regulation
Article 45 – paragraph 3

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

market, the Commission and the MDCG.

Or. fr

Amendment 603
Philippe Juvin

Proposal for a regulation
Article 45 – paragraph 5

Text proposed by the Commission	*Amendment*
5. In the light of technical progress, the Commission shall be empowered to adopt ***delegated*** acts in accordance with Article ***89*** amending or supplementing the minimum content of the certificates set out in Annex XII.	5. In the light of technical progress, the Commission shall be empowered to adopt ***implementing*** acts in accordance with Article ***88*** amending or supplementing the minimum content of the certificates set out in Annex XII.

Or. fr

Amendment 604
Philippe Juvin

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

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

Or. fr

Amendment 605
Thomas Ulmer

Proposal for a regulation
Article 47 – paragraph 1

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

Or. de

Amendment 606
Philippe Juvin

Proposal for a regulation
Article 47 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.	2. The Member State shall inform the Commission***, the notified body responsible for assessing the relevant medical device, the MDCG*** and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.

Or. fr

Amendment 607
Jolanta Emilia Hibner, Elżbieta Katarzyna Łukacijewska

Proposal for a regulation
Article 47 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Upon request by a Member State and where this is in the interest of public health or patient safety in more than one Member State, the Commission may, by means of implementing acts, extend for a determined period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).	***deleted***
On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 88(4).	

Or. pl

Justification

Art. 47 ust. 3 wskazuje, że Komisja może rozszerzyć na cały obszar EU decyzję państwa członkowskiego, które wyraziło zgodę na wprowadzenie na swoim terytorium wyrobu nie spełniającego wymagań określonych w rozporządzeniu. Jest to kwestia ściśle polityczna, bowiem państwo członkowskie jest odpowiedzialne za bezpieczeństwo swoich obywateli i jeżeli w innym kraju specjalnie powołane do tego celu organy uznają, że będą tolerowały ryzyko stosowania takich wyrobów i wydania zezwolenia, aby na ich terytorium były obecne wyroby nie spełniające wymagań, to ponoszą ryzyko na własną odpowiedzialność. Z drugiej strony, jeżeli którykolwiek kraj Wspólnoty dowie się, że inne państwo członkowskie wydało taką decyzję, to może samodzielnie wydać decyzję podobną i nie musi to być decyzja Komisji Europejskiej. Przedmiotowy przepis narusza zasadę propocjonalności i subsydiarności. Wystarczające dla osiągnięcia celu regulacji są tu działania na poziomie państw członkowskich.

Amendment 608
Thomas Ulmer, Peter Liese

Proposal for a regulation
Article 50 – paragraph 1 – point a

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

Or. de

Amendment 609
Thomas Ulmer, Peter Liese

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

Or. de

Amendment 610
Thomas Ulmer, Peter Liese

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	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.	going to be reliable and robust. ***Clinical investigations shall not be conducted if the associated risks exceed the possible benefit to be derived from the medical device.*** ***Member States should have the option of prohibiting clinical investigations of certain product groups or test fields or demanding that certain conditions be complied with.***

Or. de

Amendment 611
Thomas Ulmer, Peter Liese

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

Text proposed by the Commission	*Amendment*
The sponsor of a clinical investigation shall submit an application to the Member State(s) in which the investigation is to be conducted accompanied by the documentation referred to in Chapter II of Annex XIV. Within ***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.	The sponsor of a clinical investigation shall submit an application to the Member State(s) in which the investigation is to be conducted accompanied by the documentation referred to in Chapter II of Annex XIV. Within ***14 days*** after receipt of the application, the Member State concerned shall notify the sponsor whether the clinical performance study falls within the scope of this Regulation and whether the application is complete.

Or. de

Amendment 612
Peter Liese

Proposal for a regulation
Article 51 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	In case of more than one Member State concerned, where there is a disagreement on whether the clinical investigation should be approved, the member states concerned shall make an attempt to agree on a conclusion. If no conclusion is found, the European Commission takes a decision after hearing the member states concerned.

Or. en

Justification

The decision of the reporting member state is binding for the others. It could happen that a reporting member state supports a clinical investigation while the authorities and ethic committees of the majority of the concerned member states not. Even if the authorities and ethic committees work together to find agreement, there must a solution to resolve conflicts. The Commission is accountable to scrutiny by the EP and Council, so is better authorised to take such a decision then the reporting member state.

Amendment 613
Thomas Ulmer, Peter Liese

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

Or. de

Amendment 614
Thomas Ulmer, Peter Liese

Proposal for a regulation
Article 51 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. Member States shall ensure that they interrupt, terminate or suspend a clinical investigation if new scientific findings are available and the competent authority therefore would no longer authorise the clinical investigation or if the ethics committee would no longer authorise it.

Or. de

Justification

As a result of new scientific findings and breakthroughs, a clinical investigation may no longer be necessary. In that case, the competent authorities should have the power to halt such an investigation.

Amendment 615
Thomas Ulmer

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

Text proposed by the Commission	*Amendment*
(a) ***in the case of investigational devices classified as class III and implantable or long-term invasive devices classified as class IIa or IIb,*** as soon as the Member State concerned has notified the sponsor of its approval;	(a) as soon as the Member State concerned has notified the sponsor of its approval;

Or. de

Amendment 616
Thomas Ulmer, Peter Liese

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

Text proposed by the Commission	*Amendment*
(b) in the case of investigational devices other than those referred to in point (a) immediately after the date of application provided that the Member State concerned has so decided and that evidence is provided that the rights, safety and well-being of the subjects to the clinical investigation are protected;	***deleted***

Or. de

Amendment 617
Thomas Ulmer, Peter Liese

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. de

Amendment 618
Thomas Ulmer, Peter Liese

Proposal for a regulation
Article 51 a (new)

Text proposed by the Commission	*Amendment*
	Ethics committee

A clinical investigation may only be authorised if an independent ethics committee has delivered a positive assessment of the investigation. The statement by the ethics committee should take into account medical feasibility, the consent of the subjects after they have received full information about the possible risks and dangers associated with the clinical investigation, and the suitability of the investigating establishments and of the investigators.

The ethics committee has the purpose of protecting the rights, welfare and safety of subjects, users and third parties. The committee must be independent of the research, the sponsor and any other influence. Both national and international standards must be complied with.

The ethics committee shall be composed of an adequate number of suitably qualified members. The ethics committee shall, however, also include representatives of civil society.

Or. de

Justification

In the case of clinical investigations of medical devices, as elsewhere, clear rules need to be laid down concerning the ethics committee. It would make sense if the standards for an ethics committee in the field of medical devices were brought into line with the final version of the regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

Amendment 619
Philippe Juvin

Proposal for a regulation
Article 51 – paragraph 6 – subparagraph 1

Text proposed by the Commission	*Amendment*
Member States shall ensure that the	Member States shall ensure that the

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

Or. fr

Amendment 620
Mairead McGuinness

Proposal for a regulation
Article 51 – paragraph 6 – subparagraph 2

Text proposed by the Commission	*Amendment*
Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. In the assessment, the view of at least one person whose primary area of interest is non-scientific shall be taken into account. The view of ***at least one patient*** shall be taken into account.	Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. In the assessment, the view of at least one person whose primary area of interest is non-scientific shall be taken into account. The view of ***patients*** shall be taken into account. ***The list of the reviewers should be made available to the sponsor***

Or. en

Amendment 621
Marina Yannakoudakis

Proposal for a regulation
Article 51 – paragraph 6 – subparagraph 2

Text proposed by the Commission	*Amendment*
Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. In the assessment, the view of	Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. In the assessment, the view of

at least one person whose primary area of interest is non-scientific shall be taken into account. The view of at least one patient shall be taken into account.	***more than*** one person whose primary area of interest is non-scientific shall be taken into account. The view of at least one patient shall be taken into account.

Or. en

Justification

"at least one patient" is not sufficient. The view of one patient is not enough, as it is difficult for one patient to represent the view of all patients in an investigation.

Amendment 622
Philippe Juvin

Proposal for a regulation
Article 51 – paragraph 7

Text proposed by the Commission	*Amendment*
7. The Commission shall be empowered to adopt ***delegated*** acts in accordance with Article ***89*** amending or supplementing, in the light of technical progress and global regulatory developments, the requirements for the documentation to be submitted with the application for the clinical investigation that is laid down in Chapter II of Annex XIV.	7. The Commission shall be empowered to adopt ***implementing*** acts in accordance with Article ***88*** amending or supplementing, in the light of technical progress and global regulatory developments, the requirements for the documentation to be submitted with the application for the clinical investigation that is laid down in Chapter II of Annex XIV.

Or. fr

Amendment 623
Marina Yannakoudakis, Anna Rosbach

Proposal for a regulation
Article 53 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the exchange of information between the Member States and between them and the Commission in accordance with Article	(b) the exchange of information between the Member States and between them and the Commission in accordance with Article

56;	56; ***All relevant updates to the information concerning an investigation should be posted on the database, such as measures taken by Member States to terminate, suspend or modify an investigation, as well as updated information on the benefit-risk balance or any urgent safety measures taken.***

Or. en

Amendment 624
Rebecca Taylor

Proposal for a regulation
Article 53 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(c a) the clinical investigation reports submitted by sponsors in Article 58(5)

Or. en

Justification

It should be clarified that Clinical Investigation Reports shall be part of the information available to the public and healthcare professionals. These amendments ensure that a degree of coherency can be found with the likely outcome of the Clinical Trials negotiations.

Amendment 625
Gilles Pargneaux

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	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.	(EU) No […/…] ***and the European Databank on Medical Devices (Eudamed) established under Commission Decision 2010/227/EU***. 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.

Or. fr

Justification

The electronic system's interoperability with the European Databank on Medical Devices (Eudamed) is also important.

Amendment 626
Michèle Rivasi, Corinne Lepage

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 and patients have access to the electronic system. Access to data from the database should be granted to the public, in accordance with Regulation (EC) No 1049/2001.***

Or. en

Amendment 627
Philippe Juvin

Proposal for a regulation
Article 53 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall be empowered to adopt ***delegated*** acts in accordance with Article ***89*** determining which other information regarding clinical investigations collated and processed in the electronic system shall be publicly accessible to allow interoperability with the EU database for clinical trials on medicinal products for human use set up by Regulation (EU) No […/…]. Article 52(3) and (4) shall apply.	3. The Commission shall be empowered to adopt ***implementing*** acts in accordance with Article ***88*** determining which other information regarding clinical investigations collated and processed in the electronic system shall be publicly accessible to allow interoperability with the EU database for clinical trials on medicinal products for human use set up by Regulation (EU) No […/…]. Article 52(3) and (4) shall apply.

Or. fr

Amendment 628
Rebecca Taylor

Proposal for a regulation
Article 57 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Within one year from the end of the clinical investigation, the sponsor shall submit to the Member States concerned ***a summary of*** the results of the clinical investigation in form of a clinical investigation report referred to in Section 2.7 of Chapter I of Annex XIV. Where, for scientific reasons, it is not possible to submit the clinical investigation report within one year, it shall be submitted as soon as it is available. In this case, the clinical investigation plan referred to in Section 3 of Chapter II of Annex XIV shall specify when the results of the clinical investigation are going to be submitted, together with an explanation.	3. Within one year from the end of the clinical investigation, the sponsor shall submit to the Member States concerned the results of the clinical investigation in form of a clinical investigation report referred to in Section 2.7 of Chapter I of Annex XIV. Where, for scientific reasons, it is not possible to submit the clinical investigation report within one year, it shall be submitted as soon as it is available. In this case, the clinical investigation plan referred to in Section 3 of Chapter II of Annex XIV shall specify when the results of the clinical investigation are going to be submitted, together with an explanation.

Or. en

Justification

While the Clinical Performance Study Report is a form of summary, it is important that manufacturers understand this Report will become part of the publicly accessible information.

Amendment 629
Mairead McGuinness

Proposal for a regulation
Article 58 – paragraph 1

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

Or. en

Justification

The possibility to file via the Database should be available in the case of all studies, even when the study is conducted in only one Member State

Amendment 630
Mairead McGuinness

Proposal for a regulation
Article 58 – paragraph 3 – subparagraph 2 – point b

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

51(5).

Or. en

Amendment 631
Marina Yannakoudakis, Anna Rosbach

Proposal for a regulation
Article 59 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) new findings in relation to any event referred to in points (a) to (c).	(d) new findings in relation to any event referred to in points (a) to (c).
	Information regarding incidents that are caused by user errors should also be collected, as they are a major source of incidents with medical devices. This information can contribute to improve the safety and knowledge of the device.
	The Regulation should also provide for Member States to put in place non-electronic formats of reporting to ensure that patients who do not have online access are able to report.

Or. en

Amendment 632
Michèle Rivasi

Proposal for a regulation
Article 61 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Point a) of this Paragraph shall also apply to healthcare professional in contact with the patients harmed.

Or. en

Amendment 633
Nora Berra

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 incident in respect of devices made available on the Union market;

Or. en

Amendment 634
Mairead McGuinness, Zofija Mazej Kukovič

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 incident in respect of devices made available on the Union market;

Or. en

Amendment 635
Françoise Grossetête

Proposal for a regulation
Article 61 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Member States shall take all appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1. They shall record such reports centrally at national level. Where a competent authority of a Member	The Member States shall take all appropriate measures to encourage healthcare professionals ***including doctors and pharmacists***, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1. They shall record such reports centrally at national level.

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

Or. fr

Amendment 636
Gilles Pargneaux

Proposal for a regulation
Article 61 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Member States shall take all appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1. They shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the incident. The manufacturer shall ensure the appropriate follow-up.	The Member States shall take all appropriate measures to encourage healthcare professionals ***including doctors and pharmacists***, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1. They shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the incident. The manufacturer shall ensure the appropriate follow-up.

Or. fr

Justification

In keeping with the approach adopted in the Pharmacovigilance Directive.

Amendment 637
Peter Liese

Proposal for a regulation
Article 61 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Member States shall take all appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1. They shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the incident. The manufacturer shall ensure the appropriate follow-up.	The Member States shall take all appropriate measures to encourage healthcare professionals, ***including doctors and pharmacists,*** users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1. They shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the incident. The manufacturer shall ensure the appropriate follow-up.

Or. en

Justification

This provision reflects the approach taken in the Pharmacovigilance Directive.

Amendment 638
Mairead McGuinness, Zofija Mazej Kukovič

Proposal for a regulation
Article 61 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Member States shall take all appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1. They shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the incident. The manufacturer shall ensure the appropriate follow-up.	The Member States shall take all appropriate measures to encourage ***and facilitate*** healthcare professionals, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1. They shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the incident. The manufacturer shall ensure the appropriate follow-up.

Or. en

Amendment 639
Nora Berra

Proposal for a regulation
Article 61 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
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 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 Member States shall also provide healthcare professionals, users and patients with another forms for reporting of suspected incidents to national competent authorities.***

Or. en

Amendment 640
Marina Yannakoudakis

Proposal for a regulation
Article 61 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
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 Member States shall coordinate between them the development of standard web-based structured forms***, as well as non-electronic formats for the*** reporting of serious incidents by healthcare professionals, users and patients.

Or. en

Amendment 641
Mairead McGuinness, Zofija Mazej Kukovič

Proposal for a regulation
Article 61 – paragraph 4

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

Or. en

Amendment 642
Marina Yannakoudakis

Proposal for a regulation
Article 62 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:	1. The Commission shall, in collaboration with the Member States, ***develop further the existing European databank on medical devices (Eudamed)*** set up ***by the Commission Decision 2010/227/EU*** and manage an electronic system to collate and process the following information:

Or. en

Amendment 643
Nora Berra

Proposal for a regulation
Article 62 – paragraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(d a) the periodic safety update reports drawn by manufacturers, as referred to in Article 63a;

Or. en

Amendment 644
Thomas Ulmer

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 notified bodies ***and also to manufacturers where the information pertains to their own product***.

Or. de

Amendment 645
Rebecca Taylor

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 and to the notified bodies. ***The Commission, in consultation with the Medical Devices Coordination Group, shall provide an overview of this information, every 6 months, for the public and healthcare professionals. This information shall be accessible through the European databank in Article 27***

Or. en

Justification

Healthcare professionals and the public will benefit from an overview of vigilance and market surveillance information. As this information will require sensitive handling, the MDCG is the appropriate forum for providing this information for the European Databank

Amendment 646
Thomas Ulmer

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 healthcare professionals ***have full access to the electronic system*** and ***that*** the public have ***an*** appropriate ***level*** of access to ***it***.

Or. de

Justification

In order to make rational use of medical devices, doctors and surgeons must choose which device to use on the basis of efficiency and safety. Healthcare professionals should have access to all evidence, including details of technical performance and pre- and postmarket studies made by manufacturers when submitting their products for authorisation.

Amendment 647
Marina Yannakoudakis

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 healthcare professionals and the public have ***full*** access to the electronic system ***in line with existing data protection and intellectual property right legislation***.

Or. en

Amendment 648
Holger Krahmer

Proposal for a regulation
Article 62 – paragraph 5 a (new)

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

Or. en

Justification

The integration of the notified bodies in the exchange of information of the market surveillance authorities must be extended and clearly defined. Particularly, the notified bodies need - within the framework of automated, harmonized communication procedures - consolidated information in order to recognize developments, take new in-formation immediately into account and react promptly and appropriately to occurrences and incidents, for example through post-controls, suspension or withdrawal of a certificate.

Amendment 649
Nora Berra

Proposal for a regulation
Article 62 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5 a. The reports and information referred to in Article 62(5), shall also be automatically transmitted as regards the device in question via the electronic system to the notified body that issued the certificate in accordance with Article 45.

Or. en

Amendment 650
Thomas Ulmer

Proposal for a regulation
Article 62 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. No additional national notification system should be established: instead, only the European notification system should apply.

Or. de

Amendment 651
Nora Berra

Proposal for a regulation
Article 63 a (new)

Text proposed by the Commission	*Amendment*
	Article 63 a
	Periodic safety update reports
	1. Manufacturers of medical devices classified as class III shall report to the electronic system referred to in Article 62:
	(a) summaries of data relevant to the benefits and risks of the medical devices, including results of all studies with a consideration of their potential impact on the certification;
	(b) a scientific evaluation of the risk-benefit ratio of the medical device;
	(c) all data relating to the volume of sales of the medical devices including an estimate of the population exposed to the medical device.
	2. The frequency with which the manufacturers shall make the report referred to in the paragraph 1 shall be specified in the MDCG scientific

assessment referred to in Article 44.

Manufacturers shall submit periodic safety update reports to the competent authorities immediately upon request or at least once a year during the first 2 years following initial placing on the market of that medical device.

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

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

Or. en

Amendment 652
Mairead McGuinness, Zofija Mazej Kukovič

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

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

Or. en

Amendment 653
Nora Berra

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.***	If in the case of reports received in accordance with Article 61(3) the competent authority ascertains that the reports relate to ***an*** incident it shall notify without delay those reports to the electronic system referred to in Article 62,

Or. en

Amendment 654
Claudiu Ciprian Tănăsescu

Proposal for a regulation
Article 63 – paragraph 2

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

shall monitor the manufacturer's investigation of the incident.	shall monitor the manufacturer's investigation of the incident***, as well as they shall take into account patients' opinions***.

Or. en

Amendment 655
Mairead McGuinness, Zofija Mazej Kukovič

Proposal for a regulation
Article 63 – paragraph 2

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

Or. en

Amendment 656
Mairead McGuinness, Zofija Mazej Kukovič

Proposal for a regulation
Article 63 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
In the case of devices referred to in the	In the case of devices referred to in the first

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

Or. en

Amendment 657
Mairead McGuinness, Zofija Mazej Kukovič

Proposal for a regulation
Article 63 – paragraph 3 – subparagraph 2

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

Or. en

Amendment 658
Mairead McGuinness

Proposal for a regulation
Article 63 – paragraph 4

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

Or. en

Amendment 659
Mairead McGuinness, Zofija Mazej Kukovič

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

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

Or. en

Amendment 660
Mairead McGuinness, Zofija Mazej Kukovič

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

Text proposed by the Commission	*Amendment*
(a) to monitor the investigation of the ***serious*** incident by the manufacturer and	(a) to monitor the investigation of the incident by the manufacturer and the

the corrective action to be taken;	corrective action to be taken;

Or. en

Amendment 661
Mairead McGuinness, Zofija Mazej Kukovič

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

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

Or. en

Amendment 662
Mairead McGuinness, Zofija Mazej Kukovič

Proposal for a regulation
Article 64 – paragraph 1

Text proposed by the Commission	*Amendment*
Manufacturers of devices classified in class IIb and III shall report to the electronic system referred to in Article 62 any statistically significant increase in the frequency or severity of ***incidents that are not serious*** incidents or of expected undesirable side-effects that have a significant impact on the risk-benefit analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents or expected	Manufacturers of devices classified in class IIb and III shall report to the electronic system referred to in Article 62 any statistically significant increase in the frequency or severity of ***all*** incidents or of expected undesirable side-effects that have a significant impact on the risk-benefit analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents or expected undesirable side-effects in respect of the

undesirable side-effects in respect of the device, or category or group of devices, in question during a specific time period as established in the manufacturer's conformity assessment. Article 63 shall apply.	device, or category or group of devices, in question during a specific time period as established in the manufacturer's conformity assessment. Article 63 shall apply.

Or. en

Amendment 663
Thomas Ulmer

Proposal for a regulation
Article 64 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Medical devices which fall under legal acts of the European Union concerning the quality and safety of blood
	1. This Regulation shall not [sic: verb apparently omitted - translator's note] existing and implemented provisions at European level relating to the collection, testing, processing, storage and distribution of blood and blood components.
	2. Medical devices for the collection, testing, processing, storage and distribution of blood and blood components are dealt with mainly under European Union Directive 2002/98 and the standards adopted by the Council on 27 January 2003 for quality and safety in connection with collection, testing, processing, storage and distribution.
	3. Measures relating to traceability and vigilance in the field of blood and blood components are of a higher standard than is the case in this Regulation. They should be retained in the interests of patients.

Or. de

Amendment 664
Mairead McGuinness, Zofija Mazej Kukovič

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

Text proposed by the Commission	*Amendment*
(a) typology of ***serious*** incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;	(a) typology of incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;

Or. en

Amendment 665
Mairead McGuinness, Zofija Mazej Kukovič

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

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

Or. en

Amendment 666
Mairead McGuinness, Zofija Mazej Kukovič

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

Text proposed by the Commission	*Amendment*
(c) timelines for the reporting of ***serious*** incidents and field safety corrective actions, periodic summary reports and	(c) timelines for the reporting of incidents and field safety corrective actions, periodic summary reports and trend reports by

trend reports by manufacturers, taking into account the severity of the event to be reported as referred to in Articles 61 and 64;	manufacturers, taking into account the severity of the event to be reported as referred to in Articles 61 and 64;

Or. en

Amendment 667
Mairead McGuinness

Proposal for a regulation
Article 66 – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	In drafting the implementing acts, the Commission shall seek the prior advice of the MDAG

Or. en

Justification

To ensure transparency and full stakeholder involvement, the Commission should as a rule seek the advice of stakeholders through the Medical Device Advisory Group, MDAG.

Amendment 668
Gilles Pargneaux

Proposal for a regulation
Article 67 a (new)

Text proposed by the Commission	*Amendment*
	Article 67a
	Inspections at operators' premises
	1. As part of market surveillance activities the competent authority of each Member State shall carry out appropriate inspects to ascertain whether this Regulation is being complied with by economic operators whose devices are intended to be made available on the Union market.

Such inspections shall be carried out at the premises of economic operators, on the basis of the risk identified, by the competent authority of the Member State in which the economic operator is established.

2. The inspections shall be carried out by officials representing the competent authority who shall be empowered to:

(a) enter the premises of economic operators whose devices are intended to be made available on the Union market, for the purpose of carrying out physical checks on the premises and the practices used;

(b) take any samples required, in particular for independent analysis by an official laboratory;

(c) examine all documents and information relevant to the purpose of the inspection;

(d) inspect premises, archives and documents relating to compliance with general safety and performance requirements and the vigilance requirements to be met by economic operators.

The officials representing the competent authority may be assisted by experts appointed by that authority.

3. Following each inspection carried out under paragraph 1 of this article, the competent authority shall submit a report on compliance by the entity inspected with the legal and technical requirements applicable under this Regulation.

The competent authority which carried out the inspection shall communicate the content of this report to the inspected entity. Before adopting the report, the competent authority shall give the inspected entity the opportunity to submit comments.

The final inspection report as referred to in this paragraph shall be entered into the electronic system provided for in Article 27(f). The reports held in the electronic system may be accessed by the Member States, the Commission and the notified bodies.

4. Where the competent authority of a Member State suspects that an economic operator located in another Member State may be failing to comply with the legal requirements set out in this Regulation, or where it wishes to look into a specific issue, it may ask that Member State for further information and may, in particular, ask for an inspection to be carried out or to take part in a joint inspection. Such inspections may also be carried out at the request of a Member State or the Commission.

5. Without prejudice to any agreements concluded between the Union and third countries, the inspections referred in paragraph 1 may also take place at the premises of an economic operator established in a third country if the medical device is intended to be made available on the Union market. To this end, the economic operator established in a third country shall be required to submit to an inspection in accordance with this article.

6. Cooperation between Member States' competent authorities shall involve the pooling of information on inspection programmes and the findings of inspections carried out. Member States' competent authorities shall also cooperate in coordinating inspections in the Union and in third countries, in particular those looking into specific issues. The Commission shall be kept informed.

Or. fr

Justification

The principle of inspections being carried out by competent authorities at operators' premises needs to be established as a key part of market surveillance activities. In keeping with Directive 2001/83/EC on medicinal products for human use, a new article on inspections by competent authorities of MD operators' premises should be included.

Amendment 669
Horst Schnellhardt

Proposal for a regulation
Article 67 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and, where necessary and justified, enter the premises of economic operators and take the necessary samples of devices. They may destroy or otherwise render inoperable devices presenting a serious risk where they deem it necessary.	1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and, where necessary and justified, ***and also without announcing their intention,*** enter the premises of economic operators and take the necessary samples of devices. They may destroy or otherwise render inoperable devices presenting a serious risk where they deem it necessary.

Or. de

Justification

In order to keep cases of fraud to a minimum, it is also appropriate to carry out unannounced inspections of the manufacture of medical devices.

Amendment 670
Nora Berra

Proposal for a regulation
Article 67 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and***, where necessary and justified,*** enter the premises of economic operators and take the necessary samples of devices. They may destroy or otherwise render inoperable devices presenting a serious risk where they deem it necessary.	1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints. The competent authorities may require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and enter the premises of economic operators and take the necessary samples of devices ***for analysis by an official laboratory***. They may destroy or otherwise render inoperable devices presenting a serious risk where they deem it necessary.

Or. en

Amendment 671
Mairead McGuinness

Proposal for a regulation
Article 67 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established	1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established

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

Or. en

Amendment 672
Nora Berra

Proposal for a regulation
Article 67 – paragraph 1 a (new)

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

Or. en

Amendment 673
Thomas Ulmer

Proposal for a regulation
Article 67 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The nature and extent of unannounced inspections, and costs incurred by the economic operator as a result of unannounced inspections, may be credited against regular inspections provided that no significant shortcomings are identified during the inspection. The organisation and implementation of unannounced inspections must always take account of the principle of proportionality, particularly with reference to the hazard potential of a particular product.

Or. de

Amendment 674
Horst Schnellhardt

Proposal for a regulation
Article 67 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Member States shall periodically review and assess the functioning of their surveillance activities. ***Such reviews and assessments*** shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. The Member State concerned shall make a summary of the results accessible to the public.	2. The Member States shall periodically ***plan,*** review and assess the functioning of their surveillance activities. ***To this end, Member States shall draw up strategic monitoring plans which lay down a risk classification, surveillance intervals, the nature of the surveillance measures and the human and material resources to be used to carry out the monitoring. A review and assessment of the activities*** shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. ***The Commission may make recommendations for adjustments to the monitoring plans.*** The Member State concerned shall make a summary of the results ***and of the Commission's recommendations*** accessible to the public.

Or. de

Justification

In order to ensure that the rules are complied with and thus provide a high level of protection for patients, it is appropriate to carry out strategic surveillance of the production of medical devices on their basis of the risk they present to the health of patients.

Amendment 675
Anna Rosbach, Zofija Mazej Kukovič

Proposal for a regulation
Article 67 – paragraph 2

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

Or. en

Amendment 676
Nora Berra

Proposal for a regulation
Article 67 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5 a. Without prejudice to any international agreements concluded between the Union and third countries, checks as referred in paragraph 1 can also take place in the premises of an economic operator located in a third country, if the device is intended to be

made available on the Union market.

Or. en

Amendment 677
Nora Berra

Proposal for a regulation
Article 67 – paragraph 5 b (new)

Text proposed by the Commission	*Amendment*
	5 b. After every check, as referred in paragraph 1, the concerned competent authority shall report to the inspected economic operator on the level of compliance with this Regulation. Before adopting the report, the competent authority shall give the inspected economic operator the possibility to submit comments.

Or. en

Amendment 678
Nora Berra

Proposal for a regulation
Article 67 – paragraph 5 c (new)

Text proposed by the Commission	*Amendment*
	5 c. The Commission shall establish detailed guidelines on the principles for carrying out the checks referred to in this Article including in particular on the qualifications of inspectors, and on inspection arrangements and access to data and information held by economic operators.

Or. en

Amendment 679
Holger Krahmer

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*** and to the ***notified bodies***.

Or. en

Justification

The integration of the notified bodies in the exchange of information of the market surveillance authorities must be extended and clearly defined. Particularly, the notified bodies need - within the framework of automated, harmonized communication procedures - consolidated information in order to recognize developments, take new in-formation immediately into account and react promptly and appropriately to occurrences and incidents, for example through post-controls, suspension or withdrawal of a certificate.

Amendment 680
Rebecca Taylor

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 and to the Commission. ***The Commission, in consultation with the Medical Devices Coordination Group, shall provide an overview of this information, every 6 months, for the public and healthcare professionals. This information shall be accessible through the European databank in Article 27***

Or. en

Justification

Healthcare professionals and the public will benefit from an overview of vigilance and market surveillance information. As this information will require sensitive handling, the MDCG is the appropriate forum for providing this information for the European Databank

Amendment 681
Mairead McGuinness

Proposal for a regulation
Article 68 – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	The information in to relation to Article 68 paragraph 1, points a, b, c and d shall be made available to the MDCG who shall communicate it at the first meeting of the MDAG after the information becomes available.

Or. en

Amendment 682
Philippe Juvin

Proposal for a regulation
Article 69 – paragraph 1

Text proposed by the Commission	*Amendment*
Where the competent authorities of a Member State, based on vigilance data or other information, have sufficient reason to believe that a device presents a risk to the health or safety of patients, users or other persons, they shall carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by the device. The relevant economic operators shall cooperate as	Where the competent authorities of a Member State, based on vigilance data or other information, have sufficient reason to believe that a device presents a risk to the health or safety of patients, users or other persons, they shall carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by the device. The relevant economic operators shall cooperate as necessary with the competent authorities.

necessary with the competent authorities.	***In connection with that evaluation, the competent authorities shall inform the notified assessment bodies, in the case of class IIa, IIb and III devices, and the other competent authorities of the findings of the evaluation and the measures that are to be taken on the basis of those findings.***

Or. fr

Amendment 683
Mairead McGuinness

Proposal for a regulation
Article 69 – paragraph 1 – point 1 (new)

Text proposed by the Commission	*Amendment*
	(1) Where the competent authorities of a Member State, based on vigilance data or other information, have reason to believe that a device presents a risk to the health or safety of patients, users or other persons, they may carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by the device. The relevant economic operators shall cooperate as necessary with the competent authorities.

Or. en

Amendment 684
Mairead McGuinness

Proposal for a regulation
Article 70 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where, having performed an evaluation pursuant to Article 69, the competent	1. Where, having performed an evaluation pursuant to Article 69, the competent

authorities find that the device, which presents a risk to the health or safety of patients, users or other persons, does not comply with the requirements laid down in this Regulation, they shall ***without delay*** require the relevant economic operator to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to prohibit or restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it within a reasonable period, proportionate to the nature of the risk.	authorities find that the device, which presents a risk to the health or safety of patients, users or other persons, does not comply with the requirements laid down in this Regulation, they shall ***immediately*** require the relevant economic operator to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to prohibit or restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it within a reasonable period ***that is clearly defined and communicated to the relevant economic operator***, proportionate to the nature of the risk.

Or. en

Amendment 685
Mairead McGuinness

Proposal for a regulation
Article 70 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the competent authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 68.	2. Where the competent authorities consider that non-compliance is not restricted to their national territory, they shall ***immediately*** inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 68.

Or. en

Amendment 686
Mairead McGuinness

Proposal for a regulation
Article 70 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The economic operators shall ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.	3. The economic operators shall ***without delay*** ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.

Or. en

Amendment 687
Mairead McGuinness, Zofija Mazej Kukovič

Proposal for a regulation
Article 70 – paragraph 3 – point 1 (new)

Text proposed by the Commission	*Amendment*
	(1) Where the concerned devices are to be recalled, the economic operator shall make all reasonable efforts to complete the recall before the end of clearly defined period communicated to it by the competent authority as referred to in paragraph 1,

Or. en

Amendment 688
Mairead McGuinness

Proposal for a regulation
Article 70 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
They shall notify the Commission and the other Member States, ***without delay***, of those measures, by means of the electronic system referred to in Article 68.	They shall notify the Commission and the other Member States, ***immediately***, of those measures, by means of the electronic system referred to in Article 68.

Or. en

Amendment 689
Mairead McGuinness

Proposal for a regulation
Article 70 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any additional information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned. In the event of disagreement with the notified national measure, they shall ***without delay*** inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 68.	6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any additional information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned. In the event of disagreement with the notified national measure, they shall ***immediately*** inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 68.

Or. en

Amendment 690
Mairead McGuinness

Proposal for a regulation
Article 70 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Where, within ***two months*** of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.	7. Where, within ***one month*** of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

Or. en

Amendment 691
Mairead McGuinness

Proposal for a regulation
Article 70 – paragraph 8

Text proposed by the Commission	*Amendment*
8. All Member States shall ensure that appropriate restrictive measures are taken ***without delay*** in respect of the device concerned.	8. All Member States shall ensure that appropriate restrictive measures are taken ***immediately*** in respect of the device concerned.

Or. en

Amendment 692
Mairead McGuinness

Proposal for a regulation
Article 71 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where, within ***two months*** of receipt of the notification referred to in Article 70(4), objections are raised by a Member State against a provisional measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).	1. Where, within ***one month*** of receipt of the notification referred to in Article 70(4), objections are raised by a Member State against a provisional measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

Or. en

Amendment 693
Mairead McGuinness

Proposal for a regulation
Article 72 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where, having performed an evaluation pursuant to Article 69, a Member State finds that although a device has been legally placed on the market or put into service, it presents a risk to the health or safety of patients, users or other persons or to other aspects of the protection of public health, it shall require the relevant economic operator or operators to take all appropriate provisional measures to ensure that the device concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the device from the market or to recall it within a reasonable period, proportionate to the nature of the risk.	1. Where, having performed an evaluation pursuant to Article 69, a Member State finds that although a device has been legally placed on the market or put into service, it presents a risk to the health or safety of patients, users or other persons or to other aspects of the protection of public health, it shall ***immediately*** require the relevant economic operator or operators to take all appropriate provisional measures to ensure that the device concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the device from the market or to recall it within a reasonable period, proportionate to the nature of the risk.

Or. en

Amendment 694
Mairead McGuinness

Proposal for a regulation
Article 73 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Without prejudice to Article 70, a Member State shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is proportionate to the non-compliance where it makes one of the following findings:	1. Without prejudice to Article 70, a Member State shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is ***clearly defined and communicated and that is*** proportionate to the non-compliance where it makes one of the following findings:

Or. en

Amendment 695
Mairead McGuinness

Proposal for a regulation
Article 73 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the economic operator does not put an end to the non-compliance within the period referred to in paragraph 1, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States ***without delay*** of those measures, by means of the electronic system referred to in Article 68.	2. Where the economic operator does not put an end to the non-compliance within the period referred to in paragraph 1, the Member State concerned shall ***immediately*** take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States ***immediately*** of those measures, by means of the electronic system referred to in Article 68.

Or. en

Amendment 696
Michèle Rivasi

Proposal for a regulation
Article 74 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where a Member State, after having performed an evaluation which indicates a potential risk related to a device or a specific category or group of devices considers that the making available on the market or putting into service of such device or specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in order to protect the	1. Where a Member State, after having performed an evaluation which indicates a potential risk related to a device or a specific category or group of devices considers that the making available on the market or putting into service of such device or specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in order to protect the

health and safety of patients, users or other persons or other aspects of public health, it ***may*** take any necessary and justified provisional measures.	health and safety of patients, users or other persons or other aspects of public health, it ***shall*** take any necessary and justified provisional measures.

Or. en

Amendment 697
Michèle Rivasi

Proposal for a regulation
Article 74 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 88(4).	On duly justified imperative grounds of urgency relating to the health and safety of humans, ***or in case of lack of action by Member States in a situation of known risk,*** the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 88(4).

Or. xm

Justification

Action by Member States can be hampered either by complex administrative procedures or by pressure groups. The Commission should therefore be able to adopt immediately applicable preventive measures.

Amendment 698
Mairead McGuinness

Proposal for a regulation
Article 75 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Except in cases where immediate action is necessary for reasons of serious risk to human health or safety, the economic operator concerned shall be given the	2. Except in cases where immediate action is necessary for reasons of serious risk to human health or safety, the economic operator concerned shall be given the

opportunity to make submissions to the competent authority within an appropriate period of time before any measure is adopted. If action has been taken without the economic operator being heard, he shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.	opportunity to make submissions to the competent authority within an appropriate period of time ***that is clearly defined*** before any measure is adopted. If action has been taken without the economic operator being heard, he shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.

Or. en

Amendment 699
Mairead McGuinness

Proposal for a regulation
Article 75 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that he has taken effective corrective action.	3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator's ***satisfactorily*** demonstrating that he has taken effective corrective action.

Or. en

Amendment 700
Mairead McGuinness

Proposal for a regulation
Article 76 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member	1. The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member

States shall communicate the competent authorities to the Commission which shall publish a list of competent authorities.	States shall communicate the competent authorities to the Commission which shall publish a list of competent authorities ***and their contact details***.

Or. en

Amendment 701
Mairead McGuinness

Proposal for a regulation
Article 77 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The competent authorities of the Member States shall cooperate with each other and with the Commission and exchange with each other the information necessary to enable this Regulation to be applied uniformly.	1. The competent authorities of the Member States shall cooperate with each other and with the Commission and ***with the MDCG as appropriate and*** exchange with each other ***and the Commission*** the information necessary to enable this Regulation to be applied uniformly.

Or. en

Amendment 702
Mairead McGuinness

Proposal for a regulation
Article 78 a (new)

Text proposed by the Commission	*Amendment*
	Article 78 a
	Medical Device Advisory Group
	1bis: The Commission shall establish a European Medical Device Advisory Group (MDAG) to advise it and the MDCG on the technical, scientific, social and economic aspects of the placing on the market and availability of medical technology and related services in the Union.

The group shall be composed of representatives from associations of patients, clinicians, nurses, carers and healthcare facility managers, relevant medical device manufactures and other relevant fora.

The MDAG shall be chaired by a Commission representative.

The work of the MDAG shall be transparent and the results shall be communicated to the Commission and the Medical Devices Coordination Group and be made publicly available.

Or. en

Justification

Legitimate stakeholders, as well as the regulated industry and others should have the possibility to advise the Commission and authorities on the technical, scientific, social and commercial aspects of medical devices. For this purpose the Commission should set up a medical devices advisory group. The work of the advisory group should be transparent and the results should be made available to the Commission and the Medical Devices Coordination Group established by this Regulation.

Amendment 703
Mairead McGuinness

Proposal for a regulation
Article 78 – paragraph 2 – subparagraph 1

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

Or. en

Amendment 704
Mairead McGuinness

Proposal for a regulation
Article 78 – paragraph 2 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	The Commission shall verify the competence of the members of the MDCG. The Commission shall make public the results of its verification in each instance and provide information about the competence of the members of the MDCG.

Or. en

Justification

For the proper working of the regulation, the MDCG should be composed of persons with recognised and relevant competence in medical devices. The Article requires evidence of competence but does not clarify who should verify that competence. Competence needs to be verified and this should be a task of the Commission.

Amendment 705
Rebecca Taylor

Proposal for a regulation
Article 78 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5 a. The MDCG shall oversee the coordination group of Notified Bodies as specified in Article 39

Or. en

Justification

The MDCG should oversee the coordinating group of Notified Bodies, to ensure that attendance requirements are respected, and to allow them to be better informed of the state of

Notified Bodies across the EU

Amendment 706
Marian Harkin

Proposal for a regulation
Article 78 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The MDCG may invite, on a case-by-case basis, experts and other third parties to attend meetings or provide written contributions.	6. ***Where appropriate, organisations representing the interests of the medical device industry, healthcare professionals, laboratories, patients and consumers at Union level shall be invited to MDCG meetings in the capacity of observers.*** The MDCG may invite, on a case-by-case basis, ***other*** experts and other third parties to attend meetings or provide written contributions.

Or. en

Justification

Stakeholders should be invited to attend plenary meetings of the Medical Device Coordination Group rather than only its sub-groups to ensure continued transparency and inclusiveness of the EU regulatory system for medical devices.

Amendment 707
Mairead McGuinness

Proposal for a regulation
Article 78 – paragraph 7

Text proposed by the Commission	*Amendment*
7. The MDCG ***may*** establish standing ***or*** temporary sub-groups***.*** Where appropriate***,*** organisations representing the interests of ***the medical device industry***, healthcare professionals, laboratories, ***patients and consumers*** at Union level shall be invited in such sub-groups in the capacity of	7. The MDCG ***shall*** establish ***a*** standing ***Medical Device Advisory Group and may establish*** temporary sub-groups where appropriate***.*** Organisations representing the interests of ***patients***, healthcare professionals, laboratories, ***consumers and the medical device industry*** at Union level shall be invited in such sub-groups in the

observers.

capacity of observers.

Members of the MDAG may be invited in such sub-groups in the capacity of advisors where appropriate.

Or. en

Amendment 708
Nora Berra

Proposal for a regulation
Article 78 – paragraph 7 a (new)

Text proposed by the Commission *Amendment*

7 a. The MDCG shall establish a stakeholder dialogue group made up of stakeholders representatives organised at Union level. Such group shall act in parallel and work with the Medical Device Coordination Group (MDCG), advising the Commission and Member States on various aspects of medical technology and implementation of the Regulation.

Or. en

Amendment 709
Rebecca Taylor

Proposal for a regulation
Article 78 – paragraph 7 a (new)

Text proposed by the Commission *Amendment*

7 a. The MDCG shall support the Commission in providing an overview of vigilance data and market surveillance activities, including any preventive health protection measures taken, on a 6-monthly basis. This information shall be accessible through the European databank in Article 27.

Or. en

Justification

Healthcare professionals and the public will benefit from an overview of vigilance and market surveillance information. As this information will require sensitive handling, the MDCG is the appropriate forum for providing this information for the European Databank

Amendment 710
Rebecca Taylor

Proposal for a regulation
Article 78 – paragraph 7 b (new)

Text proposed by the Commission	*Amendment*
	7 b. The MDCG shall acts as an arbitration forum for disputes concerning Chapter IV on the competences of Notified Bodies.

Or. en

Justification

The joint assessment team and the MDCG should effectively monitor the work of Notified Bodies. Giving the MDCG the responsibility to annul the suspension of a Notified Body will increase their oversight.

Amendment 711
Mairead McGuinness

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

Text proposed by the Commission	*Amendment*
	- The functioning of the MDAG, including the adoption of opinions or recommendations or other positions by the MDAG where appropriate.

Or. en

Amendment 712
Mairead McGuinness

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

Text proposed by the Commission	*Amendment*
	(a a) to jointly assess with the Commission and the national authority responsible for notified bodies of the Member State in which it is established an application by a conformity assessment body for notification in all cases where the applicant body claims to be competent in devices listed in class III, those implanted into the body, incorporating a substance considered to be a medicinal product, or utilising non-viable tissues or cells of human or animal origin, or their derivatives.

Or. en

Amendment 713
Mairead McGuinness

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

Text proposed by the Commission	*Amendment*
	(a b) to establish and document the high level principles of competence and qualification and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing). The qualification criteria shall address the various functions within the conformity assessment process as well as the devices, technologies and areas covered by the scope of designation.

Or. en

Amendment 714
Mairead McGuinness

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

Text proposed by the Commission	*Amendment*
	(a c) to review and approve the criteria of the competent authorities of Member States in respect of article 80 - paragraph 1 - point a b - above

Or. en

Amendment 715
Mairead McGuinness

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

Text proposed by the Commission	*Amendment*
	1a) The MDCG shall create and maintain a list of appropriately qualified and recognised clinical experts and their clinical specialty which shall be made available to the conformity assessment bodies notified for class III devices, those implanted into the body, incorporating a substance considered to be a medicinal product, or utilising non-viable tissues or cells of human or animal origin, or their derivatives for the purposes of complying with the notification requirement in Article 44

Or. en

Justification

In order to guarantee full and proper assessment of clinical evidence by independent clinical

experts a European-level list of recognised clinical experts should be created. Class III notified bodies are thereafter obliged to select an expert or experts from this list in their assessments of clinical evidence.

Amendment 716
Mairead McGuinness

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

Text proposed by the Commission	*Amendment*
	1b) The MDCG shall hear the MDAG. The MDCG shall note the adoption of opinions or recommendations or other positions by the MDAG and may adopt them itself where appropriate.

Or. en

Amendment 717
Christofer Fjellner, Anna Rosbach

Proposal for a regulation
Article 80 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 44;	***deleted***

Or. en

Amendment 718
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 80 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 44;	***deleted***

Or. en

Justification

The MDCG is a crucial part in the regulatory framework. Its task should therefore be described in more detail.

Amendment 719
Philippe Juvin

Proposal for a regulation
Article 80 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 44;	***deleted***

Or. fr

Amendment 720
Françoise Grossetête

Proposal for a regulation
Article 80 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) to ***contribute to*** the scrutiny of certain conformity assessments pursuant to Article 44;	(b) to ***monitor*** the scrutiny of certain conformity assessments pursuant to Article 44;

Or. fr

Amendment 721
Nora Berra

Proposal for a regulation
Article 80 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) to ***contribute to the scrutiny of*** certain ***conformity assessments*** pursuant to Article 44;	(b) to ***provide a scientific assessment on*** certain ***types of medical devices*** pursuant to Article 44;

Or. en

Amendment 722
Holger Krahmer

Proposal for a regulation
Article 80 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) to ***contribute to the scrutiny of certain conformity assessments pursuant to Article 44***;	(b) to ***regularly monitor technical progress, in particular for class III implantable medical devices***;

Or. en

Justification

The MDCG should play a pivotal role for improving the safety of patients. This requires a detailed description and specification of the responsibilities as compared to the draft proposal including that the basic requirements and device standards must comply with technical progress. Another important aspect for the system is the market surveillance after the placing on the market. Limited financial and personnel resources call for an improved coordination and cooperation of the Member States.

Amendment 723
Holger Krahmer

Proposal for a regulation
Article 80 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) to ***contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of the clinical evaluation by manufacturers and the assessment by notified bodies;***	(c) to ***assess whether the basic requirements to the safety and performance of medical devices intended by this regulation are sufficient and to identify necessary amendments to Annex I.***

Or. en

Justification

The MDCG should play a pivotal role for improving the safety of patients. This requires a detailed description and specification of the responsibilities as compared to the draft proposal including that the basic requirements and device standards must comply with technical progress. Another important aspect for the system is the market surveillance after the placing on the market. Limited financial and personnel resources call for an improved coordination and cooperation of the Member States.

Amendment 724
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 80 – paragraph 1 – point c

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

Or. en

Justification

The MDCG is a crucial part in the regulatory framework. Its task should therefore be described in more detail.

Amendment 725
Holger Krahmer

Proposal for a regulation
Article 80 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) to ***assist the competent authorities of the Member States in their coordination activities in the fields of*** clinical ***investigations, vigilance and market surveillance;***	(d) to ***develop guidelines for*** clinical ***studies on medical devices***

Or. en

Justification

The MDCG should play a pivotal role for improving the safety of patients. This requires a detailed description and specification of the responsibilities as compared to the draft proposal including that the basic requirements and device standards must comply with technical progress. Another important aspect for the system is the market surveillance after the placing on the market. Limited financial and personnel resources call for an improved coordination and cooperation of the Member States.

Amendment 726
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 80 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) to provide advice and assist the Commission, at its request, in its assessment of any issue related to the implementation of this Regulation;	***deleted***

Or. en

Justification

The MDCG is a crucial part in the regulatory framework. Its task should therefore be described in more detail.

Amendment 727
Holger Krahmer

Proposal for a regulation
Article 80 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) ***to provide advice and assist the Commission, at its request, in its assessment of any issue related to the implementation of this Regulation***;	(e) ***to regularly review norms and standards for medical devices***;

Or. en

Justification

The MDCG should play a pivotal role for improving the safety of patients. This requires a detailed description and specification of the responsibilities as compared to the draft proposal including that the basic requirements and device standards must comply with technical progress. Another important aspect for the system is the market surveillance after the placing on the market. Limited financial and personnel resources call for an improved coordination and cooperation of the Member States.

Amendment 728
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 80 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) to contribute to harmonised administrative practice with regard to medical devices in the Member States.	***deleted***

Or. en

Justification

The MDCG is a crucial part in the regulatory framework. Its task should therefore be described in more detail.

Amendment 729
Holger Krahmer

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

Text proposed by the Commission	*Amendment*
	(f a) to develop and implement a framework for a European market surveillance programme;

Or. en

Justification

The MDCG should play a pivotal role for improving the safety of patients. This requires a detailed description and specification of the responsibilities as compared to the draft proposal including that the basic requirements and device standards must comply with technical progress. Another important aspect for the system is the market surveillance after the placing on the market. Limited financial and personnel resources call for an improved coordination and cooperation of the Member States.

Amendment 730
Anja Weisgerber, Thomas Ulmer

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

Text proposed by the Commission	*Amendment*
	(f a) (d) to continuously monitor the technical progress in particular in the field of implantable devices and assess whether the essential requirements on safety and performance provided within this Regulation are appropriate to ensure safety and performance of medical devices and identify the need to amend Annex I;

(fb) to develop guidelines on clinical trials of certain medical devices

(fc) to contribute to the development of medical devices standards;

(fd) to contribute to the development of Common Technical Specifications (CTS)

(fe) to develop and maintain a framework for a European market surveillance program;

(ff) to develop minimum requirements on a quality management system for national market surveillance authorities .

(fg) to organise joint market surveillance and joint testing projects;

(fh) to organise training programmes and exchanges of national officials on market surveillance, on notified bodies designation and monitoring and on clinical investigations;

(fi) to organise information campaigns and joint visit programmes;

(fj) to provide an opinion on the application of the classification criteria set out in Annex VII to a given device, or category or group of devices according to Article 41 paragraph 3 within six months

(fk) to provide at the Commission's request an opinion on a the classification of a device, or category or group of devices according to Article 41 paragraph 4.

Or. en

Amendment 731
Holger Krahmer

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

Text proposed by the Commission	*Amendment*
	(f b) to develop minimum requirements for a quality management system for the national market surveillance authorities;

Or. en

Justification

The MDCG should play a pivotal role for improving the safety of patients. This requires a detailed description and specification of the responsibilities as compared to the draft proposal including that the basic requirements and device standards must comply with technical progress. Another important aspect for the system is the market surveillance after the placing on the market. Limited financial and personnel resources call for an improved coordination and cooperation of the Member States.

Amendment 732
Holger Krahmer

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

Text proposed by the Commission	*Amendment*
	(f c) to organise a joint market surveillance and joint test projects in the Member States;

Or. en

Justification

The MDCG should play a pivotal role for improving the safety of patients. This requires a detailed description and specification of the responsibilities as compared to the draft proposal including that the basic requirements and device standards must comply with technical progress. Another important aspect for the system is the market surveillance after the placing on the market. Limited financial and personnel resources call for an improved coordination and cooperation of the Member States.

Amendment 733
Holger Krahmer

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

Text proposed by the Commission	*Amendment*
	(f d) to organise the sharing of competences between the Member States with regard to market surveillance, notified bodies and clinical evaluations;

Or. en

Justification

The MDCG should play a pivotal role for improving the safety of patients. This requires a detailed description and specification of the responsibilities as compared to the draft proposal including that the basic requirements and device standards must comply with technical progress. Another important aspect for the system is the market surveillance after the placing on the market. Limited financial and personnel resources call for an improved coordination and cooperation of the Member States.

Amendment 734
Holger Krahmer

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

Text proposed by the Commission	*Amendment*
	(f e) to organise information campaigns and joint verification programmes;

Or. en

Justification

The MDCG should play a pivotal role for improving the safety of patients. This requires a detailed description and specification of the responsibilities as compared to the draft proposal including that the basic requirements and device standards must comply with technical progress. Another important aspect for the system is the market surveillance after the placing on the market. Limited financial and personnel resources call for an improved coordination and cooperation of the Member States.

Amendment 735
Holger Krahmer

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

Text proposed by the Commission	*Amendment*
	(f f) to create the prerequisites that an opinion on a classification request in Annex VII for a specific medical device or groups of medical devices according to Article 41 (3) can be provided within 6 months;

Or. en

Justification

The MDCG should play a pivotal role for improving the safety of patients. This requires a detailed description and specification of the responsibilities as compared to the draft proposal including that the basic requirements and device standards must comply with technical progress. Another important aspect for the system is the market surveillance after the placing on the market. Limited financial and personnel resources call for an improved coordination and cooperation of the Member States.

Amendment 736
Holger Krahmer

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

Text proposed by the Commission	*Amendment*
	(f g) to create the prerequisites that an opinion on a request by the Commission regarding the classification of a medical device or groups of medical devices according to Article 41 (4) can be provided;

Or. en

Justification

The MDCG should play a pivotal role for improving the safety of patients. This requires a detailed description and specification of the responsibilities as compared to the draft proposal including that the basic requirements and device standards must comply with

technical progress. Another important aspect for the system is the market surveillance after the placing on the market. Limited financial and personnel resources call for an improved coordination and cooperation of the Member States.

Amendment 737
Holger Krahmer

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

Text proposed by the Commission	*Amendment*
	(f h) to develop a framework programme for post market surveillance

Or. en

Justification

The MDCG should play a pivotal role for improving the safety of patients. This requires a detailed description and specification of the responsibilities as compared to the draft proposal including that the basic requirements and device standards must comply with technical progress. Another important aspect for the system is the market surveillance after the placing on the market. Limited financial and personnel resources call for an improved coordination and cooperation of the Member States.

Amendment 738
Nora Berra

Proposal for a regulation
Article 80 a (new)

Text proposed by the Commission	*Amendment*
	Article 80 a
	Scientific Advisory Board
	1. The Commission shall set up and provide the logistic support for a Scientific Advisory Board made up of not more than 15 scientific and/or clinical experts in the field of medical devices, appointed in their personal capacity by the MDCG.

2. When appointing these experts, the Commission shall ensure a broad, appropriate and balanced coverage of the medical disciplines relevant for medical devices, the publication of any interests which might affect the conduct of their work and the signature of a confidentiality clause. The Scientific Advisory Board may establish under its responsibility expert panels for specific medical disciplines. The Commission or the MDCG may request the Scientific Advisory Board to provide scientific advice on any issue related to the implementation of this Regulation

3. The Scientific Advisory Board shall appoint one chairperson and one vice chairperson from among its members for a term of three years, renewable once. In duly justified situations, the majority of its members may request the chairperson and/or vice-chairperson to resign.

4. The Scientific Advisory Board shall establish its rules of procedure which shall, in particular, lay down procedures for:

a) the functioning of expert panel;

b) the appointment and replacement of its chairperson and vice-chairperson,

c) the scientific assessment foreseen in Article 44, including in cases of urgency,

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

Or. en

Amendment 739
Peter Liese

Proposal for a regulation
Article 81 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices;	(b) to provide scientific advice ***and technical assistance*** regarding ***the definition of*** the state of the art in relation to specific devices, or a category or group of devices;

Or. en

Justification

Improved wording and clearer definition of the tasks of the Reference laboratories

Amendment 740
Peter Liese

Proposal for a regulation
Article 81 – paragraph 2 – point f

Text proposed by the Commission	*Amendment*
(f) to contribute to the development of ***standards at*** international ***level;***	(f) to contribute to the development of ***common technical specifications (CTS) as well as of*** international ***standards***

Or. en

Justification

Reference Laboratories will have the appropriate knowledge, experience and technical skills to contribute to the development of CTS. Improvement of the wording.

Amendment 741
Mairead McGuinness

Proposal for a regulation
Article 82 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Members of the MDCG and staff of the EU reference laboratories shall not have financial or other interests in the medical	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.	device industry ***or in the supply chain*** which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. They shall declare any direct and indirect interests they may have in the medical device industry ***or in the supply chain*** and update this declaration whenever a relevant change occurs. 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.

Or. en

Amendment 742
Antonyia Parvanova

Proposal for a regulation
Article 82 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Members of the MDCG and staff of the EU reference laboratories shall not have financial or other interests in the medical device industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. They shall declare any direct and indirect interests they may have in the medical device industry and update this declaration whenever a relevant change occurs. ***Upon request,*** the declaration of interests shall be ***accessible to the public. This Article shall not apply to the representatives of stakeholder organisations participating in the sub-groups of the MDCG***.	1. Members of the MDCG 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. The declaration of interests shall be ***made publicly available on the European Commission web site***.

Or. en

Amendment 743
Michèle Rivasi

Proposal for a regulation
Article 82 – paragraph 1

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

Or. en

Amendment 744
Antonyia Parvanova

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. ***Representative of stakeholder organizations participating in the sub-groups of*** the MDCG ***shall declare any direct and indirect interests they may have in the medical device industry and update this declaration whenever a relevant change occurs. The declaration of interests*** shall be ***made publicly available on the European Commission web site. This shall not apply to representatives of the medical devices industry***.

Or. en

Amendment 745
Michèle Rivasi, Corinne Lepage

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 and other third parties invited by the MDCG on a case-by-case basis shall declare their interests in the issue in question ***and their declaration of interest shall be permanently accessible to the public***.

Or. en

Amendment 746
Nora Berra

Proposal for a regulation
Article 82 a (new)

Text proposed by the Commission	*Amendment*
	Article 82 a
	Scientific advice
	1. The Commission shall facilitate the access of manufacturers of innovative devices concerned by the scientific assessment laid down in Article 44 to scientific advice provided by the Scientific Advisory Board or by an EU reference laboratory to information concerning the criteria for an appropriate assessment of the conformity of a device, in particular with regard to the clinical data required for the clinical evaluation.
	2. The scientific advice provided by the Scientific Advisory Board or by an EU reference laboratory shall not be binding.

	3. The Commission shall publish summaries of the scientific advice referred to in paragraph 1, providing that all information of commercial confidential nature have been deleted.

Or. en

Amendment 747
Alda Sousa

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 such devices. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices.	The Commission and the Member States shall take all appropriate measures to encourage the establishment of ***medical*** devices to gather post-market experience related to the use of such devices. Such registers shall contribute to the independent evaluation of the long-term safety and performance of ***devices and to the traceability of such*** devices.

Or. en

Amendment 748
Frédérique Ries

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

devices.	the long-term safety and performance of devices.

Or. en

Justification

The development of such registries shall be coordinated and harmonised to avoid a burdensome gathering of data of limited use and to ensure that the resources put into the development of registries are efficiently used. Only if registries are organized in a coordinated and harmonized way, they can be analysed together and provide valuable post-market safety information.

Amendment 749
Mairead McGuinness

Proposal for a regulation
Article 86 – paragraph 1

Text proposed by the Commission	*Amendment*
This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles. They shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted.	This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles. They shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted. ***The structure and level of fees shall be publicly available on request.***

Or. en

Amendment 750
Andrés Perelló Rodríguez

Proposal for a regulation
Article 87 – paragraph 1

Text proposed by the Commission	*Amendment*
The Member States shall lay down the	The Member States shall lay down the

provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. The Member States shall notify those provisions to the Commission by [3 months prior to the date of application of the Regulation] and shall notify it without delay of any subsequent amendment affecting them.	provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. ***The dissuasive nature of the penalty shall be determined in relation to the financial benefit obtained as a result of the infringement.*** The Member States shall notify those provisions to the Commission by [3 months prior to the date of application of the Regulation] and shall notify it without delay of any subsequent amendment affecting them.

Or. es

Justification

In order to act as a deterrent to fraudulent conduct and ensure its effectiveness, the penalty should be significantly greater than the financial benefit obtained by the producer as a result of the infringement or fraud committed.

Amendment 751
Philippe Juvin

Proposal for a regulation
Article 89 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The power to adopt the delegated acts referred to in Articles 2(2) and (3), 4(5), 8(2), 17(4), 24(7), 25(7), 29(2), 40(2), ***41(4), 42(11), 45(5), 51(7), 53(3),*** 74(4) and 81(6) is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt the delegated acts referred to in Articles 2(2) and (3), 4(5), 8(2), 17(4), 24(7), 25(7), 29(2), 40(2), 74(4) and 81(6) is conferred on the Commission subject to the conditions laid down in this Article.

Or. fr

Amendment 752
Mairead McGuinness

Proposal for a regulation
Article 89 – paragraph 1 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	The Commission shall, in drafting delegated acts, seek the advice of the MDCG.

Or. en

Amendment 753
Philippe Juvin

Proposal for a regulation
Article 89 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The delegation of power referred to in Articles 2(2) and (3), 4(5), 8(2), 17(4), 24(7), 25(7), 29(2), 40(2), ***41(4), 42(11), 45(5), 51(7), 53(3),*** 74(4) and 81(6) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.	2. The delegation of power referred to in Articles 2(2) and (3), 4(5), 8(2), 17(4), 24(7), 25(7), 29(2), 40(2), 74(4) and 81(6) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

Or. fr

Amendment 754
Philippe Juvin

Proposal for a regulation
Article 89 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The delegation of power referred to in Articles 2(2) and (3), 4(5), 8(2), 17(4), 24(7), 25(7), 29(2), 40(2), ***41(4), 42(11), 45(5), 51(7), 53(3),*** 74(4) and 81(6) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the	3. The delegation of power referred to in Articles 2(2) and (3), 4(5), 8(2), 17(4), 24(7), 25(7), 29(2), 40(2), 74(4) and 81(6) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in

delegation of the power specified in that decision. It shall take effect the day following its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Or. fr

Amendment 755
Gaston Franco

Proposal for a regulation
Article 93 – paragraph 1

Text proposed by the Commission	*Amendment*
In accordance with the regulatory procedure referred to in Article 32(2), the Commission may, at the request of a Member State or on its own initiative, adopt the necessary measures to determine whether or not a specific product ***or group of products*** falls within the definition "cosmetic product".	In accordance with the regulatory procedure referred to in Article 32(2), the Commission may, at the request of a Member State or on its own initiative, adopt the necessary measures to determine whether or not a specific product falls within the definition "cosmetic product". ***The Standing Committee on Cosmetic Products and relevant stakeholders shall provide support, advice and expertise to the Commission on cosmetic borderline cases.***

Or. en

Justification

The qualification of a cosmetic borderline product is profoundly linked to a case by case assessment of a specific product, its presentation and claims. The cultural background and language are important in the national perception of a cosmetic product, and of its claims by consumers and are key in the qualification of a cosmetic product. In order to make well informed decisions on the status of cosmetic borderline cases, the Commission needs to be advised by experts from the Member States and the sectors concerned.

Amendment 756
Thomas Ulmer

Proposal for a regulation
Article 94 – paragraph 4

Text proposed by the Commission	*Amendment*
4. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.	4. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application ***if it has been ensured that the relevant delegated legal acts and implementing acts have been implemented***.

Or. de

Amendment 757
Michèle Rivasi, Corinne Lepage

Proposal for a regulation
Article 94 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Devices falling within the scope of this Regulation in accordance with ***point (e) of*** Article ***1(2)*** which have been legally placed on the market or put into service in accordance with the rules in force in the Member States prior to the application of this Regulation may continue to be placed on the market and put into service in the Member States concerned.	7. ***Class IIb and class III*** devices falling within the scope of this Regulation ***which have been legally placed on the market or put into service*** in accordance with ***the rules in force in the Member States prior to the application of this Regulation which are already on the market shall be subject to a market authorisation as referred to in*** Article ***41. Within a transitional period of six months following the date this Regulation enters into force, the manufacturers or the entity responsible for placing the devices on the market must report to the centralised or decentralised authorisation body -as***

applicable- the class IIb and class III medical devices they have placed on the market, together with the results of the conformity assessment procedure in order to be allowed to continue to be marketed for a period of five years of the date this Regulation enters into force. Once this period has expired, they may not continue to be placed on the market unless an authorisation has meanwhile been granted or an application for the granting of authorisation has been filed.

All other devices falling within the scope of this Regulation which have been legally placed on the market or put into service in accordance with the rules in force in the Member States prior to the application of this Regulation ***which are already on the market*** may continue to be placed on the market and put into service in the Member States concerned.

Or. en

Justification

High-risk medical devices until now could be placed on the market merely on the basis of a conformity assessment procedure performed by a notified body commissioned by the manufacturer, which led in some cases to health disasters. Once this Regulation enters into force, there should be no double standards for those devices, depending on when they entered the market.

Amendment 758
Paolo Bartolozzi, Salvatore Tatarella, Elisabetta Gardini

Proposal for a regulation
Article 97 – paragraph 3 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) Article 25(2) and (3) and Article 45(4) shall apply from [18 months after date of application referred to in paragraph 2];	(a) Article 25(2) and (3) and Article 45(4) shall apply from [18 months after date of application referred to in paragraph 2] ***provided that the relevant electronic system has been validated and in***

operation;

Or. en

Justification

The obligation to file data into an electronic system can only be fulfilled if the systems (Electronic system on registration of devices and economic operators / Electronic system to collate and process information on certificates issued by notified bodies) are ready and operational in due time.

Amendment 759
Mairead McGuinness

Proposal for a regulation
Annex 1 – part I – point 2 – point c

Text proposed by the Commission	*Amendment*
(c) reduce as far as possible the remaining risks by taking adequate protection measures, including alarms; and	(c) reduce as far as possible the remaining risks by taking adequate protection measures, including alarms; ***hence, it should take into consideration the latest tools and concepts developed in hazard and risk assessment based on human-relevant models, pathways of toxicity, adverse outcome pathways and evidence-based toxicology;*** and

Or. en

Justification

- As stated by the EC scientific committees in their discussion paper "Addressing the new challenges for Risk Assessment – Oct 2012: "A shift is foreseen towards using more and more human data on biologically significant perturbations in key toxicity pathways". Further, the REACH review earlier this year (Feb 2013), commented similarly on these mechanisms to better address the new challenges for hazard and risk assessment.

Amendment 760
Mairead McGuinness

Proposal for a regulation
Annex 1 – part I – point 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	(d a) Points a, b, c and d, above, shall not reduce the necessity for clinical investigation and post-market clinical follow up to adequately address the risks, hazards and performance of devices.

Or. en

Amendment 761
Sirpa Pietikäinen

Proposal for a regulation
Annex 1 – part II – point 7 – point 7.1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) the physical compatibility between the different manufacturers' parts of the devices which consist of more than one implantable part;

Or. en

Amendment 762
Vittorio Prodi

Proposal for a regulation
Annex 1 – part II – point 7 – point 7.4 – introductory part

Text proposed by the Commission	*Amendment*
7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and	7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and

of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 , and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) .

of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 , and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)***.*** ***Special attention shall be given to the recommendations from the EC Scientific committees (SCENIHR, SCCS and SCHER) on their discussion paper "Addressing the new challenges for Risk Assessment – Oct 2012" and REACH Review (COM(2013) 49 final – Feb 2013) which both acknowledged that "toxicology is undergoing a transition towards a more mechanistic, pathway-based, cell- and computer-based approach assessing a substance's toxic mode of action"***.

Or. en

Amendment 763
Alda Sousa

Proposal for a regulation
Annex 1 – part II – point 7 – point 7.4 – introductory part

Text proposed by the Commission	*Amendment*
7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by ***substances that may leach or leak from the device***. ***Special attention shall be given to*** substances which are	7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by ***hazardous substances***. Substances***.*** which are carcinogenic, mutagenic or toxic to reproduction, in

carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 , ***and to*** substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) .

accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 , ***shall be phased out within 5 years from the entry into force of this Regulation, unless no safer alternative substances are available. In the case that no safer alternatives exist, the medical device shall be labelled and the manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, the technical documentation and, within the instructions for use, information on residual risks for patient groups and, if applicable, on appropriate precautionary measures. Devices containing*** substances having endocrine disrupting properties ***that come into contact with the body of patients and*** for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ***, or are known or presumed endocrine disruptors pursuant to Commission Recommendation (2013/.../EU) on criteria for the identification of Endocrine Disrupters, shall be phased out within 5 years from the entry into force of this Regulation, unless no safer alternative substances are available. In the case that no safer alternatives exist, the medical device shall be labelled and the manufacturer shall provide a specific justification for the use of these***

substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, the technical documentation and, within the instructions for use, information on residual risks for patient groups and, if applicable, on appropriate precautionary measures.

Or. en

Amendment 764
Daciana Octavia Sârbu, Cătălin Sorin Ivan

Proposal for a regulation
Annex 1 – part II – point 7 – point 7.4 – introductory part

Text proposed by the Commission	*Amendment*
7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 , and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health ***and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)***.	7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 , and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health.

Or. en

Justification

The proposal limits the special attention which should be paid to endocrine disrupters to those identified under REACH. This is too restrictive. The forthcoming Commission criteria on endocrine disrupters, for example, should also be taken into account.

Amendment 765
Michèle Rivasi, Dagmar Roth-Behrendt, Åsa Westlund, Christel Schaldemose, Corinne Lepage

Proposal for a regulation
Annex 1 – part II – point 7 – point 7.4 – introductory part

Text proposed by the Commission	*Amendment*
7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 , and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health ***and*** which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) .	7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 , and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health ***or*** which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)***, or are known or presumed endocrine disrupters pursuant to Commission Recommendation (2013/.../EU) on criteria***

for the identification of endocrine disrupters.

Or. en

Justification

It is not appropriate to link the identification of endocrine disrupters (EDs) to Article 59 of REACH, as this is not a comprehensive list of EDs. Identification as ED under REACH, which is very slow (it has only occurred for very few substances so far) and which follows a different logic (candidate list), should only be one option. The Commission is currently in the process of establishing criteria for the identification of EDs and the future recommendation should provide an adequate reference.

Amendment 766
Michèle Rivasi, Dagmar Roth-Behrendt, Åsa Westlund, Christel Schaldemose, Corinne Lepage

Proposal for a regulation
Annex 1 – part II – point 7 – point 7.4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
If devices, or parts thereof, that are intended	Devices, or parts thereof, that are intended

Or. en

(AT4AM artificially cuts this subparagraph into several parts (due to the bullet points that follow after the text above). This amendment has to be read in conjunction with the amendment by the same authors to the main part of this subparagraph after the bullet points (which are not proposed to be changed).)

Justification

The start of this subparagraph needs to be modified in line with the suggestion of the interlinked amendment to move from a provision of labelling of certain CMR phthalates to a ban of CMR and ED substances, unless no alternatives are available.

Amendment 767
Alda Sousa

Proposal for a regulation
Annex 1 – part II – point 7 – point 7.4 – paragraph 1 – indent 3 – paragraph 1

Text proposed by the Commission	*Amendment*
contain, in a concentration of 0.1% by mass of the plasticised material or above, phthalates ***which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008***, these ***devices*** shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as devices containing phthalates***. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the*** manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.	contain, in a concentration of 0.1% by mass of the plasticised material or above, phthalates, these ***substances*** shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as devices containing phthalates***, phased out within 5 years from the entry into force of this Regulation, unless no safer alternatives are available. In the case that no safer alternatives exist, the medical devices shall be labelled and the*** manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures. ***If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, phthalates shall be banned as of 1st January 2017.***

Or. en

Amendment 768
Michèle Rivasi, Dagmar Roth-Behrendt, Åsa Westlund, Christel Schaldemose, Corinne Lepage

Proposal for a regulation
Annex 1 – part II – point 7 – point 7.4 – paragraph 1 – indent 3 – paragraph 1

Text proposed by the Commission	*Amendment*
contain, in a concentration of 0.1% by mass ***of the plasticised*** material ***or above, phthalates*** which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in	***shall not*** contain, in a concentration of 0.1% ***or above*** by mass ***per homogeneous*** material***, substances*** which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in

accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008, these devices shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as devices containing ***phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women,*** the manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for ***these patient groups*** and, if applicable, on appropriate precautionary measures.	accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008, ***or substances identified as endocrine disrupters pursuant to the first subparagraph, unless the manufacturer can show that there are no suitable safer substances or devices without these substances.***
	In case the manufacturer can show that there are no suitable safer substances or devices without these substances, these devices shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as devices containing ***substances which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B or substances identified as endocrine disrupters.*** The manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for ***patients*** and, if applicable, on appropriate precautionary measures.

Or. en

(Linked to the amendment by the same authors to the first eight words of this subparagraph (AT4AM aberration).)

Justification

CMR substances are banned in cosmetic products, and CMR phthalates are banned in toys. Similar restrictions should apply for medical devices where exposure in inevitable, unless there are no safer alternatives. The same should apply for known endocrine disrupters. Where no alternatives exist, manufacturers should label the devices and provide specific justification as to the compliance with the safety provisions of the regulation for devices for any patient, not just for certain risk groups.

Amendment 769
Michèle Rivasi, Dagmar Roth-Behrendt, Åsa Westlund, Christel Schaldemose, Corinne Lepage

Proposal for a regulation
Annex 1 – part II – point 7 – point 7.6

Text proposed by the Commission	*Amendment*
7.6. The devices shall be designed and manufactured in such a way as to reduce to a minimum the risks linked to the size and the properties of particles used. Special care shall be applied when devices contain or consist of nanomaterial that can be released into the patient's or user's body.	7.6. The devices shall be designed and manufactured in such a way as to reduce to a minimum the risks linked to the size and the properties of particles used. Special care shall be applied when devices contain or consist of nanomaterial that can be released into the patient's or user's body. ***The manufacturer shall provide specific evidence that the use of the nanomaterial complies with the general safety and performance requirements within the technical documentation. The specific evidence has to be shown to respond to the specific characteristics of the nanomaterial. The manufacturer shall also provide within the instructions for use, information on residual risks for patients and, if applicable, on appropriate precautionary measures.***

Or. en

Justification

When nanomaterials are being used in medical devices, manufacturers should provide specific evidence for the nanomaterial concerned that its use complies with the general safety and performance requirements. The evidence should clearly address the specific nature of the nanomaterial. This would facilitate the application of the most severe conformity assessment

as foreseen pursuant to Rule 19 and Recital 13.

Amendment 770
Michèle Rivasi, Corinne Lepage

Proposal for a regulation
Annex 1 – part II – point 8 – point 8.7 a (new)

Text proposed by the Commission	*Amendment*
	8.7a. Medical device manufacturers shall notify their users of the levels of disinfection required to ensure patient safety and of all available methods for achieving those levels of disinfection. Manufacturers shall be required to test their devices using all methods designed to ensure patient safety and to substantiate any decision to reject a solution, either by demonstrating that it is ineffective or by demonstrating that it will cause damage impairing the medical usefulness of their devices to a significantly greater degree than other solutions that they themselves recommend.

Or. xm

Justification

Manufacturers recommend protocols, methods and solutions without due regard for the real effectiveness or their availability on the relevant market. In some cases, manufacturers' recommendations state preferences based on industrial interests rather than patient safety considerations.

Amendment 771
Thomas Ulmer

Proposal for a regulation
Annex 1 – part II – point 9 – introductory part

Text proposed by the Commission	*Amendment*
9. Devices incorporating a substance considered to be a medicinal product ***and***	9. Devices incorporating a substance considered to be a medicinal product

devices composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally

Or. de

Amendment 772
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 1 – part II – point 9 – introductory part

Text proposed by the Commission	*Amendment*
9. Devices incorporating a substance considered to be a medicinal product ***and devices composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally***	9. Devices incorporating a substance considered to be a medicinal product

Or. en

Amendment 773
Mairead McGuinness

Proposal for a regulation
Annex 1 – part II – point 9 – point 9.2

Text proposed by the Commission	*Amendment*
9.2. Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body shall comply, by analogy, with the relevant requirements laid down in Annex I to Directive 2001/83/EC.	***deleted***

Or. en

Amendment 774
Holger Krahmer

Proposal for a regulation
Annex 1 – part II – point 9 – point 9.2

Text proposed by the Commission	*Amendment*
9.2. Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body shall comply, by analogy, with the relevant requirements laid down in Annex I to Directive 2001/83/EC.	***deleted***

Or. en

Justification

The safety of these devices is ensured by the compliance to recognised harmonised standards or common technical specifications. Therefore, requesting compliance with analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products (Annex I to Directive 2001/83/EC) will not provide any beneficial additional information in terms of patient safety.

Amendment 775
Thomas Ulmer

Proposal for a regulation
Annex 1 – part II – point 9 – point 9.2

Text proposed by the Commission	*Amendment*
9.2. Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body shall comply, by analogy, with the relevant requirements laid down in Annex I to Directive 2001/83/EC.	***deleted***

Or. de

Amendment 776
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 1 – part II – point 9 – point 9.2

Text proposed by the Commission	*Amendment*
9.2. Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body shall comply, by analogy, with the relevant requirements laid down in Annex I to Directive 2001/83/EC.	***deleted***

Or. en

Amendment 777
Paolo Bartolozzi, Salvatore Tatarella, Elisabetta Gardini

Proposal for a regulation
Annex 1 – part II – point 9 – point 9.2

Text proposed by the Commission	*Amendment*
9.2. Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body shall comply, by analogy, with the relevant requirements laid down in Annex I to Directive 2001/83/EC.	***deleted***

Or. en

Justification

The reference to Annex I of Directive 2011/83/EC is undue since medicinal products by definition are different in mechanism of action from devices. Referring to the Annex I of Directive 2001/83/EC for products which are not medicinal products is scientifically and technically inappropriate and it would lead to an inappropriate evaluation.

Amendment 778
Anja Weisgerber, Peter Liese

Proposal for a regulation
Annex 1 – part II – point 9 – point 9.2

Text proposed by the Commission	*Amendment*
9.2. Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body shall comply, by analogy, with the relevant requirements laid down in Annex I to Directive 2001/83/EC.	9.2. Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are ***intended to be*** absorbed by or dispersed in the human body ***in order to achieve the desired effect*** shall comply, by analogy, with the relevant requirements laid down in Annex I to Directive 2001/83/EC.

Or. de

Justification

If it is not intended that a device should be absorbed by or dispersed in the human body in order to achieve a particular medical effect, the evidence and studies pursuant to Directive 2001/83/EC on medicinal products for human use are not possible.

Amendment 779
Dan Jørgensen

Proposal for a regulation
Annex 1 – part II – point 10 – point 10.2 – point a (new)

Text proposed by the Commission	*Amendment*
	(2 a) The use of non-animal methods should be promoted. Animal use should be minimised and tests on vertebrates should be undertaken as a last resort. In accordance with Directive 2010/63/EU, tests on vertebrate animals must be replaced, restricted or refined. Therefore, we call on the Commission to lay down rules to avoid duplicative testing and duplication of tests and studies on

vertebrates should be prohibited.

Or. en

Justification

In line with the requirement in the Protocol on the Protection and Welfare of Animals as it has been implemented in Article 13 of the Treaty of the Functioning of the European Union, that the Community and the Member States pay full regard to the welfare requirements of animals in formulating and implementing policies, it should be included that animal testing is kept to an absolute minimum and carried out in line with the requirement in the Protocol on the Protection and Welfare of Animals as it has been implemented in Article 13 of the Treaty of the Functioning of the European Union, that the Community and the Member States pay full regard to the welfare requirements of animals in formulating and implementing policies, it should be included that animal testing is kept to an absolute minimum and carried out only as a last resort, and that the use of alternatives is promoted. This is also in line with the requirements under REACH, plant protection products and the biocides legislations of the EU only as a last resort, and that the use of alternatives is promoted. This is also in line with the requirements under REACH, plant protection products and the biocides legislations of the EU.

Amendment 780
Roberta Angelilli, Paolo Bartolozzi

Proposal for a regulation
Annex 1 – part II – point 11 – point 11.1 a (new)

Text proposed by the Commission	*Amendment*
	11.1a. Coupling systems shall be subject to uniform type approval procedures in order to ensure that the specified performance of such devices is not impaired. Not requiring type approval of coupling systems undermines the guarantees that such devices will be used for their intended purpose, as well as patient rights.

Or. it

Amendment 781
Thomas Ulmer

Proposal for a regulation
Annex 1 – part II – point 11 – point 11.7

Text proposed by the Commission	*Amendment*
11.7. Devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device and/or of any waste substances by the user, patient or other person.	11.7. Devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device***, of substances with which it has been treated*** and/or of any waste substances by the user, patient or other person ***and, where possible and appropriate, the device shall be replaced with a device with a higher safety standard***. ***This should particularly be intended to reduce dangers to patients and users which may arise from exposure to chemical or nuclear material.***

Or. de

Amendment 782
Marian Harkin

Proposal for a regulation
Annex 1 – part II – point 11 – point 11.7

Text proposed by the Commission	*Amendment*
11.7. Devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device and/or of any waste substances by the user, patient or other person.	11.7. Devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device and ***the substances with which the device has been exposed to and***/or of any waste substances by the user, patient or other person ***and, where possible and appropriate, replace with the use of devices and methods with improved safety features and characteristics to reduce as far as possible the exposure of patients, users and other persons to potentially harmful substances, such as chemical or nuclear material***.

Or. en

Amendment 783
Thomas Ulmer

Proposal for a regulation
Annex 1 – part II – point 13 – point 13.1 – point a

Text proposed by the Commission	*Amendment*
(a) Devices shall be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation shall be reduced as far as possible and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	(a) Devices shall be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation shall be reduced as far as possible and appropriate, compatible with the intended purpose, ***and if possible these applications shall be replaced with applications with a higher safety standard,*** whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

Or. de

Amendment 784
Thomas Ulmer, Peter Liese

Proposal for a regulation
Annex 1 – part II – point 13 – point 13.3 – paragraph 1

Text proposed by the Commission	*Amendment*
Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible and appropriate.	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible and appropriate***: where possible, methods should be selected which reduce the exposure to radiation of patients, users and other persons who may be affected***.

Or. de

Amendment 785
Thomas Ulmer

Proposal for a regulation
Annex 1 – part II – point 13 – point 13.4 – point a

Text proposed by the Commission	*Amendment*
(a) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.	(a) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use***, and if possible, devices should be used that can at any time during and after treatment monitor the emission of radiation***.

Or. de

Amendment 786
Thomas Ulmer

Proposal for a regulation
Annex 1 – part II – point 16 – introductory part

Text proposed by the Commission	*Amendment*
16. Protection against ***mechanical and thermal*** risks	16. Protection against risks ***arising from devices which are intended by manufacturers for self-testing***

Or. de

Amendment 787
Jolanta Emilia Hibner, Elżbieta Katarzyna Łukacijewska

Proposal for a regulation
Annex 1 – part III – point 19 – point 19.1 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(a a) The name of the product may not allude to the name of a medicinal product, a biocidal product, a cosmetic product or

a diet supplement.

Or. pl

Justification

Many examples can be found on the market whereby the names of medicinal products are identical to the name of a medicine or contain a major part of the name of a medicine. In the case of disinfectants, products are very often named identically to medicines and biocidal products. The provisions concerning medicinal products have thus far failed to adequately regulate this issue. Therefore, in order to ensure that products are used safely and customers are not misled, this issue should be thoroughly clarified.

Amendment 788
Gilles Pargneaux

Proposal for a regulation
Annex 1 – part III – point 19 – point 19.1 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) Labels shall be provided in a human-readable format ***but may*** be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.	(d) Labels shall be provided in a human-readable format ***and shall*** be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.

Or. fr

Justification

Medical device labels must be in both human-readable and machine-readable format, in order to ensure that there are no difficulties in recording the unique identifier.

Amendment 789
Holger Krahmer

Proposal for a regulation
Annex 1 – part III – point 19 – point 19.1 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) Labels shall be provided in a human-readable format ***but may*** be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar	(d) Labels shall be provided in a human-readable format ***and shall*** be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar

codes.	codes.

Or. en

Justification

Medical devices labels should be incorporated in both formats, human readable and machine readable, because with the machine readable format it is in most cases faster and more accurate to scan the label and to record the unique identifier in this way.

Amendment 790
Marina Yannakoudakis

Proposal for a regulation
Annex 1 – part III – point 19 – point 19.1 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) Labels shall be provided in a human-readable format ***but may be*** supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.	(d) Labels shall be provided in a human-readable format ***and shall be*** supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.

Or. en

Justification

Medical devices labels must be incorporated in human readable and machine readable formats or it may be difficult to record the unique identifier.

Amendment 791
Nora Berra

Proposal for a regulation
Annex 1 – part III – point 19 – point 19.2 – point a a (new)

Text proposed by the Commission	*Amendment*
	(a a) the mention "This product is a medical device".

Or. en

Amendment 792
Milan Cabrnoch

Proposal for a regulation
Annex 1 – part III – point 19 – 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) 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 the device is included on the list of single-use devices pursuant to Article 15(4), information to the effect that the device may not under any circumstances be reused.*** 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. cs

Amendment 793
Marina Yannakoudakis

Proposal for a regulation
Annex 1 – part III – point 19 – point 19.3 – point q

Text proposed by the Commission	*Amendment*
(q) For devices intended for use by lay persons, the circumstances when the user should consult with a healthcare professional.	(q) For devices intended for use by lay persons, the circumstances when the user should consult with a healthcare professional. ***Elements in the instructions for use for patients should be reviewed with the input of patient organisations to ensure they truly correspond to patients' needs and are understandable and accessible.***

Or. en

Amendment 794
Milan Cabrnoch

Proposal for a regulation
Annex 2 – paragraph 1 – point 2 – point b

Text proposed by the Commission	*Amendment*
(b) ***a list of the language variants for the Member States where*** the device ***is envisaged to be*** marketed.	(b) ***a link to a list of Member States in which*** the device ***has been*** marketed.

Or. cs

Amendment 795
Thomas Ulmer

Proposal for a regulation
Annex 2 – paragraph 1 – point 5 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The documentation shall contain ***a summary of***	The documentation shall contain ***all available information concerning:***

Or. de

Justification

As the primary users of medical devices, and because doctors are responsible for the safety of their patients, members of the health professions must have access to all technical and clinical data available from the manufacturers in order to make a selection among the most suitable devices for their patients and to inform them accordingly.

Amendment 796
Marina Yannakoudakis

Proposal for a regulation
Annex 2 – paragraph 1 – point 5 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The documentation shall contain ***a summary of***	The documentation shall contain ***all available information related to***

Or. en

Amendment 797
Roberta Angelilli, Paolo Bartolozzi

Proposal for a regulation
Annex 2 – paragraph 1 – point 6 – point 6.2 – point e

Text proposed by the Commission	*Amendment*
(e) If the device is to be connected to other device(s) in order to operate as intended, a description of this combination including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.	(e) If the device is to be connected to other device(s) ***by means of a coupling system*** in order to operate as intended, a description of this combination including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer. ***This coupling system shall be type approved in order to ensure that it is used as intended and that the patient receives appropriate treatment.***

Or. it

Amendment 798
Thomas Ulmer

Proposal for a regulation
Annex 4 – point 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The CE marking shall consist of the initials 'CE' taking the following form:	1. The CE marking shall consist of the initials "CE" ***with the addition of the words 'medical device'*** taking the following form:

Or. de

Amendment 799
Holger Krahmer

Proposal for a regulation
Annex 6 – heading 1

Text proposed by the Commission	*Amendment*
MINIMUM REQUIREMENTS TO BE MET BY NOTIFIED BODIES	REQUIREMENTS TO BE MET BY NOTIFIED BODIES

Or. de

Justification

If uniform requirements for notified bodies in all Member States are to be drawn up and fair and equal conditions guaranteed, reference should be made to 'requirements', not 'minimum requirements', to be met by notified bodies. What is more, this is the terminology used in Decision No 768/2008/EC of the European Parliament and of the Council concerning notified bodies.

Amendment 800
Nora Berra

Proposal for a regulation
Annex 6 – heading 1

Text proposed by the Commission	*Amendment*
MINIMUM REQUIREMENTS TO BE MET BY NOTIFIED BODIES	REQUIREMENTS TO BE MET BY NOTIFIED BODIES

Or. en

Amendment 801
Holger Krahmer

Proposal for a regulation
Annex 6 – point 1 – point 1.2 – point 1.2.1

Text proposed by the Commission	*Amendment*
1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The notified body shall also be	1.2.1. The notified body***, including its personnel*** shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The

independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer.	notified body shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer. ***This does not preclude any conformity assessment activities for economic operators or competitors, mentioned above.***

Or. en

Justification

Clarification that this requirement is also applicable to the personnel employed by the notified bodies. Clarification that a notified body can do conformity assessment activities for different economic operators producing different or similar products.

Amendment 802
Holger Krahmer

Proposal for a regulation
Annex 6 – point 1 – point 1.2 – point 1.2.4

Text proposed by the Commission	*Amendment*
1.2.4. The impartiality of the notified bodies, of their top level management ***and*** of the assessment personnel shall be guaranteed. The remuneration of the top level management ***and*** assessment personnel of a notified body shall not depend on the results of the assessments.	1.2.4. The impartiality of the notified bodies, of their top level management**,** of the assessment personnel ***and subcontractors*** shall be guaranteed. The remuneration of the top level management**,** assessment personnel ***and subcontractors*** of a notified body shall not depend on the results of the assessments.

Or. en

Justification

Where a notified body uses external consultants in its activities, these external consultants should be subject to the same requirements as the staff of the notified body.

Amendment 803
Holger Krahmer

Proposal for a regulation
Annex 6 – point 1 – point 1.5 – paragraph 1

Text proposed by the Commission	*Amendment*
The notified body shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking into account specific circumstances during an initial start-up phase.	The notified body***, including its subsidiaries,*** shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking into account specific circumstances during an initial start-up phase.

Or. en

Justification

To ensure the highest level of safety, all subsidiaries of a notified body should be subject to the same requirements as the notified body itself.

Amendment 804
Holger Krahmer

Proposal for a regulation
Annex 6 – point 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***, including subcontractors,*** is informed ***and trained on*** 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***, standards***, guidance and best practice documents adopted in the framework of this Regulation.

Or. en

Justification

Subcontractors should be held to the same high standards as the notified bodies assessment personnel.

Amendment 805
Holger Krahmer

Proposal for a regulation
Annex 6 – point 1 – point 1.6 – point 1.6.2

Text proposed by the Commission	*Amendment*
1.6.2. The notified body shall adhere to a code of conduct, addressing among other things, ethical business practices for notified bodies in the field of medical devices that is accepted by the national authorities responsible for notified bodies. The code of conduct shall provide for a mechanism of monitoring and verification of its implementation by notified bodies.	***deleted***

Or. en

Justification

The Code of Conduct was developed by most notified bodies in the sense of a voluntary self-regulatory initiative. It is based on the current regulatory framework and subject to constant modification by the notified bodies. Therefore the Regulation should not refer to such a non-legislative document. Major constituents of the content of the Code of Conduct which are so far not covered by the 'Requirements to be met by notified bodies' should be included in the Regulation.

Amendment 806
Holger Krahmer

Proposal for a regulation
Annex 6 – point 2 – point 2.2 – introductory part

Text proposed by the Commission	*Amendment*
2.2. The quality management system of the notified body shall at least address the	2.2. The quality management system of the notified body ***and its subcontractors*** shall

following: | at least address the following:

Or. en

Justification

To ensure that the highest level of safety is met, this requirement should also apply to the subcontractors of notified bodies.

Amendment 807
Holger Krahmer

Proposal for a regulation
Annex 6 – point 2 – point 2.2 – indent 8 a (new)

Text proposed by the Commission	*Amendment*
	- continuous training.

Or. en

Justification

The quality management system of notified bodies should include regular training programmes.

Amendment 808
Holger Krahmer

Proposal for a regulation
Annex 6 – point 3 – point 3.1 – point 3.1.1 – introductory part

Text proposed by the Commission	*Amendment*
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 ***and its subcontractors*** shall be capable of carrying out all the tasks assigned to it by this Regulation with the highest degree of professional integrity and the requisite technical competence in the specific field, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility.

Or. en

Justification

To ensure that the highest level of safety is met, this requirement should also apply to the subcontractors of notified bodies.

Amendment 809
Zofija Mazej Kukovič

Proposal for a regulation
Annex 6 – point 3 – point 3.1 – point 3.1.1 – introductory part

Text proposed by the Commission	*Amendment*
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. ***The process shall be monitored to ensure that it is of the requisite quality.***

Or. sl

Amendment 810
Alda Sousa

Proposal for a regulation
Annex 6 – point 3 – point 3.1 – point 3.1.1 – paragraph 1

Text proposed by the Commission	*Amendment*
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***, scientific*** and administrative tasks entailed in the conformity assessment activities in relation to which it has been notified.

Or. en

Amendment 811
Marina Yannakoudakis

Proposal for a regulation
Annex 6 – point 3 – point 3.1 – point 3.1.1 – paragraph 2

Text proposed by the Commission	*Amendment*
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. ***Permanent "in house" staff shall be used, but notified bodies must have the flexibility to hire external experts on an ad hoc and temporary basis as and when needed.***

Or. en

Amendment 812
Philippe Juvin

Proposal for a regulation
Annex 6 – point 3 – point 3.1 – point 3.1.1 – paragraph 2

Text proposed by the Commission	*Amendment*
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	This presupposes the availability within its organisation of sufficient scientific personnel who possess experience***, a university degree*** and ***the*** knowledge ***required*** 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

in Annex I.	particular, those set out in Annex I.

Or. fr

Amendment 813
Philippe Juvin

Proposal for a regulation
Annex 6 – point 3 – point 3.1 – point 3.1.1 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	The personnel responsible for carrying out the assessment tasks shall conduct unannounced inspections at least once a year of all premises at which the medical devices coming within their remit are manufactured. An unannounced inspection is one is which the manufacturer is given no advance notice of possible inspection dates and times.
	The personnel responsible for carrying out the assessment tasks shall notify all the competent authorities of the Member States affected by the manufacture and placing on the market of the medical device of the findings of the annual inspections carried out. Those findings shall be set out in a report.
	It shall also forward a record of the annual inspections carried out to the relevant national authority responsible.

Or. fr

Amendment 814
Holger Krahmer

Proposal for a regulation
Annex 6 – point 3 – point 3.1 – point 3.1.2

Text proposed by the Commission	*Amendment*
3.1.2. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with technical knowledge and sufficient and appropriate experience relating to medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data.	3.1.2. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with technical knowledge and sufficient and appropriate experience relating to medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data ***or the evaluation of an assessment made by a subcontractor.***.

Or. en

Justification

The in-house personnel of a notified body should be qualified to undertake an assessment of the technical and clinical dossiers of a device or should be qualified to evaluate the quality and appropriateness of an assessment undertaken by a subcontractor to a notified body.

Amendment 815
Marina Yannakoudakis

Proposal for a regulation
Annex 6 – point 3 – point 3.1 – point 3.1.2

Text proposed by the Commission	*Amendment*
3.1.2. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with technical knowledge and sufficient and appropriate experience relating to medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data**.**	3.1.2. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with ***medical,*** technical ***and where possible pharmacological*** knowledge and sufficient and appropriate experience relating to medical devices and the corresponding technologies to perform the conformity assessment tasks, including

the assessment of clinical data

Or. en

Amendment 816
Alda Sousa

Proposal for a regulation
Annex 6 – point 3 – point 3.1 – point 3.1.3

Text proposed by the Commission	*Amendment*
3.1.3. The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation of the personnel involved in conformity assessment activities and inform the personnel concerned about it.	3.1.3. The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation of the personnel***, including any subcontractors and subsidiaries,*** involved in conformity assessment activities and inform the personnel concerned about it.

Or. en

Amendment 817
Holger Krahmer

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.1

Text proposed by the Commission	*Amendment*
3.2.1. The Notified Body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas (e.g. biocompatibility, sterilisation, tissues	3.2.1. The Notified Body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas (e.g. biocompatibility, sterilisation, tissues

and cells of human and animal origin, clinical evaluation) covered by the scope of designation.	and cells of human and animal origin, clinical evaluation***, risk management***) covered by the scope of designation.

Or. de

Justification

The qualifications required of the staff of Notified Bodies should include 'risk management'.

Amendment 818
Mairead McGuinness

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.1

Text proposed by the Commission	*Amendment*
3.2.1. The ***Notified Body*** shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas (e.g. biocompatibility, sterilisation, tissues and cells of human and animal origin, clinical evaluation) covered by the scope of designation.	3.2.1. The ***MDCG*** shall establish and document ***the principals of high level competence and*** qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas (e.g. biocompatibility, sterilisation, tissues and cells of human and animal origin, clinical evaluation) covered by the scope of designation.

Or. en

Justification

To ensure that authorities, rather than notified bodies, set harmonised competence and qualification criteria, authorities acting through the MDCG should set criteria for competence and qualification of the notified bodies conformity assessment staff as well as the necessary procedures that need to be put in place.

Amendment 819
Alda Sousa

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.2 – paragraph 1

Text proposed by the Commission	*Amendment*
Specific qualification criteria shall be defined for the assessment of biocompatibility aspects, clinical evaluation and the different types of sterilisation processes.	Specific qualification criteria shall be defined for the assessment of biocompatibility aspects, ***safety,*** clinical evaluation and the different types of sterilisation processes.

Or. en

Amendment 820
Zofija Mazej Kukovič

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.3 – indent 5

Text proposed by the Commission	*Amendment*
– 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 ***standards-based*** conformity assessments in relation to medical devices as well as the relevant qualification criteria;

Or. sl

Amendment 821
Holger Krahmer

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.3 – indent 7 a (new)

Text proposed by the Commission	*Amendment*
	- adequate seniority / experience in

Conformity Assessments under this Regulation or previously applicable directives during a period of at least 3 years within a Notified Body. The Notified Body staff involved in certification decisions shall not have been involved in the Conformity Assessment on which a certification decision needs to be taken.

Or. en

Justification

The Code of Conduct was developed by most notified bodies in the sense of a voluntary self-regulatory initiative. It is based on the current regulatory framework and subject to constant modification by the notified bodies. Therefore the Regulation should not refer to such a non-legislative document. Major constituents of the content of the Code of Conduct which are so far not covered by the 'Requirements to be met by notified bodies' should be included in the Regulation.

Amendment 822
Marina Yannakoudakis

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.4 – introductory part

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. Notified 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 where possible pharmacology. Permanent "in house" staff shall be used, but notified bodies must have the flexibility to hire external experts on an ad hoc and temporary basis as and when needed.*** This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:

Or. en

Amendment 823
Mairead McGuinness

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.4 – indent 6 a (new)

Text proposed by the Commission	*Amendment*
	- Ensure independence and objectivity and disclose potential conflicts of interest.

Or. en

Amendment 824
Holger Krahmer

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.5 – introductory part

Text proposed by the Commission	*Amendment*
3.2.5. The personnel 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:	3.2.5. ***Product Specialist:*** The personnel responsible for carrying out product related ***reviews*** design dossier review or type examination ***of class III devices especially*** aspects such as clinical evaluation, biological safety, sterilisation, software validation shall have the following proven qualification:

Or. en

Justification

The Code of Conduct was developed by most notified bodies in the sense of a voluntary self-regulatory initiative. It is based on the current regulatory framework and subject to constant modification by the notified bodies. Therefore the Regulation should not refer to such a non-legislative document. Major constituents of the content of the Code of Conduct which are so far not covered by the 'Requirements to be met by notified bodies' should be included in the Regulation.

Amendment 825
Radvilė Morkūnaitė-Mikulėnienė

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.5 – introductory part

Text proposed by the Commission	*Amendment*
3.2.5. The personnel 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:***	3.2.5. The personnel 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 ***required specialist qualifications stipulated by the Member States. The required specialist qualifications include, for example:***

Or. lt

Amendment 826
Holger Krahmer

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.5 a (new)

Text proposed by the Commission	*Amendment*
	3.2.5 a. Product Assessor: The personnel responsible for carrying out product related reviews (technical file reviews) or type-examination of class IIa/IIb devices shall have the following proven qualifications:
	– successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering;
	– four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device (as defined within a generic device group) or technology to be assessed or related to

the scientific aspects to be assessed;

– appropriate knowledge of the general safety and performance requirements laid down in Annex I as well as related delegated and/or implementing acts, harmonized standards, CTS and guidance documents;

– appropriate knowledge and experience of risk management and related medical device standards and guidance documents;

– appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorized, and adequate authority to carry out those assessments.

Or. en

Justification

The Code of Conduct was developed by most notified bodies in the sense of a voluntary self-regulatory initiative. It is based on the current regulatory framework and subject to constant modification by the notified bodies. Therefore the Regulation should not refer to such a non-legislative document. Major constituents of the content of the Code of Conduct which are so far not covered by the 'Requirements to be met by notified bodies' should be included in the Regulation.

Amendment 827
Holger Krahmer

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.5 – indent 2

Text proposed by the Commission	*Amendment*
– four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device or technology to be assessed or related to the	– four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device ***(as defined within a generic device group)*** or technology to be assessed or related to

scientific aspects to be assessed;	the scientific aspects to be assessed;

Or. en

Justification

The Code of Conduct was developed by most notified bodies in the sense of a voluntary self-regulatory initiative. It is based on the current regulatory framework and subject to constant modification by the notified bodies. Therefore the Regulation should not refer to such a non-legislative document. Major constituents of the content of the Code of Conduct which are so far not covered by the 'Requirements to be met by notified bodies' should be included in the Regulation.

Amendment 828
Holger Krahmer

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.5 – indent 3 a (new)

Text proposed by the Commission	*Amendment*
	- In addition, qualification is based on technical or scientific specialisms e.g. sterilization, biocompatibility, animal tissue, human tissue, software, functional safety, clinical evaluation, electrical safety, packaging;

Or. en

Justification

The Code of Conduct was developed by most notified bodies in the sense of a voluntary self-regulatory initiative. It is based on the current regulatory framework and subject to constant modification by the notified bodies. Therefore the Regulation should not refer to such a non-legislative document. Major constituents of the content of the Code of Conduct which are so far not covered by the 'Requirements to be met by notified bodies' should be included in the Regulation.

Amendment 829
Alda Sousa

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.5 – indent 4 a (new)

Text proposed by the Commission	*Amendment*
	- appropriate knowledge and experience of clinical evaluation;

Or. en

Amendment 830
Marina Yannakoudakis

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.5 – indent 5 a (new)

Text proposed by the Commission	*Amendment*
	- Conformity assessment bodies which are notified for class III devices shall submit to the MDCG the list of all internal and external experts which perform the evaluation of the clinical and non-clinical parts of the conformity assessment. The MDCG is entitled to verify the appropriate qualification of the experts chosen and will publish the list.

Or. en

Justification

This will help to ensure full transparency and appropriate qualifications for the notified body experts.

Amendment 831
Holger Krahmer

Proposal for a regulation
Annex 6 – point 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	3.2.6. ***Auditor:*** The personnel responsible for carrying out audits of the manufacturer's quality ***assurance*** system

following proven qualification:

shall have the following proven qualification:

Or. en

Justification

The Code of Conduct was developed by most notified bodies in the sense of a voluntary self-regulatory initiative. It is based on the current regulatory framework and subject to constant modification by the notified bodies. Therefore the Regulation should not refer to such a non-legislative document. Major constituents of the content of the Code of Conduct which are so far not covered by the 'Requirements to be met by notified bodies' should be included in the Regulation.

Amendment 832
Radvilė Morkūnaitė-Mikulėnienė

Proposal for a regulation
Annex 6 – point 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. The personnel responsible for carrying out audits of the manufacturer's quality management system shall have the ***required specialist qualifications stipulated by the Member States. The required specialist qualifications include, for example:***

Or. lt

Amendment 833
Holger Krahmer

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.6 – indent 2 a (new)

Text proposed by the Commission	*Amendment*
	- qualification shall be based on technology as defined by IAF / EAC coding or equivalent;

Or. en

Justification

The Code of Conduct was developed by most notified bodies in the sense of a voluntary self-regulatory initiative. It is based on the current regulatory framework and subject to constant modification by the notified bodies. Therefore the Regulation should not refer to such a non-legislative document. Major constituents of the content of the Code of Conduct which are so far not covered by the 'Requirements to be met by notified bodies' should be included in the Regulation.

Amendment 834
Holger Krahmer

Proposal for a regulation
Annex 6 – point 3 – point 3.4 – point 3.4.3

Text proposed by the Commission	*Amendment*
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 implantable medical devices or technologies, the notified body shall have adequate own competence in each product area***, each treatment or medical speciality*** for which it is designated to lead the conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification.

Or. en

Justification

An adequate qualification of notified bodies should not only be determined on the basis of competence in the product area, but also in the treatment area or the medical speciality.

Amendment 835
Holger Krahmer

Proposal for a regulation
Annex 6 – point 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. Minimum time for Notified Body audit assessments
	– Notified bodies shall identify the audit duration for the stage 1 and stage 2 initial audits, and surveillance audits for each applicant and certified client
	– The effective number of personnel at the manufacturer including all individual manufacturing facilities covered by the certificate is used as a basis for calculation of audit duration
	– It is appropriate to base audit duration on the effective number of personnel of the organization, the complexity of the processes within the organization, the nature and the characteristics of the medical devices included in the scope of the audit and the different technologies that are employed to manufacture and control the medical devices. The audit duration should be adjusted based on any significant factors that uniquely apply to the organization to be audited. The notified body should exercise discretion to ensure that any variation in audit duration does not lead to a compromise on the effectiveness of audits
	– The duration of any scheduled on site audit cannot be less than one auditor/day.
	– Certification of multiple sites under one quality assurance system cannot be based on a sampling system.

Or. en

Justification

The Code of Conduct was developed by most notified bodies in the sense of a voluntary self-regulatory initiative. It is based on the current regulatory framework and subject to constant modification by the notified bodies. Therefore the Regulation should not refer to such a non-legislative document. Major constituents of the content of the Code of Conduct which are so far not covered by the 'Requirements to be met by notified bodies' should be included in the Regulation.

Amendment 836
Mairead McGuinness

Proposal for a regulation
Annex 6 – point 4 – point 4.1

Text proposed by the Commission	*Amendment*
4.1. The notified body's decision-making process shall be clearly documented, including the process for the issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.	4.1. The notified body's decision-making process shall be clearly documented ***and publicly available***, including the process for the issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.

Or. en

Amendment 837
Zofija Mazej Kukovič

Proposal for a regulation
Annex 6 – point 4 – point 4.1

Text proposed by the Commission	*Amendment*
4.1. The notified body's decision-making process shall be clearly documented, including the process for the issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.	4.1. The notified body's decision-making process ***must be transparent and*** shall be clearly documented, including the process for the issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.

Or. sl

Amendment 838
Mairead McGuinness

Proposal for a regulation
Annex 6 – point 4 – point 4.3 – introductory part

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:

Or. en

Amendment 839
Thomas Ulmer

Proposal for a regulation
Annex 7 – part III – point 4 – point 4.2 – paragraph 1 – indent 1

Text proposed by the Commission	*Amendment*
– are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III,	– are ***active and implantable devices*** intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,

Or. de

Amendment 840
Thomas Ulmer

Proposal for a regulation
Annex 7 – part III – point 4 – point 4.2 – paragraph 1 – indent 1

Text proposed by the Commission	*Amendment*
– are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III,	*Does not affect the English version*.

Or. de

Amendment 841
Thomas Ulmer

Proposal for a regulation
Annex 7 – part III – point 4 – point 4.2 – paragraph 1 – indent 3

Text proposed by the Commission	*Amendment*
– are intended specifically for use ***in direct contact with*** the central nervous system, in which case they are in class III,	– are ***active and implantable devices*** intended specifically for use ***for monitoring or diagnosis or to detect or correct faults in*** the central nervous system, ***involving direct contact with these parts of the body,*** in which case they are in class III,

Or. de

Amendment 842
Thomas Ulmer

Proposal for a regulation
Annex 7 – part III – point 4 – point 4.3 – paragraph 1 – indent 1

Text proposed by the Commission	*Amendment*
– are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III,	– are ***active or implantable devices*** intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III,

Or. de

Amendment 843
Thomas Ulmer

Proposal for a regulation
Annex 7 – part III – point 4 – point 4.3 – paragraph 1 – indent 1

Text proposed by the Commission	*Amendment*
– are intended specifically to control,	*Does not affect the English version.*

diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in class III,

Or. de

Amendment 844
Thomas Ulmer

Proposal for a regulation
Annex 7 – part III – point 4 – point 4.3 – paragraph 1 – indent 2

Text proposed by the Commission	*Amendment*
– are intended specifically for use in direct contact with the central nervous system, in which case they are in class III,	– are ***active or implantable devices*** intended specifically for use in direct contact with the central nervous system, in which case they are in class III,

Or. de

Amendment 845
Frédérique Ries

Proposal for a regulation
Annex 7 – part III – point 4 – point 4.4 – paragraph 1 – indent 2

Text proposed by the Commission	*Amendment*
– are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in class III,	– are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in class III, ***with the exception of sutures and staples.***

Or. en

Justification

The classification rule is not fully adapted to some devices like sutures and staples that may be either in class IIb or III depending on the intended use given by the manufacturer. As they are implantable, they would be subject to implant cards requirements, which would represent

a high burden without increasing safety, as many sutures or staples might be used during a surgical intervention.

Amendment 846
Thomas Ulmer

Proposal for a regulation
Annex 7 – part III – point 4 – point 4.4 – paragraph 1 – indent 8

Text proposed by the Commission	*Amendment*
– are spinal disc replacement implants ***and implantable devices that come into contact with the spinal column***, in which case they are in class III.	– are spinal disc replacement implants, in which case they are in class III.

Or. de

Amendment 847
Frédérique Ries

Proposal for a regulation
Annex 7 – part III – point 4 – point 4.4 – paragraph 1 – indent 8

Text proposed by the Commission	*Amendment*
– are spinal disc replacement implants and implantable devices that come into contact with the spinal ***column***, in which case they are in class III.	– are spinal disc replacement implants and implantable devices that come into contact with the spinal ***cord***, in which case they are in class III.

Or. en

Justification

All spinal implants that come in direct contact with the spinal cord are classified as Class III as spinal cord is defined as being part of the central nervous system. There appears to be no clinical or scientific evidence to support of the proposed up-classification for spinal implants that come in contact with the bony spine parts and the ligaments. There is a long clinical use history for these products of being safe and effective without any systematic safety problems being reported.

Amendment 848
Nora Berra

Proposal for a regulation
Annex 7 – part III – point 6 – point 6.7 – paragraph 1

Text proposed by the Commission	*Amendment*
All devices incorporating or consisting of nanomaterial ***are in class III unless the nanomaterial is encapsulated or bound in such a manner that it cannot be*** released ***into the patient's or user's body when the device is used within its intended purpose***.	All devices incorporating or consisting of nanomaterial ***intended to be intentionally*** released ***in the human body are classified as class III***.

Or. en

Justification

The risk of the use of nanomaterials shall be taken into account in the risk assessment process. However, too many products with no serious concern for health may fall under this rule. Then the up-classification in Class III shall be made only when the use of nanomaterials is intentional and part of the intended use of the product.

Amendment 849
Anja Weisgerber, Holger Krahmer

Proposal for a regulation
Annex 7 – part III – point 6 – point 6.7 – paragraph 1

Text proposed by the Commission	*Amendment*
All devices incorporating or consisting of nanomaterial ***are in class III unless the nanomaterial is encapsulated or bound in such a manner that it cannot*** be released into the ***patient's or user's*** body ***when the device is used within its intended purpose***.	All devices incorporating or consisting of nanomaterial ***deliberately intended to*** be released into the body ***are in class III***.

Or. de

Justification

Many medical devices contain nanomaterials, but do not pose any danger to the patient. In classifying medical devices containing nanomaterials, the intended effect of the nanomaterials should therefore be taken into account.

Amendment 850
Thomas Ulmer

Proposal for a regulation
Annex 7 – part III – point 6 – point 6.7 – paragraph 1

Text proposed by the Commission	*Amendment*
All devices ***incorporating or consisting*** of nanomaterial are in class III ***unless the nanomaterial is encapsulated or bound in such a manner that it cannot be released into the patient's or user's body when the device is used within its intended purpose***.	All devices ***whose mode of functioning entails the deliberate release*** of nanomaterial ***into the human body*** are in class III.

Or. de

Amendment 851
Mairead McGuinness

Proposal for a regulation
Annex 7 – part III – point 6 – point 6.7 – paragraph 1

Text proposed by the Commission	*Amendment*
All devices incorporating or consisting of nanomaterial ***are in class III unless the nanomaterial is encapsulated or bound in such a manner that it cannot be*** released ***into the patient's or user's body when the device is used within its intended purpose***.	All devices incorporating or consisting of nanomaterial ***intended to be intentionally*** released ***in the human body are classified as class III***.

Or. en

Amendment 852
Marian Harkin

Proposal for a regulation
Annex 7 – part III – point 6 – point 6.7 – paragraph 1

Text proposed by the Commission	*Amendment*
All devices incorporating or consisting of nanomaterial ***are in class III unless the nanomaterial is encapsulated or bound in such a manner that it cannot be*** released ***into the patient's or user's body when the device is used within its intended purpose***.	All devices incorporating or consisting of nanomaterial ***intended to be intentionally*** released ***in the human body are classified as class III***.

Or. en

Justification

A rule classifying all medical devices containing unbound nanomaterials as highest risk, class III medical devices is scientifically unjustified and would create critical problems for healthcare. Class III classification should apply only to devices for which release of nanomaterials is intended. The definition of nanomaterials as contained in Recommendation 2011/696/EU and reflected in the Regulation (Article 2, paragraph 1, point (15)) would result in most particulate solids being seen as nanomaterials. This would include foodstuffs such as flour, salt, spices, carbon black in car tyre or printer's ink, fillers and pigments in cosmetics, toys, paint, varnish etc. The definition does not distinguish between true nanomaterials (containing a high amount or all particles in the nanorange) and other particulate solids that can be safely used. The highest risk classification should be reserved for medical devices containing unbound nanomaterials. Since the term 'unbound' is not defined in the rule, it could be interpreted as referring to every release of a nanoparticle from a medical device. This is not helpful as from a scientific standpoint the complete absence of release cannot be demonstrated. In conjunction with the definition of nanomaterial, the application Rule 19 as proposed would result in many medical devices that are classified today as lowest risk, class I or medium risk, class IIa or class IIb to be classified as class III medical devices. This would include for instance surgical stockings, bandaging materials, catheters, tubes for administration of nutrition or gases, medical gloves and many other devices.

Amendment 853
Holger Krahmer

Proposal for a regulation
Annex 7 – part III – point 6 – point 6.8

Text proposed by the Commission	*Amendment*
6.8. Rule 20	***deleted***
All devices intended to be used for aphaeresis, such as aphaeresis machines, sets, connectors and solutions, are in class	

III.

Or. en

Justification

Medical devices utilised in the process of aphaeresis are different and wide-ranging and as such it is not appropriate to classify them in a one size fits all manner as Class III. Furthermore, measures on traceability, vigilance, adverse event reporting foreseen for Class III medical devices are already covered by the EU Directives on quality and safety of blood and the EU Pharmaceuticals legislation for these devices alongside national laws and measures.

Amendment 854
Thomas Ulmer

Proposal for a regulation
Annex 7 – part III – point 6 – point 6.8 – paragraph 1

Text proposed by the Commission	*Amendment*
All devices intended to be used for aphaeresis, such as aphaeresis machines, sets, connectors and solutions, are in class III.	***deleted***

Or. de

Justification

Medical devices manufactured for the field of aphaeresis differ in design and use. It therefore does not seem right that all these products should be lumped together in Class III.

Amendment 855
Mairead McGuinness

Proposal for a regulation
Annex 7 – part III – point 6 – point 6.8 – paragraph 1

Text proposed by the Commission	*Amendment*
All devices intended to be used for aphaeresis, such as aphaeresis machines, sets, connectors and solutions, are in class	***deleted***

III.

Or. en

Amendment 856
Marina Yannakoudakis

Proposal for a regulation
Annex 7 – part III – point 6 – point 6.8 – paragraph 1

Text proposed by the Commission	*Amendment*
All devices intended to be used for aphaeresis, such as aphaeresis machines, sets, connectors and solutions, are in class ***III***.	All devices intended to be used for aphaeresis, such as aphaeresis machines, sets, connectors and solutions, are in class ***IIB***.

Or. en

Amendment 857
Paolo Bartolozzi, Salvatore Tatarella, Elisabetta Gardini

Proposal for a regulation
Annex 7 – part III – point 6 – point 6.9

Text proposed by the Commission	*Amendment*
6.9. Rule 21	***deleted***
Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body are in class III.	

Or. en

Justification

Rule 21 classifies devices in the highest risk class only on the basis of the route of administration. This does not reflect the risks connected with most of these products. Plus, classifying such low risk products in class III would be against public safety. It takes away the necessary attention from truly high risk products, and it would lengthen certification so that therapeutic devices will not be available on the market in time.

Amendment 858
Nora Berra

Proposal for a regulation
Annex 7 – part III – point 6 – point 6.9 – paragraph 1

Text proposed by the Commission	*Amendment*
Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by ***or*** dispersed in the human body are in class III.	Devices that are composed of substances or combination of substances ***primarily*** intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by ***and*** dispersed in the human body ***in order to achieve their intended purpose*** are in class III.

Or. en

Amendment 859
Holger Krahmer

Proposal for a regulation
Annex 8 – point 3 – point 3.2 – introductory part

Text proposed by the Commission	*Amendment*
3.2. Application of the quality management system shall ensure that the devices conform to the provisions of this Regulation which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.	3.2. Application of the quality management system shall ensure that the devices conform to the provisions of this Regulation which apply to them at every stage, from design to final inspection ***and delivery***. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.

Or. en

Justification

The quality assurance system should not only cover the processes up to the final inspection. It should also cover all aspects that are relevant for conformity with the legal requirements and the quality of the product (e.g. proper transport and warehousing).

Amendment 860
Mairead McGuinness

Proposal for a regulation
Annex 8 – point 3 – point 3.2 – paragraph 1 – point d – indent 2

Text proposed by the Commission	*Amendment*
– the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;	– the product identification ***and traceability*** procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

Or. en

Amendment 861
Paolo Bartolozzi, Salvatore Tatarella, Elisabetta Gardini

Proposal for a regulation
Annex 8 – point 3 – point 3.3 – point a

Text proposed by the Commission	*Amendment*
(a) The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 3.2. ***Unless duly substantiated,*** it shall presume that quality management systems which satisfy the relevant harmonised standards ***or CTS*** conform to the requirements ***covered by the standards or CTS***.	(a) The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 3.2. It shall presume that quality management systems which satisfy the relevant harmonised standards conform to the requirements ***referred to in Section 3.2***.

Or. en

Justification

Harmonized standards are used as a means to provide a presumption of conformity to the Essential Requirements set out in the Medical Devices Directives. If a harmonized standard is consider insufficient to ensure an appropriate quality management system, then the standard should be amended and not supplemented by a CTS which would be valid only for the EU. Moreover, it is not clear on which basis a notified body could consider a specific harmonized standard insufficient to cope with requirements of section 3.2.

Amendment 862
Christel Schaldemose

Proposal for a regulation
Annex 8 – point 3 – point 3.4

Text proposed by the Commission	*Amendment*
3.4. ***The manufacturer shall inform*** the notified body ***which approved the quality management system of any plan for substantial changes to the quality management system or the product-range covered***. The notified body ***shall assess the changes proposed and verify whether after these changes the quality management system still meets the requirements referred to in Section 3.2. It shall notify*** the manufacturer ***of its decision which shall contain the conclusions of the audit and a reasoned assessment.*** The approval of any substantial change to the quality management system or the product-range covered shall take the form of a supplement to the EU full quality assurance certificate.	3.4. ***In cooperation*** the notified body***, the manufacturer shall define which changes are to be characterised as substantial and should be reported to the notified body***. The notified body ***shall conduct audits to check that the manufacturer's descriptions of substantial changes are adequate and that*** the manufacturer ***complies with these***. The approval of any substantial change to the quality management system or the product-range covered shall take the form of a supplement to the EU full quality assurance certificate.

Or. da

Amendment 863
Mairead McGuinness

Proposal for a regulation
Annex 8 – point 4 – point 4.1

Text proposed by the Commission	*Amendment*
4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality management system.	4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils ***all*** the obligations imposed by the approved quality management system.

Or. en

Amendment 864
Holger Krahmer

Proposal for a regulation
Annex 8 – point 4 – point 4.3

Text proposed by the Commission	*Amendment*
4.3. The notified body shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer applies the approved quality management system and the post-market surveillance plan, and shall supply the manufacturer with an assessment report. This shall include inspections on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. ***At the time of such inspections, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.***	4.3. The notified body shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer applies the approved quality management system and the post-market surveillance plan, and shall supply the manufacturer with an assessment report. This shall include inspections on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors.

Or. de

Justification

The obligation to carry out or ask for tests in order to check that the quality assurance system is working properly under paragraph 4.3 is part of the inspections and not of the regular auditions. 'ISO/IEC Guide 67 - Conformity assessment; Fundamentals of product certification', Table 1, System 5 lists several examples of surveillance activities. The different

options for surveillance assessments should be defined in different paragraphs of Annex VIII Point 4 and should not be mixed up together.

Amendment 865
Holger Krahmer

Proposal for a regulation
Annex 8 – point 4 – point 4.3

Text proposed by the Commission	*Amendment*
4.3. The notified body shall ***periodically, at least once every 12 months***, carry out appropriate audits and assessments to make sure that the manufacturer applies the approved quality ***management*** system and the post-market surveillance plan, and shall supply the manufacturer with an assessment report. This shall include inspections on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such inspections, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.	4.3. The notified body shall ***once a year***, carry out appropriate audits and assessments to make sure that the manufacturer applies the approved quality ***assurance*** system and the post-market surveillance plan, and shall supply the manufacturer with an assessment report. This shall include inspections on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such inspections, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

Or. en

Justification

Specifying that audits have to be conducted at least 'once every 12 months' limits the flexibility of manufacturers and notified bodies to an excessive degree. Conducting audits 'once a year' (in accordance with ISO/IEC 17021) leaves more room to fulfil the legal obligations.

Amendment 866
Holger Krahmer

Proposal for a regulation
Annex 8 – point 4 – point 4.4 – introductory part

Text proposed by the Commission	*Amendment*
4.4. The notified body shall randomly perform ***unannounced factory*** inspections ***to the manufacturer*** and, if appropriate, ***of*** the manufacturer's suppliers and/or subcontractors***, which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment.*** The notified body shall ***establish a plan for the unannounced inspections which must not be disclosed to*** the manufacturer.	4.4. The notified body shall randomly perform ***- at least once in 5 years and for each manufacturer and generic device group - unannounced*** inspections ***at the relevant manufacturing sites*** and, if appropriate, ***at*** the manufacturer's suppliers and/or subcontractors***. The notified body shall establish a plan for the unannounced inspections which must not be disclosed to the manufacturer.***
	At the time of such unannounced inspections, the notified body shall ***carry out or ask for tests in order to check that the quality assurance system is working properly. It shall provide*** the manufacturer ***with an inspection report***.

Or. en

Justification

The number of unannounced inspections has to be clearly defined in order to strengthen the necessary controls and to guarantee unannounced inspections at the same level and frequency in all Member States. Therefore unannounced inspections should be performed at least once in a certification cycle and for each manufacturer and generic device group. Because of the vital importance of this instrument, the scope and procedures of the unannounced inspections should be stated in the Regulation itself instead of in down streamed rules such as an implementing act.

Amendment 867
Nora Berra

Proposal for a regulation
Annex 8 – point 4 – point 4.4 – introductory part

Text proposed by the Commission	*Amendment*
4.4. The notified body shall randomly perform ***unannounced factory*** inspections	4.4. The notified body shall randomly perform ***at least once every five years and***

to the manufacturer and, if appropriate, ***of*** the manufacturer's suppliers and/or subcontractors, which ***may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment. The notified body shall establish a plan for the unannounced inspections which must not be disclosed to the manufacturer***.

for each manufacturer and generic device group unannounced inspections ***at the relevant manufacturing sites*** and, if appropriate, ***at*** the manufacturer's suppliers and/or subcontractors, ***The notified body shall establish a plan for the unannounced inspections*** which ***must not be disclosed to the manufacturer. At the time of such inspections, the notified body shall carry out the tests or ask to carry them in order to check that the quality management system is working properly. It shall provide the manufacturer with an inspection report and with a test report***.

Or. en

Amendment 868
Holger Krahmer

Proposal for a regulation
Annex 8 – point 4 – point 4.4 – introductory part

Text proposed by the Commission	*Amendment*
4.4. The notified body shall randomly perform unannounced ***factory*** inspections ***to the manufacturer*** and, if appropriate, of the manufacturer's suppliers and/or subcontractors***, which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment***. The notified body shall establish a plan for the unannounced inspections which must not be disclosed to the manufacturer.	4.4. The notified body shall randomly perform unannounced inspections ***of the relevant production plants*** and, if appropriate, of the manufacturer's suppliers and/or subcontractors, ***at least every 5 years and for each manufacturer and each specific product group***. The notified body shall establish a plan for the unannounced inspections which must not be disclosed to the manufacturer. ***In these unannounced inspections, the notified body shall check whether the quality management system is working properly or shall arrange for such checks to be performed. The notified body shall provide the manufacturer with an inspection report.***

Or. de

Justification

The number of unannounced inspections has to be clearly defined. Unannounced inspections should be performed at least once in a certification cycle and for each manufacturer and generic device group. The scope and procedures of the unannounced inspections should be stated in the Regulation itself. 'Where necessary' and 'and, if a test has been carried out, with a test report' should be deleted because the tests always have to be carried out. The differentiation between 'test report' and 'inspection report' is not necessary as the 'test report' is part of the 'inspection report'.

Amendment 869
Mairead McGuinness

Proposal for a regulation
Annex 8 – point 4 – point 4.4 – introductory part

Text proposed by the Commission	*Amendment*
4.4. The notified body shall randomly perform unannounced factory inspections to the manufacturer and***, if appropriate, of the manufacturer's*** suppliers and/or subcontractors***, which may be combined with*** the periodic surveillance assessment referred to in Section 4.3. ***or be performed in addition to this surveillance assessment.*** The notified body shall establish a plan for the unannounced inspections which must not be disclosed to the manufacturer.	4.4. The notified body shall randomly perform unannounced factory inspections to the manufacturer and ***its*** suppliers and/or subcontractors ***in addition to*** the periodic surveillance assessment referred to in Section 4.3. The notified body shall establish a plan for the unannounced inspections which must not be disclosed to the manufacturer. ***The notified body shall carry out at least one unannounced inspection every three years.***

Or. en

Amendment 870
Peter Liese

Proposal for a regulation
Annex 8 – point 4 – point 4.4 – introductory part

Text proposed by the Commission	*Amendment*
4.4. The notified body shall randomly perform unannounced factory inspections	4.4. The notified body shall randomly perform unannounced factory inspections

to the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment. The notified body shall establish a plan for the unannounced inspections which must not be disclosed to the manufacturer.	to the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment. The notified body shall establish a plan for the unannounced inspections which must not be disclosed to the manufacturer. ***The notified body shall carry out such inspections at least once every three years.***

Or. en

Justification

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

Amendment 871
Holger Krahmer

Proposal for a regulation
Annex 8 – point 4 – point 4.4 – paragraph 2

Text proposed by the Commission	*Amendment*
Instead of, or in addition to**,** the sampling from the production, the notified body shall take samples of devices from the market ***to verify that*** the manufactured device is in conformity with the technical documentation and/or design dossier. Prior to the sampling, the notified body shall specify the relevant sampling criteria and testing procedure.	In addition to the sampling from the production, the notified body shall ***if possible itself*** take samples of devices from the market ***or otherwise arrange for this to be done by external market surveillance authorities***. ***Checks on whether*** the manufactured device is in conformity with the technical documentation and/or design dossier ***must be performed at least once within five years for each manufacturer and each specific product group***. Prior to the sampling, the notified body shall specify the relevant sampling criteria and testing procedure. ***The taking of the sample and its examination shall be performed at the manufacturer's expense.***

Or. de

Justification

Taking samples from the market is often not possible as the notified bodies do not have sufficient intervention powers. In these cases the sampling should be carried out through the market surveillance authorities. To ensure that sufficient samples are taken all notified bodies are be obliged to check at least once in a given certification cycle.

Amendment 872
Linda McAvan

Proposal for a regulation
Annex 8 – point 4 – point 4.4 – paragraph 3

Text proposed by the Commission	*Amendment*
The notified body shall provide the manufacturer with an inspection report which shall include, if applicable, the result of the sample check.	The notified body shall provide the manufacturer with an inspection report which shall include, if applicable, the result of the sample check. ***This report shall be made public.***

Or. en

Justification

One of the key lessons learnt after the PiP scandal is the need for unannounced inspections. In the interests of transparency, the inspection report should be made public.

Amendment 873
Holger Krahmer

Proposal for a regulation
Annex 8 – point 4 – point 4.5 – paragraph 1

Text proposed by the Commission	*Amendment*
In the case of devices classified as class III, the surveillance assessment shall also include a check of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, the coherence between the quantities of produced or purchased parts and/or materials and the quantities of	***deleted***

finished products.

Or. en

Justification

A check of the coherence between the quantity of produced or purchased raw material or crucial components approved for the type and the quantity of finished products is often not possible. The tasks and competences of the notified bodies are in the field of technical examinations and not business analyses. Checking the coherence is generally the duty of the manufacturer for financial accounting reasons.

Amendment 874
Holger Krahmer

Proposal for a regulation
Annex 8 – point 4 – point 4.6

Text proposed by the Commission	*Amendment*
4.6. The notified body shall ensure that the composition of the assessment team assures experience with the technology concerned, continuous objectivity and neutrality***; this shall include a rotation of the members of the assessment team at appropriate intervals***. ***As a general rule,*** a lead auditor shall not lead and attend an audit for more than ***three*** consecutive years in respect to the same manufacturer.	4.6. The notified body shall ensure that the composition of the assessment team assures experience with the technology concerned, continuous objectivity and neutrality. A lead auditor shall not lead and attend an audit for more than ***five*** consecutive years in respect to the same manufacturer.

Or. en

Justification

The necessary expertise and experience with the medical device to be assessed has to be assured consistently over the whole certification cycle. The lead auditor shall be authorized to lead and attend an audit for up to five consecutive years in line with the regular certification cycle of five years for medical devices. The other members of an assessment team should not rotate because of their subordinated responsibility to the lead auditor.

Amendment 875
Mairead McGuinness

Proposal for a regulation
Annex 8 – point 5 – point 5.3 a (new)

Text proposed by the Commission	*Amendment*
	5.3 a. 5.3bis For devices in class III the clinical part of the dossier shall be evaluated by an appropriate clinical expert among those contained in the list developed by the MDCG according to Art. 80 g)

Or. en

Amendment 876
Holger Krahmer

Proposal for a regulation
Annex 8 – point 8 – introductory part

Text proposed by the Commission	*Amendment*
8. The manufacturer or his authorised representative shall, for a period ***ending*** at least ***five years, and in the case of implantable devices at least 15*** years***, after the last device has been placed on the market***, keep at the disposal of the competent authorities:	8. The manufacturer or his authorised representative shall, for a period at least ***equivalent to the lifetime of the medical device as defined by the manufacturer, but not less than 10*** years ***from the date of product release by the manufacturer***, keep at the disposal of the competent authorities:

Or. en

Justification

The retention periods for the documents should be adapted in order to fulfil and harmonize with international standards (compare e.g. ISO 13485).

Amendment 877
Holger Krahmer

Proposal for a regulation
Annex 9 – point 7 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The manufacturer or his authorised representative shall, for a period ***ending*** at least ***five years, and in the case of implantable devices at least 15*** years***, after the last device has been placed on the market***, keep at the disposal of the competent authorities:	The manufacturer or his authorised representative shall, for a period at least ***equivalent to the lifetime of the medical device as defined by the manufacturer, but not less than 10*** years ***from the date of product release by the manufacturer***, keep at the disposal of the competent authorities:

Or. en

Justification

The retention periods for the documents should be adapted in order to fulfil and harmonize with international standards (compare e.g. ISO 13485).

Amendment 878
Holger Krahmer

Proposal for a regulation
Annex 10 – point 4 – paragraph 2

Text proposed by the Commission	*Amendment*
In the case of devices classified as class III, the surveillance shall also include a check of the coherence between the quantity of produced or purchased raw material or crucial components approved for the type and the quantity of finished products.	***deleted***

Or. en

Justification

A check of the coherence between the quantity of produced or purchased raw material or crucial components approved for the type and the quantity of finished products is often not possible. The tasks and competences of the notified bodies are in the field of technical examinations and not business analyses. Checking the coherence is generally the duty of the manufacturer for financial accounting reasons.

Amendment 879
Holger Krahmer

Proposal for a regulation
Annex 10 – point 6 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The manufacturer or his authorised representative shall, for a period ***ending*** at least ***five years, and in the case of implantable devices at least 15*** years***, after the last device has been placed on the market***, keep at the disposal of the competent authorities:	The manufacturer or his authorised representative shall, for a period at least ***equivalent to the lifetime of the medical device as defined by the manufacturer, but not less than 10*** years ***from the date of product release by the manufacturer***, keep at the disposal of the competent authorities:

Or. en

Justification

The retention periods for the documents should be adapted in order to fulfil and harmonize with international standards (compare e.g. ISO 13485).

Amendment 880
Holger Krahmer

Proposal for a regulation
Annex 10 – point 7 – point 7.5 – introductory part

Text proposed by the Commission	*Amendment*
7.5. By way of derogation from Section 6, the manufacturer or his authorised representative shall, for a period ***ending*** at least ***five years after the last*** device ***has been placed on the market***, keep at the disposal of the competent authorities:	7.5. By way of derogation from Section 6, the manufacturer or his authorised representative shall, for a period at least ***equivalent to the lifetime of the medical*** device ***as defined by the manufacturer, but not less than 10 years from the date of product release by the manufacturer***, keep at the disposal of the competent authorities:

Or. en

Justification

The retention periods for the documents should be adapted in order to fulfil and harmonize with international standards (compare e.g. ISO 13485).

Amendment 881
Holger Krahmer

Proposal for a regulation
Annex 10 – heading 3 – Part B

Text proposed by the Commission	*Amendment*
Part B: Product verification	Part B: ***EU*** Product verification

Or. en

Amendment 882
Holger Krahmer

Proposal for a regulation
Annex 10 – Part B – point 4 – introductory part

Text proposed by the Commission	*Amendment*
4. The notified body shall carry out the appropriate examinations and tests in order to ***verify*** the conformity of the device with the requirements of the Regulation by examining and testing every product as specified in Section 5.	4. The notified body shall carry out the appropriate examinations and tests in order to ***assess*** the conformity of the device with the requirements of the Regulation by examining and testing every product as specified in Section 5 ***or by examination and testing of the products on a statistical basis as specified in section 6***.

Or. en

Justification

In line with Decision 768/2008/EC, Module F, number 5, the option to conduct statistical verifications should be added, because in particular, products cannot be assessed by means of product verification without the statistical verification processes.

Amendment 883
Holger Krahmer

Proposal for a regulation
Annex 10 – Part B – point 5 a (new)

Text proposed by the Commission *Amendment*

5 a. Statistical verification of conformity

Or. en

Justification

In line with Decision 768/2008/EC, Module F, number 5, the option to conduct statistical verifications should be added, because in particular, products cannot be assessed by means of product verification without the statistical verification processes.

Amendment 884
Holger Krahmer

Proposal for a regulation
Annex 10 – Part B – point 5 a – part 5.1 (new)

Text proposed by the Commission *Amendment*

5.1. The manufacturer shall present the manufactured products in the form of homogeneous batches. The proof of homogeneity for the presented products shall be part of the batch documentation.

Or. en

Justification

In line with Decision 768/2008/EC, Module F, number 5, the option to conduct statistical verifications should be added, because in particular, products cannot be assessed by means of product verification without the statistical verification processes.

Amendment 885
Holger Krahmer

Proposal for a regulation
Annex 10 – Part B – point 5 a - part 5.2 (new)

Text proposed by the Commission *Amendment*

5.2. A random sample is taken from each batch. The products which make up the

sample shall be examined individually and the appropriate physical or laboratory tests defined in the relevant standard(s) referred to in Article 6 or equivalent tests shall be carried out in order to verify the conformity of the devices with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them.

Or. en

Justification

In line with Decision 768/2008/EC, Module F, number 5, the option to conduct statistical verifications should be added, because in particular, products cannot be assessed by means of product verification without the statistical verification processes.

Amendment 886
Holger Krahmer

Proposal for a regulation
Annex 10 – Part B – point 5 a – part 5.3 (new)

Text proposed by the Commission	*Amendment*
	5.3. Statistical control of products shall be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the harmonized standards or equivalent tests referred to in Article 6, taking account of the specific nature of the product categories in question.

Or. en

Justification

In line with Decision 768/2008/EC, Module F, number 5, the option to conduct statistical verifications should be added, because in particular, products cannot be assessed by means of product verification without the statistical verification processes.

Amendment 887
Holger Krahmer

Proposal for a regulation
Annex 10 – Part B – point 5 a – part 5.4 (new)

Text proposed by the Commission	*Amendment*
	5.4. The notified body shall affix, or have affixed, its identification number to each approved device and shall draw up an EU product verification certificate relating to the tests carried out.
	All products in the batch may be put on the market except any in the sample which failed to conform.
	If a batch is rejected, the competent notified body must take appropriate measures to prevent the batch from being placed on the market.
	In the event of frequent rejection of batches, the notified body may suspend the statistical verification.

Or. en

Justification

In line with Decision 768/2008/EC, Module F, number 5, the option to conduct statistical verifications should be added, because in particular, products cannot be assessed by means of product verification without the statistical verification processes.

Amendment 888
Holger Krahmer

Proposal for a regulation
Annex 10 – Part B – point 7 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The manufacturer or his authorised representative shall, for a period ***ending*** at least ***five years, and in the case of***	The manufacturer or his authorised representative shall, for a period at least ***equivalent to the lifetime of the medical***

implantable devices at least 15 years***, after the last device has been placed on the market***, keep at the disposal of the competent authorities:

device as defined by the manufacturer, but not less than 10 years ***from the date of product release by the manufacturer***, keep at the disposal of the competent authorities:

Or. en

Justification

The retention periods for the documents should be adapted in order to fulfil and harmonize with international standards (compare e.g. ISO 13485).

Amendment 889
Holger Krahmer

Proposal for a regulation
Annex 10 – Part B – point 8 – point 8.4 – introductory part

Text proposed by the Commission	*Amendment*
8.4. By way of derogation from Section 7, the manufacturer or his authorised representative shall, for a period ***ending*** at least ***five years after the last*** device ***has been placed on the market***, keep at the disposal of the competent authorities:	8.4. By way of derogation from Section 7, the manufacturer or his authorised representative shall, for a period at least ***equivalent to the lifetime of the medical*** device ***as defined by the manufacturer, but not less than 10 years from the date of product release by the manufacturer***, keep at the disposal of the competent authorities:

Or. en

Justification

The retention periods for the documents should be adapted in order to fulfil and harmonize with international standards (compare e.g. ISO 13485).

Amendment 890
Thomas Ulmer

Proposal for a regulation
Annex 13 – point 2

Text proposed by the Commission	*Amendment*
2. Confirmation of conformity with the	2. Confirmation of conformity with the

requirements concerning the characteristics and performances referred to in Section 1 of Annex I, under the normal conditions of use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, shall be based on clinical data.	requirements concerning the characteristics and performances referred to in Section 1 of Annex I, under the normal conditions of use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, shall be based on clinical data. ***Data from independent scientific institutions or medical societies based on their own collections of clinical data shall also be taken into account.***

Or. de

Amendment 891
Marina Yannakoudakis

Proposal for a regulation
Annex 13 – point 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. the involvement of independent scientific bodies such as academic institutions or medical societies in the collection and/or analysis of the clinical data

Or. en

Amendment 892
Holger Krahmer

Proposal for a regulation
Annex 13 – point 5

Text proposed by the Commission	*Amendment*
5. In the case of implantable devices ***and devices falling within class III***, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone. Demonstration of equivalence	5. In the case of implantable devices, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone. Demonstration of equivalence in accordance with Section 4

in accordance with Section 4 shall generally not be considered as sufficient justification within the meaning of the first sentence of this paragraph.	shall generally not be considered as sufficient justification within the meaning of the first sentence of this paragraph.

Or. en

Justification

In case of devices manufactured utilising tissues or cells of human or animal origin, it is often possible to draw on the clinical experience and literature reports of the safety and performance of equivalent devices or to use compliance with recognised standards to satisfy the clinical evidence requirements

Amendment 893
Nora Berra

Proposal for a regulation
Annex 13 – point 5

Text proposed by the Commission	*Amendment*
5. In the case of implantable devices and devices falling within class III, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone. Demonstration of equivalence in accordance with Section 4 shall ***generally*** not be considered as sufficient justification within the meaning of the first sentence of this paragraph.	5. In the case of implantable devices and devices falling within class III, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone. ***For novel products,*** demonstration of equivalence in accordance with Section 4 shall not be considered as sufficient justification within the meaning of the first sentence of this paragraph. ***However, for iteration of devices already on the market and for which clinical data are available and for which the data from the post-market surveillance are not indicating any safety concerns, demonstration of equivalence may be considered as a sufficient justification. For devices submitted to the scientific assessment foreseen in this Regulation, demonstration of equivalence shall be assessed by the MDCG.***

Or. en

Amendment 894
Thomas Ulmer

Proposal for a regulation
Annex 13 – point 5

Text proposed by the Commission	*Amendment*
5. In the case of implantable devices and devices falling within class III, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone. Demonstration of equivalence in accordance with Section 4 shall generally not be considered as sufficient justification within the meaning of the first sentence of this paragraph.	5. In the case of implantable devices and devices falling within class III, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone. ***In the case of novel devices,*** demonstration of equivalence in accordance with Section 4 shall generally not be considered as sufficient justification within the meaning of the first sentence of this paragraph.

Or. de

Amendment 895
Marina Yannakoudakis, Anna Rosbach

Proposal for a regulation
Annex 13 – point 5 a (new)

Text proposed by the Commission	*Amendment*
	5 a. All clinical data collected by the manufacturer as part of a PMCF should be made accessible to health professionals.

Or. en

Amendment 896
Holger Krahmer

Proposal for a regulation
Annex 13 – point 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 implantable 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

The safety of other class III medical devices such as devices incorporating a gelatin capsule, is ensured and assessed by a clinical investigations performed prior to their CE-marking.

Amendment 897
Anna Rosbach

Proposal for a regulation
Annex 14 – part I – point 1 – paragraph 1

Text proposed by the Commission	*Amendment*
Every step in the clinical investigation, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving	Every step in the clinical investigation, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving

Human Subjects, adopted by the 18th World Medical Association General Assembly in Helsinki, Finland, in 1964, and ***last amended by the 59th World Medical Association General Assembly in Seoul, Korea, in 2008***.	Human Subjects, adopted by the 18th World Medical Association General Assembly in Helsinki, Finland, in 1964, and ***any subsequent amendments***.

Or. en

Justification

It is important to ensure that clinical investigations will always have to live up to the latest amended version of the Declaration of Helsinki

Amendment 898
Thomas Ulmer, Peter Liese

Proposal for a regulation
Annex 14 – part I – point 1 – paragraph 1

Text proposed by the Commission	*Amendment*
Every step in the clinical investigation, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th World Medical Association General Assembly in Helsinki, Finland, in 1964, and last amended by the 59th World Medical Association General Assembly in Seoul, Korea, in 2008.	Every step in the clinical investigation, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964 and last amended by the 59th World Medical Association General Assembly in Seoul, Korea, in 2008. ***Regulation of the detailed requirements relating to the participation of subjects in clinical trials shall be the responsibility of the Member States.***

Or. de

Justification

This amendment is intended to make it clear that Member States must define the conditions

for the participation of subjects in clinical trials. In this regard they are bound by the minimum standards taken as a basis by the World Medical Association in its Declaration of Helsinki (2008 version).

Amendment 899
Peter Liese

Proposal for a regulation
Annex 14 – part I – point 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. Clinical investigations on incapacitated subjects
	In the case of incapacitated subjects who have not given, or who have not refused to give, informed consent before the onset of their incapacity, clinical investigations may be conducted only where, in addition to the general conditions, all of the following conditions are met:
	– the informed consent of the legal representative has been obtained which represents the subject's presumed will and may be revoked at any time, without detriment to the subject;
	– the incapacitated subject has received adequate information in relation to that person's capacity for understanding regarding the investigation and its risks and benefits;
	– the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing this information to refuse participation in, or to be withdrawn from, the clinical investigation at any time is duly taken into consideration by the investigator;
	– no incentives or financial inducements are given other than compensation for participation in the clinical investigation;
	– such research is essential to validate data obtained in a clinical investigation on persons able to give informed consent

or by other research methods;

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

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

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

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

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

Or. en

Justification

Compared to the proposal on clinical trials for medicinal products the provisions on clinical investigations are very weak and imprecise. Clinical investigations may include a very significant risk for the patient. Therefore the provisions need to be specified.

Amendment 900
Peter Liese

Proposal for a regulation
Annex 14 – part I – point 1 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1b. Clinical investigation on minors

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

– the informed consent of the legal representative has been obtained, whereby consent shall represent the minor's presumed will;

– the minor has received all relevant information in a way adapted to the minor's age and maturity, from a medical doctor (either the investigator or member of the study team) trained or experienced in working with children, regarding the investigation, the risks and the benefits;

– the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to above to refuse participation in, or to be withdrawn from, the clinical investigation at any time, is duly taken into consideration by the investigator;

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

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

– such research either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;

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

– some direct benefit for the group of patients is obtained from the clinical investigation

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

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

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

Or. en

Justification

Compared to the proposal on clinical trials for medicinal products the provisions on clinical investigations are very weak and imprecise. Clinical investigations may include a very significant risk for the patient. The proposal seeks to maintain at least the standard of protection which is guaranteed for clinical trials with medicinal products since 2001 through Directive 2001/20 EC.

Amendment 901
Thomas Ulmer, Peter Liese

Proposal for a regulation
Annex 14 – part II – point 3 – point 3.1 – point 3.1.3

Text proposed by the Commission	*Amendment*
3.1.3. Information on the principal investigator, coordinating investigator, including their qualifications, and on the investigation site(s).	3.1.3. Information on the principal investigator, coordinating investigator, including their qualifications, and on the investigation site(s)***, as well as information about the contract between the sponsor and the investigating establishment, together with details of the funding***.

Or. de

Justification

It is standard procedure for ethics committees to have access to the contracts between the sponsor and the investigating establishments, and for them to be required to take these into account in evaluating the protocol for the study

Amendment 902
Thomas Ulmer, Peter Liese

Proposal for a regulation
Annex 14 – part II – point 3 – point 3.1 – point 3.1.4

Text proposed by the Commission	*Amendment*
3.1.4. Overall synopsis of the clinical investigation.	3.1.4. Overall synopsis of the clinical investigation ***in the national language of the country concerned***.

Or. de

Justification

To permit an objective evaluation of applicability, a summary of the plan for the investigation in the appropriate national language is vital.

Amendment 903
Thomas Ulmer, Peter Liese

Proposal for a regulation
Annex 14 – part II – point 3 – point 3.15 a (new)

Text proposed by the Commission	*Amendment*
	3.15 a. A plan for the further treatment of subjects after the clinical investigation.

Or. de

Justification

The Declaration of Helsinki lays down that the protocol must define an agreement on access by subjects, after the study, to interventions which have been identified as useful during the study or access to other care or support.

Amendment 904
Christofer Fjellner

Proposal for a regulation
Annex 15

Text proposed by the Commission	*Amendment*
List of products covered by the last subparagraph of the definition of 'medical device' referred to in number (1) of Article 2(1)	***deleted***
1. Contact lenses;	
2. Implants for modification or fixation of body parts;	
3. Facial or other dermal or mucous membrane fillers;	
4. Equipment for liposuction;	
5. Invasive laser equipment intended to be used on the human body;	
6. Intense pulsed light equipment.	

Or. en

Justification

Implants or other invasive products in Annex XV (aesthetic products) without medical purpose should not be considered medical devices and should not be regulated by the proposed regulation on medical devices. Including products that do not have a medical purpose could undermine the term medical devices, and make the regulation on medical devices indistinct. This regulation is intended to ensure that medical devices placed on the market are secure and works as intended. In order to be placed on the market the medical benefits of the product has to outweigh the risk. This is not applicable for implants and other invasive products in Annex XV. Aesthetic products should be regulated in a separate regulation that could cover a wider range of aesthetic products. This regulation could refer to the regulation on medical devices where applicable.

Amendment 905
Linda McAvan

Proposal for a regulation
Annex 15 – point 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. Chemical peels

Or. en

Justification

There is currently confusion about which regulation - if any - applies to chemical peels for the skin, and some may fall into a loophole.

Amendment 906
Nora Berra

Proposal for a regulation
Annex 15 – point 4

Text proposed by the Commission	*Amendment*
4. Equipment for liposuction;	4. Equipment for liposuction ***and lipolysis***;

Or. fr

Amendment 907
Linda McAvan

Proposal for a regulation
Annex 15 – point 5

Text proposed by the Commission	*Amendment*
5. ***Invasive*** laser equipment intended to be used on the human body;	5. Laser equipment intended to be used on the human body;

Or. en

Justification

All laser equipment used for cosmetic procedures should be regulated as a medical device. Many dermatological lasers are marketed as "non-invasive" or "minimally invasive", so there could be confusion about what is covered. Even the newer, low risk vascular lasers can result in scarring.