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Committee on the Environment, Public Health and Food Safety

2012/0267(COD)

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AMENDMENTS
75 – 237

Draft report
Peter Liese
(PE506.196v01-00)

on the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices

Proposal for a regulation
(COM(2012)0541 – C7-0317/2012 – 2012/0267(COD))

AM_Com_LegReport

Amendment 75
Françoise Grossetête

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) There are specific features of in vitro diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the in vitro diagnostic medical device sector which require the adoption of a specific legislation, distinct from the legislation on other medical devices, whereas the horizontal aspects common to both sectors should be aligned.	(5) There are specific features of in vitro diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the in vitro diagnostic medical device sector which require the adoption of a specific legislation, distinct from the legislation on other medical devices, whereas the horizontal aspects common to both sectors should be aligned ***without compromising the need for innovation in the Union***.

Or. en

Amendment 76
Milan Cabrnoch

Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) In situations in which a product is not conceived by its manufacturer to be used for medical purposes, its certification as an in vitro diagnostic medical device cannot be required; likewise a product cannot be an accessory to a specific in vitro diagnostic medical device if it is not specifically conceived by its manufacturer to enable or assist the intended purpose of the in vitro diagnostic medical device.

Or. en

Amendment 77
Margrete Auken

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) It should be the responsibility of the ***Member States*** to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. If necessary, the Commission may decide, on a case-by-case basis, whether or not a product falls within the definition of an in vitro diagnostic medical device or of an accessory to an in vitro diagnostic medical device.	(8) It should be the responsibility of the ***Commission*** to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. If necessary, the Commission may decide, on a case-by-case basis, whether or not a product falls within the definition of an in vitro diagnostic medical device or of an accessory to an in vitro diagnostic medical device.

Or. en

Justification

Necessary to guarantee uniform implementation of the regulation in different Member States

Amendment 78
Dagmar Roth-Behrendt

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) It should be the responsibility of the ***Member States*** to decide on a case-by-case basis whether or not a product ***falls*** within the scope of this Regulation***. If necessary, the Commission may decide, on a case-by-case basis, whether or not a product falls*** within the definition of an in vitro diagnostic medical device or of an accessory to an in vitro diagnostic medical device.	(8) ***In order to ensure consistent classification across all Member States,*** it should be the responsibility of the ***Commission*** to decide on a case-by-case basis whether or not a product ***or groups of products fall*** within the scope of this Regulation ***and*** within the definition of an in vitro diagnostic medical device or of an accessory to an in vitro diagnostic medical device.

Or. en

Amendment 79
Dagmar Roth-Behrendt

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) A multidisciplinary advisory committee of experts and representatives of stakeholder and civil society organisations should be set up in accordance with the conditions and modalities defined in Article 78a of Regulation (EU) [Ref. of future Regulation on medical devices] in order to provide scientific advice to the Commission, the Medical Device Coordination Group (MDCG) and Member States on issues of in vitro diagnostic medical technology, classification and other aspects of implementation of this Regulation as necessary.

Or. en

Amendment 80
Alda Sousa

Proposal for a regulation
Recital 9

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

Or. en

Justification

The words health institution have been excised – since health institutions will be exempt from the Regulation, then the target of this recital is actually the commercial laboratories which will not be exempt.

Amendment 81
Alda Sousa

Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) Having regard to the principle of subsidiarity, devices which are produced within health institution laboratories for use in that environment and are not subject to commercial transactions are not covered by this Regulation.

Or. en

Amendment 82
Esther de Lange

Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) It is of the highest importance that patients receive clear information in cases of serious incidents with medical devices. Therefore, Member States should not give any conflicting advice to their citizens on what action to take in cases of serious incidents, in order to prevent unequal information for patients in different Member States, which can lead to confusion of patients.

Or. en

Amendment 83
Rebecca Taylor, Linda McAvan, Marina Yannakoudakis

Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) In the case of urgent or unmet medical needs for patients, such as emerging pathogens and rare diseases, single health institutions should have the possibility to manufacture, modify and use devices in-house and therefore address, within a non-commercial and flexible framework, specific needs which can not be met by an available CE-marked device.

Or. en

Justification

The proposal removes the possibility of health institutions producing or modifying class D devices. There are patient needs for which there are no commercially available IVD Devices, such as the diagnosis of very rare diseases, or the identification of emerging pathogens. Health institutions play a vital role in protecting public health, by manufacturing these devices in-house. These amendments seek to maintain this public health function whilst ensuring patient safety is paramount.

Amendment 84
Alda Sousa

Proposal for a regulation
Recital 9 b (new)

Text proposed by the Commission	*Amendment*
	(9b) However, devices which are manufactured within non-health-institution laboratories and put into service without being placed onto the

market are subject to this Regulation.

Or. en

Amendment 85
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*
(27) The traceability of in vitro diagnostic medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of in vitro diagnostic medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve purchase-policy and stock-management by hospitals.	(27) The traceability of in vitro diagnostic medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of in vitro diagnostic medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve purchase-policy and stock-management by hospitals***, pharmacies and in wholesale***. ***The UDI system should be compatible with other systems which are already on the market.***

Or. de

Amendment 86
Peter Liese, Alda Sousa, Margrete Auken, Paolo Bartolozzi, Anne Delvaux, Anna Rosbach, Thomas Ulmer, Zofija Mazej Kukovič, Renate Sommer, Miroslav Mikolášik

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*
(27) The traceability of in vitro diagnostic medical devices by means of a Unique	(27) The traceability of in vitro diagnostic medical devices by means of a Unique

Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of in vitro diagnostic medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve purchase-policy and stock-management by hospitals.	Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of in vitro diagnostic medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve purchase-policy and stock-management by hospitals***, wholesalers and pharmacists and be compatible with other authentication systems already in place in those settings***.

Or. en

Justification

It is likely an electronic medicine authentication system will be put in place pursuant to Falsified Medicines Directive. It is important that the systems for in vitro diagnostic medical devices and medicines are compatible. Otherwise this will bring a significant and possible unmanageable burden for the agents of the supply chain working with both kinds of products

Amendment 87
Dagmar Roth-Behrendt

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) Transparency and ***better*** information are essential to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.	(28) Transparency and ***adequate access to*** information***, appropriately presented for the intended user,*** are essential to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

Or. en

Amendment 88
Dagmar Roth-Behrendt

Proposal for a regulation
Recital 29

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

Or. en

Amendment 89
Rebecca Taylor

Proposal for a regulation
Recital 30

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

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 90
Dagmar Roth-Behrendt

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(30) Eudamed's electronic systems regarding devices on the market, the relevant economic operators and certificates should enable the public to be adequately informed about devices on the Union market. The electronic system on clinical performance studies should serve as tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and, in this case, to report serious adverse events. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of their assessment by national competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.	(30) Eudamed's electronic systems regarding devices on the market, the relevant economic operators and certificates should enable the public ***and healthcare professionals*** to be adequately informed about devices on the Union market***. Adequate levels of access for the public and healthcare professionals to those parts of Eudamed's electronic systems which provide key information on in vitro diagnostic medical devices that may pose a risk to public health and safety is essential. Where such access is limited, it should be possible, upon a reasoned request, to disclose existing information for in vitro diagnostic medical devices, unless the limitation of access is justified on grounds of confidentiality***. The electronic system on clinical performance studies should serve as tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and, in this case, to report serious adverse events. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of their assessment by national competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.

Or. en

Amendment 91
Alda Sousa

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) For ***high-risk*** in vitro diagnostic medical devices, manufacturers should summarise the main safety and performance aspects of the device and the outcome of the clinical evaluation in a document that should be publicly available.	(32) For ***Class C and Class D*** in vitro diagnostic medical devices, manufacturers should summarise the main safety and performance aspects of the device and the outcome of the clinical evaluation in a document that should be publicly available.

Or. en

Justification

Makes the recital consistent with Article 24.

Amendment 92
Dagmar Roth-Behrendt

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) For high-risk in vitro diagnostic medical devices, manufacturers should ***summarise the main safety and performance aspects of the device and the outcome of the*** clinical ***evaluation in a document that*** should be publicly available.	(32) For high-risk in vitro diagnostic medical devices, manufacturers should ***provide the national authority or the Agency, as relevant, involved in the marketing authorisation procedure, with a full report on the safety and*** clinical ***performance aspects of that device. A summary of that report*** should be publicly available ***via Eudamed***.

Or. en

Amendment 93
Dagmar Roth-Behrendt

Proposal for a regulation
Recital 35

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

Or. en

Amendment 94
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) For high risk in vitro diagnostic medical devices, authorities should be informed at an early stage about devices which are subject to conformity assessment and be given the right, on scientifically	(35) For high risk in vitro diagnostic medical devices, ***relevant*** authorities ***at national and Union level*** should be informed at an early stage about devices which are subject to conformity assessment

valid grounds, to scrutinise the preliminary assessment conducted by notified bodies, in particular regarding devices for which no common technical specifications exist, devices which are novel or for which a novel technology is being used, devices belonging to a category of devices with increased serious incident rates, or devices for which significant discrepancies in the conformity assessments by different notified bodies have been identified in respect of substantially similar devices. The process foreseen in this Regulation does not prevent a manufacturer from informing voluntarily a competent authority of his intention to file an application for conformity assessment for a high risk in vitro diagnostic medical device before submitting the application to the notified body.

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

Or. en

Justification

Necessary to clarify which authorities are referred to in the recital.

Amendment 95
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) For high risk in vitro diagnostic medical devices, authorities should be informed at an early stage about devices which are subject to conformity assessment and be given the right, on scientifically valid grounds, to scrutinise the preliminary assessment conducted by notified bodies, in particular regarding devices for which	(35) For high risk in vitro diagnostic medical devices, authorities should be informed at an early stage about devices which are subject to conformity assessment and be given the right, on scientifically valid grounds, to scrutinise the preliminary assessment conducted by notified bodies, in particular regarding devices for which

no common technical specifications exist, devices which are novel or for which a novel technology is being used, devices belonging to a category of devices with increased serious incident rates, or devices for which significant discrepancies in the conformity assessments by different notified bodies have been identified in respect of substantially similar devices. The process foreseen in this Regulation does not prevent a manufacturer from informing voluntarily a competent authority of his intention to file an application for conformity assessment for a high risk in vitro diagnostic medical device before submitting the application to the notified body.	no common technical specifications exist, devices which are novel or for which a novel technology is being used, devices belonging to a category of devices with increased serious incident rates, or devices for which significant discrepancies in the conformity assessments by different notified bodies have been identified in respect of substantially similar devices. The process foreseen in this Regulation does not prevent a manufacturer from informing voluntarily a competent authority of his intention to file an application for conformity assessment for a high risk in vitro diagnostic medical device before submitting the application to the notified body. ***For high-risk in vitro diagnostic medical devices of class D a market authorization procedure is created.***

Or. en

Amendment 96
Dagmar Roth-Behrendt

Proposal for a regulation
Recital 35 a (new)

Text proposed by the Commission	*Amendment*
	(35a) The conformity assessment procedure should not be applicable for class D in vitro diagnostic medical devices. A swift centralized marketing authorization procedure should be introduced for innovative class D devices. A swift decentralized marketing authorization procedure should be introduced for all other class D devices, with the possibility for manufacturers of those types of devices to rather apply to the centralized marketing authorization procedure.

Or. en

Amendment 97
Margrete Auken

Proposal for a regulation
Recital 38

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

Or. en

Amendment 98
Dagmar Roth-Behrendt

Proposal for a regulation
Recital 38

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

Or. en

Amendment 99
Margrete Auken

Proposal for a regulation
Recital 42 a (new)

Text proposed by the Commission	*Amendment*
	(42a) To ensure general market safety, any natural or legal person has the right to make public or distribute in good faith information on a fact, an item of data or an action, as soon as a lack of knowledge of this fact, this item of data or this action appears to present a danger to health or the environment.

Or. en

Justification

This recital aims to protect whistleblowers.

Amendment 100
Dagmar Roth-Behrendt

Proposal for a regulation
Recital 44 a (new)

Text proposed by the Commission	*Amendment*
	(44a) An interventional clinical performance studies or any other clinical performance study should only start after being granted a positive evaluation by an independent ethics committee. Member States should take the necessary measures to establish Ethics Committees where such committees do not exist.

Or. en

Amendment 101
Dagmar Roth-Behrendt

Proposal for a regulation
Recital 45

Text proposed by the Commission	*Amendment*
(45) Sponsors of interventional clinical performance studies and other clinical performance studies involving risks for the subjects to be conducted in more than one Member State should be given the possibility to submit a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety related aspects of the device for performance evaluation and of the scientific design of the clinical performance study to be conducted in several Member Stats, such single application should facilitate the coordination between the Member States under the direction of a coordinating Member State. ***The coordinated assessment should not include the assessment of intrinsically national, local and ethical aspects of a clinical performance study, including informed consent.*** Each Member State should retain the ultimate responsibility for deciding whether the clinical performance study may be conducted on its territory.	(45) Sponsors of interventional clinical performance studies and other clinical performance studies involving risks for the subjects to be conducted in more than one Member State should be given the possibility to submit a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety related aspects of the device for performance evaluation and of the scientific design of the clinical performance study to be conducted in several Member Stats, such single application should facilitate the coordination between the Member States under the direction of a coordinating Member State. Each Member State should retain the ultimate responsibility for deciding whether the clinical performance study may be conducted on its territory.

Or. en

Amendment 102
Rebecca Taylor

Proposal for a regulation
Recital 49

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

Or. en

Justification

The Vigilance procedures in Chapter VII will only function correctly if healthcare professionals feel able to report incidents without fear of retribution. In some circumstances, anonymous whistle-blower protection may be needed in order to ensure full and frank incident reporting.

Amendment 103
Dagmar Roth-Behrendt

Proposal for a regulation
Recital 49

Text proposed by the Commission	*Amendment*
(49) Healthcare professionals and patients should be empowered to report suspected serious incidents at national level using harmonised formats. The national competent authorities should inform manufacturers and ***share the information with their peers*** when they confirm that a serious incident has occurred in order to minimise recurrence of those incidents.	(49) ***Member States should take all necessary measures to raise awareness among healthcare professionals, users and patients about the importance of reporting suspected serious incidents.*** Healthcare professionals and patients should be empowered to report suspected serious incidents at national level using harmonised formats. ***In order to minimise the recurrence of such incidents,*** the national competent authorities should inform manufacturers and ***report the information via the respective electronic***

	system in Eudamed when they confirm that a serious incident has occurred in order to minimise recurrence of those incidents.

Or. en

Amendment 104
Dagmar Roth-Behrendt

Proposal for a regulation
Recital 53

Text proposed by the Commission	*Amendment*
(53) The Member States shall levy fees for the designation and monitoring of notified bodies to ensure sustainability of the monitoring of those bodies by Member States and to establish a level playing field for notified bodies.	(53) The Member States shall levy fees for the designation and monitoring of notified bodies to ensure sustainability of the monitoring of those bodies by Member States and to establish a level playing field for notified bodies. ***These fees should be comparable across Member States and should be made public.***

Or. en

Amendment 105
Dagmar Roth-Behrendt

Proposal for a regulation
Recital 54

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

Or. en

Amendment 106
Dagmar Roth-Behrendt

Proposal for a regulation
Recital 54 a (new)

Text proposed by the Commission	*Amendment*
	(54a) Member States should adopt regulations on standard fees for notified bodies, which should be comparable across Member States. The Commission should provide guidelines to facilitate the comparability of those fees. Member States should transmit their list of standard fees to the Commission and ensure that the notified bodies registered on their territory make the lists of standard fees for their conformity assessment activities publicly available.

Or. en

Amendment 107
Dagmar Roth-Behrendt

Proposal for a regulation
Recital 55

Text proposed by the Commission	*Amendment*
(55) ***An expert committee, the*** Medical Device Coordination Group (MDCG), composed of persons designated by the Member States, based on their role and expertise in the field of medical devices and in vitro diagnostic medical devices, should be established in accordance with the conditions and modalities defined in Article 78 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices, to provide advice to the Commission and to	(55) ***A*** Medical Device Coordination Group (MDCG), composed of persons designated by the Member States, based on their role and expertise in the field of medical devices and in vitro diagnostic medical devices, should be established in accordance with the conditions and modalities defined in Article 78 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices, to provide advice to the Commission and to assist the

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

Or. en

Amendment 108
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 55

Text proposed by the Commission	*Amendment*
(55) An expert committee, the Medical Device Coordination Group (MDCG), composed of persons designated by the Member States, based on their role and expertise in the field of medical devices and in vitro diagnostic medical devices, should be established in accordance with the conditions and modalities defined in Article 78 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation.	(55) An expert committee, the Medical Device Coordination Group (MDCG), composed of persons designated by the Member States, based on their role and expertise in the field of medical devices and in vitro diagnostic medical devices, should be established in accordance with the conditions and modalities defined in Article 78 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices, to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation. ***Prior to taking up their duties, members of the MDCG shall make available a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be prejudicial to their independence. Those declarations shall be verified by the Commission.***

Or. en

Amendment 109
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 65

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

Or. en

Justification

The electronic system plays a vital role in this regulation and should be put in place and become fully effective after 12 years.

Amendment 110
Margrete Auken

Proposal for a regulation
Article 1 – paragraph 6

Text proposed by the Commission	*Amendment*
6. This Regulation shall not affect national laws which require that certain devices may only be supplied on a medical prescription.	6. This Regulation shall not affect national laws which require that certain devices may only be supplied on a medical prescription. ***Direct to consumer advertising of devices classed as prescription only by this regulation shall be illegal.***
	The following devices may only be supplied on a medical prescription:
	1) Class D devices
	2) Class C devices in the following categories:
	(a). devices for genetic testing;
	(b). companion diagnostics.
	The Commission shall be empowered to adopt delegated acts in accordance with Article 85 to decide on self-testing devices and other category C tests after consultation with stakeholders.

Or. en

Amendment 111
Peter Liese, Christel Schaldemose, Alda Sousa, Paolo Bartolozzi, Anne Delvaux, Anna Rosbach, Thomas Ulmer, Zofija Mazej Kukovič, Renate Sommer, Mairead McGuinness, Richard Seeber, Miroslav Mikolášik

Proposal for a regulation
Article 1 – paragraph 6

Text proposed by the Commission	*Amendment*
6. This Regulation shall not affect national laws which require that certain devices may only be supplied on a medical prescription.	6. This Regulation ***requires that certain devices may only be supplied on a medical prescription but*** shall not affect national laws which require that certain ***other*** devices may also only be supplied on a medical prescription. ***Direct to consumer advertising of devices classed as prescription only by this regulation shall***

be illegal.

The following devices may only be supplied on a medical prescription:

1) Class D devices

2) Class C devices in the following categories:

(a) devices for genetic testing;

(b) companion diagnostics.

The Commission shall be empowered to adopt delegated acts in accordance with Article 85 to decide on other category C tests after consultation with stakeholders.

Or. en

Amendment 112
Rebecca Taylor

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 1 – indent 1

Text proposed by the Commission	*Amendment*
– diagnosis, prevention, monitoring, treatment or alleviation of disease,	– diagnosis, prevention, monitoring, ***prediction, prognosis,*** treatment or alleviation of disease,

Or. en

Justification

The prediction and prognosis of diseases are vital functions of devices

Amendment 113
Milan Cabrnoch

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 3

Text proposed by the Commission	*Amendment*
(3) **'**accessory to an in vitro diagnostic medical device**'** means an article which, whilst not being an in vitro diagnostic medical device, is intended by its manufacturer to be used together with one or several particular in vitro diagnostic medical device(s) to specifically enable ***or assist*** the in vitro diagnostic medical device(s) to be used in accordance with its/their intended purpose(s)***;***	(3) **'**accessory to an in vitro diagnostic medical device**'** means an article which, whilst not being an in vitro diagnostic medical device, is intended by its manufacturer to be used together with one or several particular in vitro diagnostic medical device(s) to specifically enable the in vitro diagnostic medical device(s) to be used in accordance with its/their intended purpose(s) ***or to specifically assist the medical functionality of the in vitro diagnostic medical device(s) in view of its/their intended purpose(s);***

Or. en

Amendment 114
Milan Cabrnoch

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 4

Text proposed by the Commission	*Amendment*
(4) 'accessory to an in vitro diagnostic medical device' means an article which, whilst not being an in vitro diagnostic medical device, is intended by its manufacturer to be used together with one or several particular in vitro diagnostic medical device(s) to specifically enable ***or assist*** the in vitro diagnostic medical device(s) to be used in accordance with its/their intended purpose(s);	(4) 'accessory to an in vitro diagnostic medical device' means an article which, whilst not being an in vitro diagnostic medical device, is intended by its manufacturer to be used together with one or several particular in vitro diagnostic medical device(s) to specifically enable the in vitro diagnostic medical device(s) to be used in accordance with its/their intended purpose(s) ***or to specifically support the medical applications of the device(s) in respect of its/their intended purpose(s)***;

Or. cs

Amendment 115
Peter Liese, Alda Sousa, Margrete Auken, Paolo Bartolozzi, Anne Delvaux, Anna

Rosbach, Thomas Ulmer, Zofija Mazej Kukovič, Renate Sommer, Nora Berra, Miroslav Mikolášik

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 4

Text proposed by the Commission	*Amendment*
(4) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons***;***	(4) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons***, including testing services offered to lay persons by means of information society services;***

Or. en

Justification

Self--testing devices have specific conformity assessment requirements, e.g. studies with users and instructions etc. in language of intended users, which are designed to mitigate the risks specific to such devices, i.e. the lack of medical/technical/scientific training of lay user. This specific type of risk is the same whether the test is purchased as a kit in a shop or as a service over the internet.

Amendment 116
Peter Liese

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 6

Text proposed by the Commission	*Amendment*
(6) 'companion diagnostic' means a device specifically intended to select patients with a previously diagnosed condition or predisposition as eligible for a ***targeted*** therapy;	(6) 'companion diagnostic' means a device specifically intended to select patients with a previously diagnosed condition or predisposition as eligible for a ***specific*** therapy;

Or. en

Amendment 117
Alda Sousa

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 6

Text proposed by the Commission	*Amendment*
(6) **'**companion diagnostic**'** means a device ***specifically*** intended to ***select*** patients ***with a previously diagnosed condition or predisposition as eligible for a targeted therapy***;	(6) **'**companion diagnostic' means a device intended to ***provide information that is essential for the safe and effective use of a corresponding therapeutic product. The use of a companion diagnostic with a particular therapeutic product is indicated as desirable in the instructions for use in the labelling of both the diagnostic device and the corresponding therapeutic product, as well as in the labelling of any generic equivalents of the therapeutic product or is the stated intended purpose of the diagnostic device.*** ***An IVD companion diagnostic device could be essential for the safe and effective use of a corresponding therapeutic product to:*** ***–*** ***identify*** patients ***who are most likely to benefit from a particular therapeutic product;*** ***– identify patients likely to be at increased risk for serious adverse reactions as a result of treatment with a particular therapeutic product;*** ***– monitor response to treatment for the purpose of adjusting treatment (e.g. schedule, dose, discontinuation) to achieve improved safety or effectiveness.***

Or. en

Justification

The current definition is too limited, e.g. it does not include companion diagnostics used to guide dosage decisions (e.g. pharmacogenetic tests for warfarin treatment) which may have an important role to play in ensuring the safety and effectiveness of a specific drug.

Amendment 118
Alda Sousa

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 10

Text proposed by the Commission	*Amendment*
(10) **'**label**'** means the written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit, or on the packaging of multiple devices;	(10) **'**label**'** means the written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit, or on the packaging of multiple devices ***or on the manufacturer's website***;

Or. en

Justification

The current definition of a label does not cover laboratory-developed tests. Recipients of the results generated by such devices should have the same access to the information contained on the label as do users of other IVD devices.

Amendment 119
Alda Sousa

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 12 a (new)

Text proposed by the Commission	*Amendment*
	(12a) 'novel device' means:
	– a device which incorporates technology (the analyte, technology or test platform) not previously used in diagnostics, or;
	– an existing device which is being used for a new intended purpose for the first time;

Or. en

Amendment 120
Peter Liese, Christel Schaldemose, Alda Sousa, Margrete Auken, Paolo Bartolozzi, Anne Delvaux, Anna Rosbach, Thomas Ulmer, Zofija Mazej Kukovič, Renate Sommer,

Mairead McGuinness, Richard Seeber, Nora Berra, Miroslav Mikolášik

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 12 a (new)

Text proposed by the Commission	*Amendment*
	(12a) ' device for genetic testing' means an in vitro diagnostic medical device the purpose of which is to identify a genetic characteristic of a person which is inherited or acquired during prenatal development.

Or. en

Justification

Other definition compared to Amendment 18 in the draft report

Amendment 121
Anna Rosbach, Christofer Fjellner

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 3 – point 21

Text proposed by the Commission	*Amendment*
(21) 'health institution' means an organisation whose primary purpose is the care or treatment of patients ***or the promotion of public health***;	(21) 'health institution' means an organisation whose primary purpose is the care or treatment of patients;

Or. en

Justification

It is too unclear what could fall under the category of a organisation who's primary purpose is "the promotion of public health" since it is not defined elsewhere. So to avoid confusion and uncertainties it should be deleted.

Amendment 122
Alda Sousa

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 3 – point 21

Text proposed by the Commission	*Amendment*
(21) ‘health institution’ means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health***;***	(21) ‘health institution’ means an organisation ***within a Member State's public healthcare system*** whose primary purpose is the care or treatment of patients or the promotion of public health; ***commercial laboratories which provide diagnostic services are not health institutions.***

Or. en

Amendment 123
Antonyia Parvanova

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 3 – point 21

Text proposed by the Commission	*Amendment*
(21) ‘health institution’ means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health;	(21) ‘health institution’ means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health***, with the exclusion of laboratories providing commercial clinical services***;

Or. en

Amendment 124
Milan Cabrnoch

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 3 – point 22

Text proposed by the Commission	*Amendment*
(22) ‘health institution’ means an organisation whose primary purpose is the	(22) ‘health institution’ means an organisation whose primary purpose is the

care or treatment of patients ***or the promotion of public health***;	care or treatment of patients ***and which has the legal capacity to carry out such activities***;

Or. cs

Amendment 125
Alda Sousa

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 5 – point 32

Text proposed by the Commission	*Amendment*
(32) ***'***clinical performance***'*** means the ***ability of a device to yield results that are correlated with a particular*** clinical ***condition or a physiological state in accordance with the target population and*** intended ***user;***	(32) ***'***clinical performance***'*** means the ***clinical validity, and if appropriate, the*** clinical ***utility of the device in relation to its*** intended ***purpose;***

Or. en

Amendment 126
Alda Sousa

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 5 – point 32 a (new)

Text proposed by the Commission	*Amendment*
	(32a) 'clinical validity' means a device's ability to detect or predict a particular clinical condition or physiological state in relation to its intended purpose (e.g. screening, diagnosis, prognosis);

Or. en

Amendment 127
Alda Sousa

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 5 – point 32 b (new)

Text proposed by the Commission	*Amendment*
	(32b) 'clinical utility' means the anticipated effect(s) of the clinical use of the test result, including on health outcomes, where the intended purpose of a device, as stated by the manufacturer, includes a clinical use such as selection of a therapy (e.g. companion diagnostic);

Or. en

Amendment 128
Alda Sousa

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 5 – point 38

Text proposed by the Commission	*Amendment*
(38) **'**diagnostic specificity**'** means the ***ability of a device to recognize the absence of a target marker associated with a particular disease or condition;***	(38) **'**diagnostic specificity**'** means the ***proportion of subjects who do not have or a specified clinical disorder whose test results are negative or within the defined decision limit;***

Or. en

Amendment 129
Alda Sousa

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 5 – point 39

Text proposed by the Commission	*Amendment*
(39) **'**diagnostic sensitivity**'** means the ***ability of a device to identify the presence of a target marker associated with a particular disease or condition***;	(39) **'**diagnostic sensitivity**'** means the ***proportion of subjects with a well-defined clinical disorder whose test values are positive or exceed a defined decision limit (i.e. a positive result and identification of***

the subjects who have a disease);

Or. en

Amendment 130
Antonyia Parvanova

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 5 – point 45

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

Or. en

Amendment 131
Anna Rosbach

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 5 – point 47 – indent 2 – point iii

Text proposed by the Commission	*Amendment*
(iii) hospitalisation or ***extending the duration of*** hospitalisation,	(iii) hospitalisation or ***prolongation of patient*** hospitalisation,

Or. en

Justification

This wording brings the text in line with ISO 14155:2011 Clinical investigation of medical devices for human subjects — Good clinical practice

Amendment 132
Peter Liese, Nora Berra

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 5 – point 48

Text proposed by the Commission	*Amendment*
(48) 'device deficiency' means any inadequacy in the identity, quality, ***durability***, reliability, safety or performance of a device for performance evaluation, including malfunction, use errors or inadequacy in the information supplied by the manufacturer;	(48) 'device deficiency' means any inadequacy in the identity, quality, ***stability***, reliability, safety or performance of a device for performance evaluation, including malfunction, use errors or inadequacy in the information supplied by the manufacturer;

Or. en

Justification

The meaning of the term "durability" is not entirely clear and could be subject to misunderstanding

Amendment 133
Alda Sousa

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 7 – point 58 a (new)

Text proposed by the Commission	*Amendment*
	(58a) 'laboratory-developed test' means a device that is manufactured and used only within a single site. This includes devices which a laboratory develops de novo, or develops or modifies from a published source, or develops or modifies from any other source, and devices for which a laboratory:
	– changes the intended purpose of a device already placed on the market or put into service;
	– modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

Or. en

Justification

Recitals 9 and 15 and Articles 4 and 5 reflect the desire to ensure that IVD devices developed and used within a single site (subject of course to the health institution exemption, see below) are subject to the requirements of the Regulation. However, the Regulation lacks a clear definition of such devices. Such a definition is needed in order to avoid confusion.

Amendment 134
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 7 – point 58 a (new)

Text proposed by the Commission	*Amendment*
	(58a) 'ethics committee' means an independent body in a Member State ensuring that the rights, safety and well-being of subjects are protected. It shall act in accordance with the laws and regulations of the country or countries in which the research is to be conducted and shall abide by all relevant international norms and standards. The Ethics Committee shall consist of a reasonable number of members who collectively possess the relevant qualifications and experience to be able to review and evaluate the scientific, medical and ethical aspects of the proposed test.

Or. en

Justification

To achieve the best possible protection of the subject, it is necessary to make authorisation by the Member States contingent on the decision of the interdisciplinary and independent Ethics Committee.

Amendment 135
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 2 – title

Text proposed by the Commission	*Amendment*
Chapter ***II***	Chapter ***VI***
Making available of devices, obligations of economic operators, CE marking, free movement	Making available of devices, obligations of economic operators, CE marking, free movement

Or. en

Amendment 136
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 4 – paragraph 5 – subparagraph 1

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

Or. en

Justification

In-vitro devices manufactured within a single health institution and used for patients must be publicly known thereby allowing Member States to ensure appropriate safety requirements to these devices.

Amendment 137
Alda Sousa

Proposal for a regulation
Article 4 – paragraph 5 – subparagraph 1

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

Or. en

Amendment 138
Rebecca Taylor, Linda McAvan, Marina Yannakoudakis

Proposal for a regulation
Article 4 – paragraph 5 – subparagraph 1

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

Or. en

Justification

The corrected terminology is 'accredited to'

Amendment 139
Alda Sousa

Proposal for a regulation
Article 4 – paragraph 5 – subparagraph 2

Text proposed by the Commission	*Amendment*
Devices classified as class D in accordance with the rules set out in Annex VII, even if manufactured and used within a single health institution, shall comply with the requirements of this Regulation. However, the provisions regarding CE marking set out in Article 16 and the obligations referred to in	***deleted***

Articles 21 to 25 shall not apply to those devices.

Or. en

Amendment 140
Peter Liese

Proposal for a regulation
Article 4 – paragraph 5 – subparagraph 2

Text proposed by the Commission	*Amendment*
Devices classified as class D in accordance with the rules set out in Annex VII, ***even*** if manufactured and used within a single health institution, shall ***comply with*** the requirements of this Regulation***. However***, ***the provisions regarding CE marking set out in Article 16 and the obligations*** referred to in ***Articles 21 to 25*** shall ***not apply to those*** devices.	Devices classified as class D in accordance with the rules set out in Annex VII, if manufactured and used within a single health institution, shall ***be exempt from*** the requirements of this Regulation, ***with the exception of Article 59(4) and general safety performance requirements set out in Annex 1 where the following conditions are met:*** ***(a) the recipient patient or patient group's specific needs can not be met by an available CE-marked device;*** ***(b) the health institution is accredited to ISO standard 15189 quality management system, or any other equivalent recognised standard;*** ***(c) the health institution provides the competent authority*** referred to in ***Article 26 with a list of such devices, which*** shall ***include a justification of their manufacturing, modification or use, in particular, where similar devices have been made available on the market. This information shall be made public.*** ***Member States shall retain the right to restrict the in-house manufacture and use of any specific type of in-vitro diagnostic device in relation to aspects that are not covered by this Regulation, and may also make the manufacture and use of the*** devices ***concerned subject to further***

safety requirements.

Or. en

Amendment 141
Rebecca Taylor, Linda McAvan, Marina Yannakoudakis

Proposal for a regulation
Article 4 – paragraph 5 – subparagraph 2

Text proposed by the Commission	*Amendment*
Devices classified as class D in accordance with the rules set out in Annex VII, ***even*** if manufactured and used within a single health institution, shall ***comply with*** the requirements of this Regulation***. However***, ***the provisions regarding CE marking set out in Article 16 and the obligations*** referred to in ***Articles 21 to 25*** shall ***not apply to those*** devices.	Devices classified as class D in accordance with the rules set out in Annex VII, if manufactured and used within a single health institution, shall ***be exempt from*** the requirements of this Regulation***, with the exception of Article 59(4)***, ***where the following conditions are met;***
	(a) the recipient patient or patient group's specific needs can not be met by an available CE-marked device;
	(b) the health institution is accredited to EN ISO standard 15189 quality management system, or any other equivalent recognised standard;
	(c) the health institution provides their competent authority referred to in ***Article 26 with a list of such devices, which*** shall ***include a justification of their manufacturing or modification, in particular, where similar*** devices ***have been made available on the market. This information shall be updated yearly, and shall be made public***.

Or. en

Justification

The proposal removes the possibility of health institutions producing or modifying class D devices. There are patient needs for which there are no commercially available IVD Devices,

such as the diagnosis of very rare diseases, or the identification of emerging pathogens. Health institutions play a vital role in protecting public health, by manufacturing these devices in-house. These amendments seek to maintain this public health function whilst ensuring patient safety is paramount.

Amendment 142
Rebecca Taylor, Linda McAvan, Marina Yannakoudakis

Proposal for a regulation
Article 4 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. Member States shall retain the right to restrict the in-house manufacture and use of any specific type of in-vitro diagnostic device in relation to aspects that are not covered by this Regulation, and may also make the manufacture and use of the devices concerned subject to further safety requirements.

Or. en

Justification

The proposal removes the possibility of health institutions producing or modifying class D devices. There are patient needs for which there are no commercially available IVD Devices, such as the diagnosis of very rare diseases, or the identification of emerging pathogens. Health institutions play a vital role in protecting public health, by manufacturing these devices in-house. These amendments seek to maintain this public health function whilst ensuring patient safety is paramount.

Amendment 143
Anja Weisgerber, Peter Liese

Proposal for a regulation
Article 4 a (new)

Text proposed by the Commission	*Amendment*
	Article 4a
	Genetic information, counselling and free

consent

1. A device may only be used for the purpose of a genetic test if that test is conducted by persons admitted to the medical profession under the applicable national legislation.

2. A product may only be used for the purposes of a genetic test if the rights, safety and well-being of the test subjects are protected and the clinical data generated in the course of the testing are expected to be reliable and robust.

3. Before using a device for the purpose of a genetic test the person referred to in paragraph 1 shall provide the test subject concerned with appropriate information on the nature, the significance and the implications of the genetic test.

4. Before using a device for the purpose of a genetic test the person referred to in paragraph 1 shall provide the test subject concerned with appropriate and comprehensible genetic counselling without prejudging the outcome. The genetic counselling shall include medical, ethical, social, psychological and legal aspects.

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

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

6. In the case of minors, the informed consent of the parents or legal representative shall be obtained. That consent shall represent the minor's

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

Devices providing an indication of a genetic disease which develops in adulthood or affects family planning may not be used on minors unless preventive treatment is available and can be provided before the person being tested reaches the age at which he or she can give informed consent.

7. No prenatal genetic examination designed to detect the genetic predisposition of an embryo or a foetus to a disease may be conducted if, on the basis of current medical knowledge and technology, it is generally accepted that the disease in question will not manifest itself before the individual concerned reaches the age of 18.

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

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

Or. de

Justification

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

Amendment 144
Peter Liese, Christel Schaldemose, Alda Sousa, Margrete Auken, Paolo Bartolozzi, Anne Delvaux, Anna Rosbach, Thomas Ulmer, Zofija Mazej Kukovič, Renate Sommer, Mairead McGuinness, Richard Seeber, Miroslav Mikolášik

Proposal for a regulation
Article 4 a (new)

Text proposed by the Commission	*Amendment*
	Article 4a
	1. A device may only be used for the purpose of a genetic test if the indication is given by persons admitted to the medical profession under the applicable national legislation after a personal consultation.
	2. A device may be used for purposes of a genetic test only in a way that the rights, safety and well-being of the subjects are protected and that the clinical data generated in the course of the genetic testing are going to be reliable and robust.
	3. Information. Before using a device for the purpose of a genetic test the person mentioned in paragraph 1 shall provide the person concerned with appropriate information on the nature, the significance and the implications of the genetic test.
	4. Genetic counselling. Appropriate genetic counselling is mandatory before using a device for the purpose of predictive and prenatal testing and after a genetic condition has been diagnosed. It shall include medical, ethical, social, psychological and legal aspects and has to

be addressed by physicians qualified in genetic counselling.

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

5. Consent. A device may only be used for the purpose of a genetic test after the person concerned has given free and informed consent to it. The consent has to be given explicitly and in writing. It can be revoked at any time in writing or orally.

6. Testing of minors. In case of minors the informed consent of the parents or legal representative shall be obtained; consent must represent the minor's presumed will and may be revoked at any time, without detriment to the minor. In case of incapacitated adults not able to give informed legal consent, the informed consent of the legal representative shall be obtained; consent must represent the presumed will and may be revoked at any time, without detriment to the person.

Devices predicting a genetic condition that has implications for diseases in adulthood or for family planning shall not be used in minors unless preventive means are available before reaching the age when the person tested is able to give consent.

7. A device may only be used for the determination of sex in connection with prenatal diagnosis, if the determination fulfils a medical purpose and if there is a risk of serious gender specific hereditary diseases. By way of derogation of Article 2(1) and (2) this also applies to products which are not intended to fulfil a specific medical purpose.

8. The provisions of this Article on the use

of devices for the purpose of genetic tests do not prevent the Member States from maintaining or introducing for reasons of health protection or public order more stringent national legislation in this field.

Or. en

Justification

New element in paragraph 5 compared to the wording in the draft report (Amendment 30). This amendment clarifies also the purpose of Article 4a paragraph 4 after consultation with the shadows and experts. It needs to be made clear that genetic counselling is not mandatory when it just confirms a specific diagnosis and it is also not necessary for companion diagnostics or when the genetic test shows a normal finding.

Amendment 145
Alda Sousa

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. ***Without prejudice to national legislation regarding the exercise of the medical profession,*** a device that is not placed on the market but is used in the context of a commercial activity for the provision of a diagnostic or therapeutic service offered by means of ***information society services as defined in Article 1(2) of Directive 98/34/EC or by other*** means of ***communication*** to a natural or legal person established in the Union shall comply with this Regulation.	2. A device that is not placed on the market but is used in the context of a commercial activity for the provision of a diagnostic or therapeutic service offered by ***any*** means of ***communication (including by*** means of ***information society services)*** to a natural or legal person established in the Union shall comply with this Regulation.

Or. en

Amendment 146
Jolanta Emilia Hibner

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

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

Or. pl

Justification

Zapisy, które zostały zaproponowane przez Komisję w projektach rozporządzeń nie są wystarczające i tym samym nie zabezpieczają w przedmiotowym zakresie interesów państw członkowskich. Utrzymanie propozycji komisyjnej, która została już ugruntowana w praktyce organów kompetentnych spowoduje, że w internecie będą obecne reklamy wprowadzające w błąd potencjalnego nabywcę wyrobów, gdyż będzie można oferować produkty, dla których nie przeprowadzono procedury oceny zgodności, a dopiero w momencie ich sprzedaży, będzie trzeba zapewnić, że taki wyrób spełnia wymagania. Jest to niepokojące i dlatego należy umożliwić organom kompetentnym, możliwość zdobycia wiedzy, kto zamieszczał takie ogłoszenia w przypadku otrzymania sygnału z rynku, że właśnie wyrób niespełniający wymagań, w tym nawet niebezpieczny dla zdrowia lub życia użytkownika, został w taki sposób sprzedany i aby dostarczyciele usług internetowych udostępniali dane o podmiotach zamieszczających reklamy wyrobów w internecie.

Amendment 147
Jolanta Emilia Hibner

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

Text proposed by the Commission	*Amendment*
	2b. There shall be a prohibition on the marketing, placing in use, distribution, delivery and making available of products whose names, labelling or instructions for use may mislead with regard to the product's characteristics and effects by:
	a) ascribing characteristics, functions and effects to the product which the product does not have;

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

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

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

Or. pl

Justification

Kwestie podnoszone w powyższej poprawce, w ogóle nie znalazły się w propozycjach nowych przepisów. Należy wprowadzić zakaz reklamy wprowadzającej w błąd, co do właściwości i przeznaczenia wyrobów, gdyż wpłynie to pozytywnie na ochronę europejczyków przed nieetycznym postępowaniem, które może doprowadzić nawet do zaniechania właściwego leczenia medycznego przy zastosowaniu wyrobu, który obiecywał dużo, ale w zasadzie nie leczy lub nie udowodniono wskazania zawartego w instrukcjach o dane kliniczne. W obszarze produktów leczniczych regulacja idzie nawet dalej, gdyż każda reklama, powinna być zaopatrzona w stosowne zdanie informujące, że przed skorzystaniem z leku należy skorzystać z konsultacji lekarza lub farmaceuty, jednakże dla wyrobów medycznych wydaje się na razie wystarczające, aby zawrzeć zaproponowane powyżej przepisy.

Amendment 148
Anna Rosbach

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where no harmonised standards exist or where ***relevant harmonised standards are not sufficient,*** the Commission shall be empowered to adopt common technical specifications (CTS) in respect of the	1. ***For Class D devices and as needed for companion diagnostics,*** where no harmonised standards exist or where ***there is a need to address a public health concern*** the Commission shall be

general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evidence and post-market follow-up set out in Annex XII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 84(3).	empowered to adopt common technical specifications (CTS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evidence and post-market follow-up set out in Annex XII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 84(3).

Or. en

Justification

This is shifting the consultation process to the development of Common Technical Specifications for companion diagnostics, setting up minimal performance requirements for those tests. Those minimal performance requirements would also be available to the users ensuring a better transparency of the system. In addition, the consultation of EMA or competent authorities for medicinal products would not be appropriate in regard to the performance of the IVD tests to be used together with the personalized medicine. None of them have the necessary competences and mandate regarding the assessment of the safety and performance of those tests.

Amendment 149
Anna Rosbach

Proposal for a regulation
Article 7 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The relevant scientific experts from the various interested parties shall be involved in the drafting of the common technical specifications.

Or. en

Justification

In the context of shifting from the consultation process to the development of Common Technical Specifications for companion diagnostics, it must be ensured that the experts from all interested parties are involved. In particular, for the development of CTS on companion

diagnostics, experts from the IVD sector as well as from competent authorities for medicinal products and/or from EMA shall be involved.

Amendment 150
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 8 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
2. Manufacturers shall draw up the technical documentation which shall allow assessment of the conformity of the device with the requirements of this Regulation. The technical documentation shall include the elements set out in Annex II.	2. Manufacturers shall draw up the technical documentation which shall allow assessment of the conformity of the device with the requirements of this Regulation. The technical documentation shall include the elements set out in Annex II ***and be made accessible to the public***.

Or. en

Justification

Technical data and clinical evidence submitted by manufacturers must be made publicly available to guarantee safe and quality products to the consumer.

Amendment 151
Milan Cabrnoch

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

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

Or. cs

Amendment 152
Antonyia Parvanova

Proposal for a regulation
Article 8 – paragraph 7 – subparagraph 2

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

Or. en

Amendment 153
Milan Cabrnoch

Proposal for a regulation
Article 8 – paragraph 8

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

Or. cs

Amendment 154
Antonyia Parvanova

Proposal for a regulation
Article 8 – paragraph 8

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

Or. en

Amendment 155
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 8 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Manufacturers shall, in response to a reasoned request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any corrective action taken to eliminate the risks posed by devices which they have placed on the market or put into service.	9. Manufacturers shall, in response to a reasoned request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any corrective action taken to eliminate the risks posed by devices which they have placed on the market or put into service. ***If facts exist that give reason to assume that an in-vitro medical device has caused damage, the potentially harmed user, his successor in title, his compulsory health insurance or other third parties affected***

by the damage may also demand the information referred to in sentence 1 from the manufacturer or his authorised representative.

This right to information shall also exist, subject to the conditions set forth in sentence 1, against the competent authorities of the Member States which are responsible for the surveillance of the respective medical device, as well as against any notified body that issued a certificate pursuant to Article 45 or was otherwise involved in the conformity assessment procedure of the medical device in question.

Or. en

Justification

To ensure that users will not lack access to information that would demonstrate the defectiveness of in-vitro medical devices that has hurt the users, this new right to information would redress the balance to the benefit of users.

Amendment 156
Andrés Perelló Rodríguez

Proposal for a regulation
Article 8 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Manufacturers shall, in response to a reasoned request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language which can be easily understood by ***that authority***. They shall cooperate with ***that*** authority, at its request, on any corrective action taken to eliminate the risks posed by devices which they have placed on the market or put into service.	9. Manufacturers shall, in response to a reasoned request from a competent authority ***or medical association or institution***, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language which can be easily understood by ***the applicant***. They shall cooperate with ***the competent*** authority, at its request, on any corrective action taken to eliminate the risks posed by devices which they have

placed on the market or put into service.

Or. es

Amendment 157
Jolanta Emilia Hibner

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

Text proposed by the Commission	*Amendment*
	10a. The manufacturer of the product shall be responsible for the product, for carrying out a conformity assessment on the product before it is placed on the market, and for placing the product on the market. If the manufacturer is neither resident nor based in a Member State, this responsibility shall be borne by the authorised representative for that product. Where the manufacturer has not designated an authorised representative, or where the manufacturer or authorised representative is not responsible for placing the product on the market, responsibility shall be borne by the entity that placed the product on the market.

Or. pl

Justification

Obecnie stosowana jest koncepcja, że za wyrób odpowiada wytwórca. W przypadku wytwórcy mającego swoją siedzibę w państwie trzecim, dalej jest on odpowiadzialny za wyrób, bo autoryzowany przedstawiciel zajmuje się tylko przekazywaniem informacji wytwórcy. W tej sytuacji bardzo ciężko prowadzi się postępowania wyjaśniające, nie mówiąc już o ewentualnych roszczeniach europejczyków za ewentualne szkody wyrządzone przez wyroby. Brak podmiotu odpowiedzialnego za wyrób wprowadzony do obrotu na rynku europejskim sprawia, że osoby które ucierpiały w skutek wadliwego wyrobu, nie mogą dochodzić naprawienia szkody.

Amendment 158
Andrés Perelló Rodríguez

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

Text proposed by the Commission	*Amendment*
	10a. Manufacturers of medical devices must be covered by an insurance policy or equivalent financial guarantee to meet claims for health damage arising from unsafe medical devices.
	Manufacturers shall bear the cost to the health system of treatment, operations and diagnostic procedures practiced on patients as a result of defects in or malfunctioning of health devices detected by the health authorities or the manufacturers themselves.
	They shall also bear the cost of withdrawing, repairing or replacing the products involved in these situations.

Or. es

Justification

Recent incidents involving fraudulent breast implants, in which patients have had to undergo corrective surgery and other expensive treatments to monitor or diagnose their condition, have highlighted the need for a legal clause requiring manufacturers to have insurance to cover damages to patients and the costs incurred by the health service.

Amendment 159
Pilar Ayuso, Cristina Gutiérrez-Cortines

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

Text proposed by the Commission	*Amendment*
	10a. Manufacturers of medical devices must be covered by an insurance policy or equivalent financial guarantee to meet claims for health damage arising from unsafe medical devices.

Or. es

Justification

Recent incidents involving fraudulent breast implants, in which patients have had to undergo corrective surgery and other expensive treatments to monitor or diagnose their condition, have highlighted the need for a legal clause requiring manufacturers to have insurance to cover damages to patients and the costs incurred by the health service.

Amendment 160
Pilar Ayuso, Cristina Gutiérrez-Cortines

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

Text proposed by the Commission	*Amendment*
	10b. Manufacturers shall bear the cost to the health system of treatment, operations and diagnostic procedures practiced on patients as a result of defects in or malfunctioning of health devices detected by the health authorities or the manufacturers themselves.
	They shall also bear the cost of withdrawing, repairing or replacing the products involved in these situations.

Or. es

Justification

Recent incidents involving fraudulent breast implants, in which patients have had to undergo corrective surgery and other expensive treatments to monitor or diagnose their condition, have highlighted the need for a legal clause requiring manufacturers to have insurance to cover damages to patients and the costs incurred by the health service.

Amendment 161
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 8 a (new)

Text proposed by the Commission	*Amendment*
	Article 8 a
	To ensure that patients harmed will be compensated for any damages and to avert manufacturer's insolvency, manufacturers shall be obliged to take out liability insurance with sufficient minimum coverage.

Or. en

Justification

Liability insurance with sufficient minimum coverage would ensure that the risk of damage as well as the risk of the manufacturer's insolvency is averted from the injured patients and the payers liable for the cost of treatment.

Amendment 162
Milan Cabrnoch

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The designation shall be valid only when accepted in writing by the authorised representative ***and shall be effective at least for all devices of the same generic device group***.	2. The designation shall be valid only when accepted in writing by the authorised representative.

Or. cs

Amendment 163
Milan Cabrnoch

Proposal for a regulation
Article 9 – paragraph 3 – subparagraph 2 – point a

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

Or. cs

Amendment 164
Milan Cabrnoch

Proposal for a regulation
Article 11 – paragraph 2 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) that the ***appropriate*** conformity assessment procedure has been carried out by the manufacturer;	(a) ***they shall verify*** that the conformity assessment procedure has been carried out by the manufacturer;

Or. cs

Amendment 165
Milan Cabrnoch

Proposal for a regulation
Article 11 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Where an importer considers ***or has reason to believe*** that a device is not in conformity with the requirements of this Regulation, ***he shall not place the device on the market until it has been brought into conformity. Where the device*** presents a risk, the importer shall inform the manufacturer and his authorised	Where an importer considers that a device is not in conformity with the requirements of this Regulation ***or*** presents a risk, the importer shall inform the manufacturer and his authorised representative to that effect, as well as the competent authority of the Member State***, and shall only place the device on the market with the agreement***

representative to that effect, as well as the competent authority of the Member State ***in which he is established***.

of the manufacturer.

Or. cs

Amendment 166
Milan Cabrnoch

Proposal for a regulation
Article 11 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Importers ***shall indicate their name, registered trade name or registered trade mark and the address of their registered place of business at which they can be contacted and their location can be established on the device or on its packaging or in a document accompanying the device. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer***.	3. Importers ***shall ensure that their device is registered in the electronic system in accordance with Article 23(2)***.

Or. cs

Amendment 167
Milan Cabrnoch

Proposal for a regulation
Article 11 – paragraph 5

Text proposed by the Commission	*Amendment*
5. ***Importers shall ensure that, while a*** device ***is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I***.	5. ***When deemed appropriate with regard to the risks presented by a device, importers shall investigate and keep a register of complaints, of non-compliant products and of cases in which a product is withdrawn from the market or from circulation, and shall notify the manufacturer, the authorised***

representative and the distributors of this.

Or. cs

Amendment 168
Milan Cabrnoch

Proposal for a regulation
Article 11 – paragraph 6

Text proposed by the Commission	*Amendment*
6. ***When deemed appropriate with regard to the risks presented by a*** device, ***importers shall, in order to protect the health and safety of patients and users, carry out sample testing of marketed products, investigate complaints and keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and shall keep the manufacturer, authorised representative and distributors informed of such monitoring***.	6. ***Manufacturers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall inform the manufacturer and the authorised representative. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 43 for the device in question, giving details, in particular, of the non-compliance and of any corrective action taken***.

Or. cs

Amendment 169
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 12 – paragraph 2 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
Before making a device available on the market distributors shall verify that the following requirements are met:	Before making a device available on the market ***for the first time,*** distributors shall verify that the following requirements are met:

Or. de

Justification

Within the supply chain, distributors are responsible for product safety. Outside it, responsibility for product safety and for completeness of documentation lies with the manufacturer or importer.

Amendment 170
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 12 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(7);	(b) ***in the absence of a declaration of conformity by the manufacturer or importer,*** the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(7);

Or. de

Justification

Within the supply chain, distributors are responsible for product safety. Outside it, responsibility for product safety and for completeness of documentation lies with the manufacturer or importer.

Amendment 171
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 12 – paragraph 2 – subparagraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the manufacturer and, where applicable, the importer have complied with the requirements set out in ***Article 22 and*** Article 11(3) ***respectively***.	(c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article 11(3).

Or. de

Justification

Within the supply chain, distributors are responsible for product safety. Outside it, responsibility for product safety and for completeness of documentation lies with the manufacturer or importer.

Amendment 172
Milan Cabrnoch

Proposal for a regulation
Article 12 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Where a distributor considers ***or has reason to believe*** that a device is not in conformity with the requirements of this Regulation***, he shall not make the device available on the market until it has been brought into conformity***. ***Where the device*** presents a risk, the ***distributor*** shall inform the manufacturer and***, where applicable,*** his authorised representative ***and the importer*** to that effect, as well as the competent authority of the Member State ***in which he is established***.	Where a distributor considers that a device is not in conformity with the requirements of this Regulation ***or*** presents a risk, the ***distributor*** shall inform the manufacturer and his authorised representative to that effect, as well as the competent authority of the Member State***, and shall only place the device on the market with the agreement of the manufacturer***.

Or. cs

Amendment 173
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 12 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make	4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and***, within***

sure that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.	***their respective area of activity,*** make sure that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

Or. de

Justification

A distinction should be made between the various participants in the supply chain.

Amendment 174
Peter Liese, Alda Sousa, Margrete Auken, Paolo Bartolozzi, Anne Delvaux, Anna Rosbach, Thomas Ulmer, Zofija Mazej Kukovič, Renate Sommer, Miroslav Mikolášik

Proposal for a regulation
Article 12 – paragraph 4

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

Or. en

Justification

The proposal does not distinguish between the different roles and responsibilities of the stakeholders involved in the supply chain of in vitro diagnostic medical devices. All distributors have the same obligations, some of which are in practice unworkable. This proposal would link the obligation to the activity carried out by the distributor. The amendment adopts the approach in Article 19(2) of Regulation 18/2002 on Food Safety.

Amendment 175
Milan Cabrnoch

Proposal for a regulation
Article 12 – paragraph 6

Text proposed by the Commission	*Amendment*
6. ***Distributors shall, in response to a request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of a device. This obligation shall be considered fulfilled when the authorised representative for the device in question, where applicable, provides the required information.*** Distributors shall cooperate with competent national authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market.	6. Distributors shall cooperate with competent national authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market.

Or. cs

Amendment 176
Anna Rosbach

Proposal for a regulation
Article 13 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) a diploma, certificate or other evidence	(a) a diploma, certificate or other evidence

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

Or. en

Justification

It must be ensured that the diploma or certificate of the qualified person is on a sufficiently high level. Furthermore two years of industry experience does not guarantee a sufficient level of "expert knowledge".

Amendment 177
Peter Liese, Paolo Bartolozzi, Anne Delvaux, Thomas Ulmer, Renate Sommer, Miroslav Mikolášik

Proposal for a regulation
Article 13 – paragraph 1 – point a

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

Or. en

Justification

The institution of a qualified person doesn't exist in the current directive. It imposes new

burden for companies, especially for SMEs. This is necessary but we should not go further than the situation in the more advanced member states.

Amendment 178
Anna Rosbach

Proposal for a regulation
Article 13 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) ***five*** years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices.	(b) ***10*** years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices ***as well as a proven in-depth knowledge of both the therapeutic area and the product type(s) concerned.***

Or. en

Amendment 179
Peter Liese, Paolo Bartolozzi, Anne Delvaux, Thomas Ulmer, Renate Sommer, Miroslav Mikolášik

Proposal for a regulation
Article 13 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) ***five*** years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices.	(b) ***two*** years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices.

Or. en

Justification

The institution of a qualified person doesn't exist in the current directive. It imposes new burden for companies, especially for SMEs. This is necessary but we should not go further than the situation in the more advanced member states.

Amendment 180
Anna Rosbach

Proposal for a regulation
Article 13 – paragraph 4 – point a

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

Or. en

Justification

It must be ensured that the diploma or certificate of the qualified person is on a sufficiently high level. Furthermore two years of industry experience does not guarantee a sufficient level of "expert knowledge".

Amendment 181
Anna Rosbach

Proposal for a regulation
Article 13 – paragraph 4 – point b

Text proposed by the Commission	*Amendment*
(b) ***five*** years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices.	(b) ***ten*** years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices ***as well as a proven in-depth knowledge of both the therapeutic area and the product(s) concerned.***.

Or. en

Amendment 182
Peter Liese

Proposal for a regulation
Article 14 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Distributors or affiliates who carry out – on behalf of the manufacturer – one or several of the activities mentioned under paragraph 2 points (a) and (b) – are exempted from additional requirements under points (3) and (4).

Or. en

Justification

Manufacturers market their products in the individual Member States through subsidiaries or distributors. On behalf of the manufacturer, the latter also perform activities as referred to in Article 14(2), acting on instructions from, and coordinating their work with, the manufacturer. In this case there is no justification for additional requirements regarding characterisation of the activity or regarding procedural matters and communications with the manufacturer and the authorities, and such requirements would result in a good deal of expense.

Amendment 183
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 16 a (new)

Text proposed by the Commission	*Amendment*
	Article 16a
	The granting of the CE-marking is followed by the publication of a summary describing the basis for granting the CE-marking.

Or. en

Justification

Granting of the CE-marking by notified bodies must be justified in a summary explaining the reason for granting access to the market.

Amendment 184
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 3 – title

Text proposed by the Commission	*Amendment*
*Chapter **III***	Chapter ***VII***
Identification and traceability of devices, registration of devices and of economic operators, summary of safety and performance, European databank on medical devices	Identification and traceability of devices, registration of devices and of economic operators, summary of safety and performance, European databank on medical devices

Or. en

Amendment 185
Milan Cabrnoch

Proposal for a regulation
Article 21 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
For devices, other than devices for performance evaluation, economic operators shall be able to identify the following, for ***the*** period ***referred to in Article 8(4)***:	For devices, other than devices for performance evaluation, economic operators shall be able to identify the following, for ***a*** period ***of 10 years***:

Or. cs

Amendment 186
Alda Sousa

Proposal for a regulation
Article 21 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) any ***health institution*** or healthcare professional to whom they have supplied a device.	(c) any ***organization*** or healthcare professional to whom they have supplied a device.

Or. en

Amendment 187
Rebecca Taylor

Proposal for a regulation
Article 22 – paragraph 2 – point e – point i

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

Or. en

Justification

The UDI System is a vital component of the new Regulatory system, and providers of UDIs should ensure a greater degree of permanence to their role

Amendment 188
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 22 – paragraph 8 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) compatibility with medical device identification systems already on the market.

Or. de

Justification

So that the process runs smoothly, it is important that traceability systems be technically compatible.

Amendment 189
Peter Liese, Alda Sousa, Margrete Auken, Paolo Bartolozzi, Anne Delvaux, Anna Rosbach, Thomas Ulmer, Renate Sommer, Miroslav Mikolášik

Proposal for a regulation
Article 22 – paragraph 8 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) the compatibility with other traceability systems used by the stakeholders involved with medical devices.

Or. en

Justification

It is likely an electronic medicine authentication system will be out in place pursuant to Falsified Medicines Directive. It is important that the systems for in vitro medical devices and medicines are compatible, otherwise this will bring a significant and possibly unmanageable burden for the agents of the supply chain working with both kinds of products.

Amendment 190
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information that is necessary and proportionate to describe and identify the device and to identify the manufacturer and, where applicable, the authorised representative and the importer. The details	1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information that is necessary and proportionate to describe and identify the device and to identify the manufacturer and, where applicable, the authorised representative and the importer***, and to***

regarding the information to be submitted by the economic operators are laid down in Part A of Annex V.	***ensure transparency and safe and effective use by making available to users current evidence concerning the clinical validity and, where applicable, utility of the device***. The details regarding the information to be submitted by the economic operators are laid down in Part A of Annex V.

Or. en

Justification

The principal role of the electronic system set up by the Commission is to ensure public insight through transparent access to information regarding the clinical validity and safe performance of the in-vitro devices.

Amendment 191
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 24 – paragraph 1

Text proposed by the Commission	*Amendment*
1. In the case of devices classified as class C and D, other than devices for performance evaluation, the manufacturer shall draw up a ***summary*** of safety and performance. It shall be written in a way that is clear to the intended user. The draft of this ***summary*** shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 40 and shall be validated by that body.	1. In the case of devices classified as class C and D, other than devices for performance evaluation, the manufacturer shall draw up a ***extensive report*** of safety and performance. It shall be written in a way that is clear to the intended user. The draft of this ***extensive report*** shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 40 and shall be validated by that body.

Or. en

Amendment 192
Antonyia Parvanova

Proposal for a regulation
Article 24 – paragraph 1

Text proposed by the Commission	*Amendment*
1. In the case of devices classified as class C and D, other than devices for performance evaluation, the manufacturer shall draw up a summary of safety and performance. It shall be written in a way that is clear to the intended user. The draft of this summary shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 40 and shall be validated by that body.	1. In the case of devices classified as class C and D, other than devices for performance evaluation, the manufacturer shall draw up a summary of safety and performance. It shall be ***made publicly available and*** written in a way that is clear to the intended user. The draft of this summary shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 40 and shall be validated by that body.

Or. en

Amendment 193
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 25 – paragraph 1

Text proposed by the Commission	*Amendment*
The Commission shall develop and manage the European databank on medical devices (Eudamed) in accordance with the conditions and modalities established by Article 27 of Regulation (EU) [Ref. of future Regulation on medical devices].	The Commission shall develop and manage the European databank on medical devices (Eudamed) in accordance with the conditions and modalities established by Article 27 of Regulation (EU) [Ref. of future Regulation on medical devices]***and ensure public access to it***.

Or. en

Justification

In order to allow for full transparency regarding the quality of products and to demonstrate their safe usage, all relevant information concerning the safety, performance and incidents of in-vitro devices must be publicly available.

Amendment 194
Rebecca Taylor

Proposal for a regulation
Article 25 – paragraph 1

Text proposed by the Commission	*Amendment*
The Commission shall develop and manage the European databank on medical devices (Eudamed) in accordance with the conditions and modalities established by Article 27 of Regulation (EU) [Ref. of future Regulation on medical devices].	The Commission shall develop and manage the European databank on medical devices (Eudamed) in accordance with the conditions and modalities established by Article 27 of Regulation (EU) [Ref. of future Regulation on medical devices]. ***The Commission shall consult patients groups and healthcare professionals when developing the European Databank***

Or. en

Justification

The European Databank provides the main portal through which vital public health related information can be accessed. Information related to registered devices, economic operators, clinical investigations, vigilance data and market-surveillance activities should be available, for both the general public and for healthcare professionals.

Amendment 195
Christofer Fjellner, Anna Rosbach

Proposal for a regulation
Article 26 – paragraph 1 – subparagraph 2 (new)

Text proposed by the Commission	*Amendment*
	Member States may decide that the assessment and monitoring referred to in the first subparagraph shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

Or. en

Justification

Where a Community harmonization legislation provides that a body for conformity assessment shall be appointed for its implementation, transparent accreditation, as provided for in Regulation (EC) No 765/2008, should be considered the preferred means of demonstrating the technical competence of those bodies. However, national authorities may consider that they possess the appropriate means of carrying out this evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements. A transparent accreditation system would strengthen the principle of mutual recognition.

Amendment 196
Dagmar Roth-Behrendt

Proposal for a regulation
Article 26 – paragraph 6 – subparagraph 1

Text proposed by the Commission	*Amendment*
The national authority responsible for notified bodies shall have a sufficient number of competent personnel ***at its disposal*** for the proper performance of its tasks.	The national authority responsible for notified bodies shall have a sufficient number of ***permanent and*** competent personnel ***"in house"*** for the proper performance of its tasks. ***Compliance with that requirement shall be assessed in the peer-review referred to in paragraph 8.*** ***In particular, the personnel of the national authority responsible for auditing the work of personnel of notified bodies in charge of carrying out product related reviews shall have proven qualifications equivalent to those of the personnel of the notified bodies as laid down in point 3.2.5. of Annex VI.*** ***Similarly, the personnel of the national authority responsible for auditing the work of personnel of notified bodies in charge of carrying out audits of the manufacturer's quality management system shall have proven qualifications equivalent to those of the personnel of the notified bodies as laid down in point 3.2.6. of Annex VI.***

Or. en

Amendment 197
Dagmar Roth-Behrendt

Proposal for a regulation
Article 26 – paragraph 6 – subparagraph 2

Text proposed by the Commission	*Amendment*
Without prejudice to Article 31(3), where a national authority is responsible for the designation of notified bodies in the field of products other than in vitro diagnostic medical devices, the competent authority for in vitro diagnostic medical devices shall be consulted on all aspects specifically related to such devices.	Where a national authority is responsible for the designation of notified bodies in the field of products other than in vitro diagnostic medical devices, the competent authority for in vitro diagnostic medical devices shall be consulted on all aspects specifically related to such devices.

Or. en

Amendment 198
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 26 – paragraph 7

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

Or. en

Amendment 199
Dagmar Roth-Behrendt

Proposal for a regulation
Article 26 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Member States shall provide the Commission and the other Member States with information on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any changes thereto.	7. Member States shall provide the Commission and the other Member States with ***all*** information ***they request*** on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any changes thereto.

Or. en

Amendment 200
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 26 – paragraph 8 – subparagraph 2

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

Or. en

Amendment 201
Dagmar Roth-Behrendt

Proposal for a regulation
Article 26 – paragraph 8 – subparagraph 2

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

Or. en

Amendment 202
Dagmar Roth-Behrendt

Proposal for a regulation
Article 27 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil their tasks for which they are designated in accordance with this Regulation. Minimum requirements to be met by notified bodies are set out in Annex VI.	1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil their tasks for which they are designated in accordance with this Regulation. ***In this respect, permanent "in house" administrative, technical and scientific personnel, with pharmacological, medical and technical knowledge is crucial.*** Minimum requirements to be met by notified bodies are set out in Annex VI. ***In particular, in accordance with point 1.2. of Annex VI, the notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities and avoid conflict of interests.***

Or. en

Amendment 203
Dagmar Roth-Behrendt

Proposal for a regulation
Article 28 – paragraph 1

Text proposed by the Commission	*Amendment*
1. ***Where a notified body subcontracts specific tasks connected with conformity*** assessment ***or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the relevant requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly***.	1. ***Notified body shall have permanent "in house" competent personnel and expertise, both in technical fields linked with the*** assessment ***of the performance of the devices, and in the medical field. They shall have the capacity to evaluate "in house" the quality of subcontractors.***
	Subcontracting shall be awarded to public entities. Contracts can also be awarded to external experts for the assessment of innovative medical devices or technologies where clinical expertise is limited.

Or. en

Amendment 204
Dagmar Roth-Behrendt

Proposal for a regulation
Article 28 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the relevant requirements set out in Annex VI and shall inform the national authority responsible for notified bodies

accordingly.

Or. en

Amendment 205
Dagmar Roth-Behrendt

Proposal for a regulation
Article 28 – paragraph 2 a (new)

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

Or. en

Amendment 206
Dagmar Roth-Behrendt

Proposal for a regulation
Article 28 – paragraph 3

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

Or. en

Amendment 207
Dagmar Roth-Behrendt

Proposal for a regulation
Article 28 – paragraph 4

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

Or. en

Amendment 208
Christofer Fjellner, Anna Rosbach

Proposal for a regulation
Article 29 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
The application shall ***specify*** the conformity assessment activities, the conformity assessment procedures and the devices for which the body claims to be competent, supported by documentation proving compliance with all the requirements set out in Annex VI.	The application shall ***be accompanied by a description of*** the conformity assessment activities, the conformity assessment procedures and the devices for which the body claims to be competent, ***as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Annex VI or*** supported by documentation proving compliance with all the requirements set out in Annex VI.

Or. en

Amendment 209
Christofer Fjellner

Proposal for a regulation
Article 29 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VI, the relevant documentation may be submitted in form of a valid certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008. The conformity assessment body shall be presumed to be in conformity with the requirements covered by the certificate delivered by such accreditation body.	***deleted***

Or. en

Amendment 210
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 30 – paragraph 3

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

Or. en

Justification

The guarantee the experts have all the necessary expertise and can discuss the matter thoroughly, the joint assessment team should include at least three experts.

Amendment 211
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 30 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
Within 90 days after designation of the joint assessment team, the national authority responsible for notified bodies and the joint assessment team shall review the documentation submitted with the application in accordance with Article 29 and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process. Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 29(2), unless ***the Commission representative*** mentioned in Article 30(3) requests the on-site assessment.	Within 90 days after designation of the joint assessment team, the national authority responsible for notified bodies and the joint assessment team shall review the documentation submitted with the application in accordance with Article 29 and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process. Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 29(2), unless ***a member of the joint assessment team*** mentioned in Article 30(3) requests the on-site assessment.

Or. en

Amendment 212
Dagmar Roth-Behrendt

Proposal for a regulation
Article 30 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
Findings regarding non-compliance of ***a*** body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team ***with a view to finding common agreement with respect to the assessment of the application. Divergent opinions shall be identified in the*** assessment ***report of the national authority responsible***.	Findings regarding non-compliance of ***an applicant conformity assessment*** body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team***. The national authority shall set out in the assessment report the measures it will take to ensure compliance of that applicant conformity*** assessment ***body with the requirements set out in Annex VI***.

Or. en

Amendment 213
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 30 – paragraph 6

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

Or. en

Amendment 214
Dagmar Roth-Behrendt

Proposal for a regulation
Article 30 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The joint assessment team shall provide its opinion regarding the assessment report and the draft notification within 21 days of receipt of those documents and the Commission shall immediately submit this opinion to the MDCG. Within 21 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft notification ***which*** the relevant national authority shall ***duly take into consideration for*** its decision on the designation of the notified body.	6. The joint assessment team shall provide its opinion regarding the assessment report and the draft notification within 21 days of receipt of those documents and the Commission shall immediately submit this opinion to the MDCG. Within 21 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft notification***.*** The relevant national authority shall ***base*** its decision on the designation of the notified body ***on this recommendation by the MDCG. In case where its decision differs from that recommendation, the national authority shall provide the MDCG with all necessary justifications***.

Or. en

Amendment 215
Dagmar Roth-Behrendt

Proposal for a regulation
Article 31 – paragraph 2

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

Or. en

Amendment 216
Dagmar Roth-Behrendt

Proposal for a regulation
Article 31 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where a national authority responsible for notified bodies is responsible for designation of notified bodies in the field of products other than in vitro diagnostic medical devices, the competent authority for in vitro diagnostic medical devices shall provide, prior to the notification, a positive opinion on the notification and its scope.	***deleted***

Or. en

Amendment 217
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 31 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The notification shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the opinion of the joint assessment team and the recommendation of the MDCG. Where the notifying Member State does not ***follow*** the recommendation of the MDCG, it ***shall*** provide a duly substantiated ***justification***.	5. The notification shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the opinion of the joint assessment team and the ***binding*** recommendation of the MDCG. Where the notifying Member State does not ***agree with*** the recommendation of the MDCG, it ***may*** provide a duly substantiated ***argumentation for its opinion that will be publicly available***.

Or. en

Amendment 218
Dagmar Roth-Behrendt

Proposal for a regulation
Article 31 – paragraph 8

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

Or. en

Amendment 219
Margrete Auken

Proposal for a regulation
Article 32 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission shall make accessible to the public the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them ***and*** the activities for which they have been notified. The Commission shall ensure that the list is kept up to date.	2. The Commission shall make accessible to the public the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them***,*** the activities for which they have been notified ***and all documents for the notification procedure as referred to in Article 31(5)***. The Commission shall ensure that the list is kept up to date.

Or. en

Amendment 220
Dagmar Roth-Behrendt

Proposal for a regulation
Article 32 – paragraph 2

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

Or. en

Amendment 221
Dagmar Roth-Behrendt

Proposal for a regulation
Article 33 – paragraph 1 – subparagraph 2

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

Or. en

Amendment 222
Dagmar Roth-Behrendt

Proposal for a regulation
Article 33 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Notified bodies shall respond without delay to requests relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission. The national authority responsible for notified bodies of the Member State in which the body is established shall enforce requests submitted by authorities of any other Member State or by the Commission ***unless*** there is a legitimate reason for not doing so ***in which case both sides may*** consult the MDCG***. The notified body or their*** national authority responsible for notified bodies ***may request that any information transmitted to the authorities of another Member State or to the Commission shall be treated as confidential***.	2. Notified bodies shall respond without delay***, and at least within 15 days,*** to requests relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission. The national authority responsible for notified bodies of the Member State in which the body is established shall enforce requests submitted by authorities of any other Member State or by the Commission***. Where*** there is a legitimate reason for not doing so***, the notified bodies shall explain these reasons and shall*** consult the MDCG***, which shall then issue a recommendation. The*** national authority responsible for notified bodies ***shall comply with the MDCG's recommendation***.

Or. en

Amendment 223
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 33 – paragraph 5

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

Or. en

Amendment 224
Rebecca Taylor

Proposal for a regulation
Article 34 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations, the authority shall suspend, restrict, or fully or partially withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. ***A*** suspension shall ***not exceed a period of one year, renewable once for the same period***. Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.	Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations, the authority shall suspend, restrict, or fully or partially withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. ***Suspension shall apply until a decision to annul the*** suspension ***has been reached by the MDCG, which*** shall ***follow an assessment by a joint assessment team designated in accordance with the procedure described in Article 30(3) and (4)***. Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.

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 225
Dagmar Roth-Behrendt

Proposal for a regulation
Article 34 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
The national authority responsible for	The national authority responsible for

notified bodies shall immediately inform the Commission and the other Member States of any suspension, restriction or withdrawal of a notification.	notified bodies shall immediately ***and at least within 10 days,*** inform the Commission and the other Member States of any suspension, restriction or withdrawal of a notification.

Or. en

Amendment 226
Dagmar Roth-Behrendt

Proposal for a regulation
Article 34 – paragraph 4

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

Or. en

Amendment 227
Dagmar Roth-Behrendt

Proposal for a regulation
Article 34 – paragraph 5 – subparagraph 2

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

Or. en

Amendment 228
Rebecca Taylor

Proposal for a regulation
Article 35 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
3. Where the Commission ***ascertains*** that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the notification if necessary.	3. Where the Commission***, in consultation with the Medical Devices Coordination Group, decides*** that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the notification***,*** if necessary***, in line with Article 34(2)***.

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 229
Rebecca Taylor

Proposal for a regulation
Article 37 – paragraph 1

Text proposed by the Commission	*Amendment*
The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of the coordination group of notified bodies referred to in Article 39 of Regulation [Ref. of future Regulation on medical devices].	The Commission***, in consultation with the Medical Devices Coordination Group,*** shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of the coordination group of notified bodies referred to in Article 39 of Regulation [Ref. of future Regulation on medical devices].

Or. en

Justification

The coordination group should be an effective forum for discussion, and should allow experience-sharing between Notified Bodies, but also between Notified Bodies and competent authorities

Amendment 230
Dagmar Roth-Behrendt

Proposal for a regulation
Article 37 – paragraph 1

Text proposed by the Commission	*Amendment*
The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of the coordination group of notified bodies referred to in Article 39 of Regulation [Ref. of future Regulation on medical devices].	The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of the coordination group of notified bodies referred to in Article 39 of Regulation [Ref. of future Regulation on medical devices]. ***This group shall meet on a regular basis and at least twice a year.***

Or. en

Amendment 231
Rebecca Taylor

Proposal for a regulation
Article 37 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	The group shall meet, at the least, every 6 months

Or. en

Justification

The coordination group should be an effective forum for discussion, and should allow scrutiny by the Commission and competent authorities. The minimum frequency of their meetings should be defined in the text

Amendment 232
Rebecca Taylor

Proposal for a regulation
Article 37 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	The Commission or the MDCG may request the participation of any notified body.

Or. en

Justification

The coordination group should be an effective forum for discussion, and should allow scrutiny by the Commission and competent authorities. It should be made clear that attendance is compulsory if requested by the Commission or MDCG

Amendment 233
Rebecca Taylor

Proposal for a regulation
Article 37 – paragraph 2 c (new)

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

Or. en

Justification

The coordination group should be an effective forum for discussion, and should allow experience-sharing between Notified Bodies, but also between Notified Bodies and competent authorities. The modalities for the functioning of the coordination group should be further developed through implementing acts

Amendment 234
Dagmar Roth-Behrendt

Proposal for a regulation
Article 38 – title

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

Or. en

Amendment 235
Dagmar Roth-Behrendt

Proposal for a regulation
Article 38 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies in accordance with this Regulation.	1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies in accordance with this Regulation. ***These fees shall be comparable across Member States and the level of the fees shall be made public.***

Or. en

Amendment 236
Dagmar Roth-Behrendt

Proposal for a regulation
Article 38 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 setting out the structure and the level of the fees referred to in paragraph 1, taking into account the objectives of protection of human health and safety, support of innovation ***and cost-effectiveness***. Particular attention shall be paid to the interests of notified bodies that received a certificate delivered by the national accreditation body as referred to in Article 29(2) and notified bodies that are small and medium-sized enterprises as defined by the Commission Recommendation 2003/361/EC.	2. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 setting out the structure and the ***comparable*** level of the fees referred to in paragraph 1, taking into account the objectives of protection of human health and safety, support of innovation***, cost-effectiveness and the need to create a level-playing field across Member States***. Particular attention shall be paid to the interests of notified bodies that received a certificate delivered by the national accreditation body as referred to in Article 29(2) and notified bodies that are small and medium-sized enterprises as defined by the Commission Recommendation 2003/361/EC.

Or. en

Amendment 237
Dagmar Roth-Behrendt

Proposal for a regulation
Article 38 a (new)

Text proposed by the Commission	*Amendment*
	Article 38a
	Transparency on fees charged by notified bodies for conformity assessment activities
	1. Member States shall adopt regulations on standard fees for notified bodies.
	2. Fees shall be comparable across Member States. The Commission shall provide guidelines to facilitate comparability of those fees within 24 months from the date of entry into force of this Regulation.
	3. Member States shall transmit their list of standard fees to the Commission.
	4. The national authority shall ensure that the notified bodies make the lists of standard fees for the conformity assessment activities publicly available.

Or. en