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Committee on the Environment, Public Health and Food Safety

2012/0267(COD)

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AMENDMENTS
238 - 399

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 238
Margrete Auken

Proposal for a regulation
Chapter 5 – title

Text proposed by the Commission	*Amendment*
Classification and conformity assessment	Classification***, marketing authorisation*** and conformity assessment

Or. en

Amendment 239
Alda Sousa

Proposal for a regulation
Article 39 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Devices shall be divided into class A, B, C and D, taking into account their intended purpose and inherent risks. Classification shall be carried out in accordance with the classification criteria set out in Annex VII.	1. Devices shall be divided into class A, B, C and D, taking into account their intended purpose***, novelty, complexity*** and inherent risks. Classification shall be carried out in accordance with the classification criteria set out in Annex VII.

Or. en

Amendment 240
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 5 – title

Text proposed by the Commission	*Amendment*
Chapter ***V***	Chapter ***III***
Classification and conformity assessment	***Marketing authorisation*** and conformity assessment

Or. en

Amendment 241
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 5 – section 1 – title

Text proposed by the Commission	*Amendment*
Section 1 – Classification	***Chapter II*** Classification

Or. en

Amendment 242
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 5 – section 1 a – Article 39 a (new)

Text proposed by the Commission	*Amendment*
	Section 1a – Marketing authorisation
	Article 39 a (new)
	General principles regarding the marketing authorisation
	1. None of the innovative class D devices may be placed on the market within the Union unless a Union marketing authorisation has been granted through the centralised procedure referred to in Article 39c, and in accordance with the provisions of this Regulation.
	2. None of the non-innovative class D devices may be placed on the market of a Member State unless a national marketing authorisation has been granted by the competent authority of that Member State through the decentralised procedure referred to in Article 39d, and in accordance with the provisions of this

Regulation.

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

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 to amend the list set out in paragraph 1, in the light of technical progress.

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

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

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

7. All applications for marketing authorisation and granted marketing authorisations under the provisions of Articles 39c, 39d, 39e and 39f as well as the information referred to in Article 39b shall be entered either by the Commission or the Member States, as relevant, in the electronic system referred to in Article 39b(1), without delay and at the latest 15 days after receipt.

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

Or. en

Amendment 243
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 5 – Section 1 a – Article 39 b (new)

Text proposed by the Commission	*Amendment*
	Article 39 b (new)
	Electronic system on marketing authorisations
	1. The Commission shall, in collaboration with the Member States, set up and manage an electronic registration system for the applications for marketing authorisations and granted marketing authorisations under this Section and to collate and process the following information:
	- the name of the manufacturer,
	- the name and the risk-class of the medical device,
	- the applicable procedure,
	- in the case of a decentralised procedure, the Member State in which the manufacturer has applied,
	- the documentation accompanying the application for a marketing authorisation,
	- the assessment report for the medical device issued during the marketing authorisation procedure,
	- the date of the marketing authorisation approval and, where different, the date on which the device is placed on the market,
	- any information regarding the suspension or withdrawal of the marketing authorisation.
	2. The information collated and processed in the electronic system which relates to

the centralised procedure as referred to in Article 39c shall be entered into the electronic registration system by the European Medicines Agency

The information collated and processed in the electronic system which relates to the decentralised procedure as referred to in Article 39d shall be entered into the electronic registration system by the Member States.

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

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

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

Or. en

Amendment 244
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 5 – Section 1 a – Article 39 c (new)

Text proposed by the Commission	*Amendment*
	Article 39 c (new)
	Centralised procedure
	1. A Committee for the Authorisation of In Vitro Diagnostic Medical Devices is

hereby established in accordance with the provisions of Article 39d. The Committee shall be part of the European Medicines Agency.

2. The Committee for the Authorisation of In Vitro Diagnostic Medical Devices shall be responsible for drawing up the opinion of the Agency on any matter concerning the admissibility of applications submitted in accordance with the centralised procedure, the granting, variation, suspension or revocation of an authorisation to place class D devices on the market.

3. Each application for the devices referred to in Article 39a (1) shall include the particulars and documents as referred to in Annexes VII, IX and X, as relevant.

4. The application shall be accompanied by the fee payable to the Agency for examining the application.

5. The Agency shall ensure that the opinion of the Committee for the Authorisation of In Vitro Diagnostic Medical Devices is issued within 210 days from receipt of a valid application.

The Committee for the Authorisation of Medical Devices shall be given at least 80 days from receipt of an application for analysing the scientific data in the documentation accompanying an application for a marketing authorisation. On the basis of a duly reasoned request, from the Committee for the Authorisation of In Vitro Diagnostic Medical Devices, the Agency may extend that period.

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

referred to in paragraph 5 shall be suspended until the additional information requested has been supplied.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15. The Commission shall take a final decision within 30 days from the end of the examination procedure referred to in Article 84(3).

16. The refusal of a marketing authorisation shall constitute a prohibition on the placing on the market of the devices referred to in Article 39a(1) throughout the Union.

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

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

Or. en

Amendment 245
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 5 – Section 1 a – Article 39 d (new)

Text proposed by the Commission	*Amendment*
	Article 39d
	Committee for the Authorisation of In Vitro Diagnostic Medical Devices
	1. The Committee for the Authorisation of In Vitro Diagnostic Medical Devices shall be composed of the following:
	(a) one member and one alternate member appointed by each Member State, in accordance with paragraph 3 of this Article;
	(b) six members appointed by the Commission, with a view to ensuring that the relevant expertise in the field of medical devices is available within the Committee, on the basis of a public call for expressions of interest;
	(c) one member and one alternate member appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European

Parliament, in order to represent healthcare professionals;

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

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

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

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

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

once.

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

6. The mandate of the Committee for the Authorisation of In Vitro Diagnostic Medical Devices shall cover all aspects of the evaluation of medical devices in the scope of the procedures under Articles 39c and 39f ;

Or. en

Amendment 246
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 5 – Section 1 a – Article 39 e (new)

Text proposed by the Commission	*Amendment*
	Article 39e
	Decentralised procedure
	1. Member States shall verify through the electronic system on marketing authorisations referred to in Article 39b that no other application is currently being reviewed, and that no other marketing authorisation has been granted for the same medical device.
	2. Where a Member State notes that another application for a marketing authorisation for the same in vitro diagnostic medical device is being examined in another Member State, the Member State concerned shall decline to assess the application and immediately inform the applicant.
	3. Where a Member State has authorised a in vitro diagnostic medical device which is the subject of an application for a marketing authorisation in another

Member State, the latter shall reject the application and immediately inform the applicant.

4. Member States shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for devices referred to in Article 39a (2) is completed within a maximum of 210 days after the submission of a valid application.

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

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

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

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

9. The national competent authority shall

draw up an assessment report and make comments on the file, notably as regards the result of the clinical investigations and the risk management system.

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

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

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

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

Or. en

Amendment 247
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 5 – Section 1 a – Article 39 f (new)

Text proposed by the Commission	*Amendment*
	Article 39f
	Mutual recognition of decentralised marketing authorisation
	1. The MDCG as established by Article 76 shall be responsible for the examination

of any question relating to a marketing authorisation in more than one Member State of a medical device eligible for authorisation in accordance with the procedure laid down in Article 39e.

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

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

4. In cases where the in vitro diagnostic medical device has not received a marketing authorisation at the time of application, the applicant shall request

the reference Member State to prepare a draft assessment report. The reference Member State shall prepare the report within 120 days after receipt of a valid application and it shall send them to the Member States concerned and to the applicant.

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

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

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

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

9. If the Member States fail to reach an agreement within the 60-day period laid down in paragraph 7, the Agency shall be informed immediately, with a view to the application of the procedure under Article 39g. The Agency shall be provided with a detailed statement of the matters on which the Member States have been unable to reach agreement and the reasons for their disagreement. A copy shall be transmitted to the applicant.

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

11. In the circumstances referred to in paragraph 9, Member States that have approved the assessment report of the reference Member State may, at the request of the applicant, authorise the medical device without waiting for the outcome of the procedure laid down in Article 39g. In that event, the authorisation granted shall be without prejudice to the outcome of that procedure.

Or. en

Amendment 248
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 5 – Section 1 a – Article 39 g (new)

Text proposed by the Commission	*Amendment*
	Article 39g
	Arbitration procedure in the event of disagreement over mutual recognition of decentralised marketing authorisation
	1. Where reference is made to the procedure laid down in this Article, the Committee on Medical Devices referred to

in Article 84(1) shall consider the matter concerned and shall issue a reasoned opinion within 60 days of the date on which the matter was referred to it.

In urgent cases, and on a proposal from its Chairperson, the Committee may agree to a shorter deadline.

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

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

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

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

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

Within 60 days following receipt of the grounds for the request, the Committee shall re-examine its opinion. It shall appoint a different rapporteur and, where

necessary, a different co-rapporteur from the rapporteur and co-rapporteur appointed for the initial opinion. The re-examination procedure shall deal only with the points of the opinion identified by the applicant or the marketing authorisation holder and shall be based only on the scientific data available when the Committee adopted the initial opinion. The applicant or the marketing authorisation holder may request that the Committee consult the advisory committee as established by Article 78a of Regulation (EU) [Ref. future Regulation on medical devices] in connection with the re-examination.

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

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

In the event of a favourable opinion concerning the application for a mutual recognition of decentralised marketing authorisation for a medical device as referred to in Article 39f, the following documents shall be annexed to the opinion:

(a) the dossier documents, as referred to in Article 39f (2);

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

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

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

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

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

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

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

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

7. Member States may request in writing that the draft decision referred to in paragraph 6 be discussed by a plenary meeting of the Committee on Medical Devices, as referred to in Article 84(1), stating their reasons in detail.

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

consideration.

8. The Commission shall take a final decision in accordance with, and within 30 days after the end of, the procedure referred to in Article 84(3). The Commission shall update the information on the concerned device in the electronic system referred to in Article 39b.

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

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

Or. en

Amendment 249
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 5 – Section 1 a – Article 39 h (new)

Text proposed by the Commission	*Amendment*
	Article 39h
	Variation to a marketing authorisation
	1. Any application by the marketing authorization holder to vary a marketing authorization which has been granted in accordance with the provisions of Articles 39c, 39e and 39f shall be submitted to all the Member States which have previously authorized the in vitro diagnostic medical

device concerned.

The Commission shall, in consultation with the Agency, be empowered to adopt delegated acts in accordance with Article 85 of this Regulation in order to adopt the appropriate arrangements for the examination of variations to the terms of a marketing authorization.

2. In case of arbitration submitted to the Commission, the procedure laid down in Article 39g shall apply by analogy to variations made to marketing authorizations.

3. Where a Member State considers that the variation of a marketing authorization which has been granted in accordance with the provisions of this Chapter or its suspension or withdrawal is necessary for the protection of public health, the Member State concerned shall forthwith refer the matter to the Agency for the application of the procedure laid down in Article 39g.

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

Or. en

Amendment 250
Margrete Auken

Proposal for a regulation
Article 39 a (new)

Text proposed by the Commission	*Amendment*
	Article 39 a
	Marketing authorisation procedure
	1. Devices of class D may only be placed on the market within the Union when a Union marketing authorisation has been granted through the centralised procedure referred to in Article 41c, and in accordance with the provisions of this Regulation.
	2. Devices referred to in paragraphs 1 and which are already on the Union market at the date of entry into force of this Regulation, shall be required to have a marketing authorisation, in accordance with the procedures set out in this Section, as from the expiry date of the validity of their certificate.
	3. A marketing authorisation granted under this Section shall be valid for five years. The marketing authorisation may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the Agency.
	4. All applications for marketing authorisation and granted marketing authorisations under the provisions of Articles 41c, 41d, 41e and 41f as well as the information referred to in Article 41b shall be entered either by the Commission or the Member States, as relevant, in the electronic system referred to in Article 41b(1), without delay and at the latest 15 days after receipt. Before commencing the review of an application for a medical device, the Committee for the Authorisation of Medical Devices, as referred to in Article 41c, or the competent authority of the relevant Member State shall verify that no other application has been introduced for the same medical device.

Or. en

Amendment 251
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 39 b (new)

Text proposed by the Commission	*Amendment*
	Article 39 b
	Electronic system on marketing authorisations
	1. The Commission shall, in collaboration with the Member States, set up and manage an electronic registration system for the applications for marketing authorisations and granted marketing authorisations under this Section and to collate and process the following information:
	- the name of the manufacturer,
	- the name of the in vitro diagnostic medical device,
	- the documentation accompanying the application for a marketing authorisation,
	- the assessment report for the in vitro diagnostic medical device issued during the marketing authorisation procedure,
	- the date of the marketing authorisation approval and, where different, the date on which the device is placed on the market,
	- any information regarding the suspension or withdrawal of the marketing authorisation.
	2. The information collated and processed shall be entered into the electronic registration system by the European Medicines Agency.
	3. In case where this information needs to be updated, with regards to placing of the

device on the market, the suspension or withdrawal of the device from the market, the manufacturer shall immediately inform the Agency, who shall immediately update the information in the electronic system.

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

Or. en

Amendment 252
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 39 c (new)

Text proposed by the Commission	*Amendment*
	Article 39 c
	Centralised procedure
	1. A Committee for the Authorisation of In Vitro Diagnostic Medical Devices is hereby established in accordance with the provisions of Article 39d. The Committee shall be part of the European Medicines Agency.
	2. The Committee for the Authorisation of In Vitro Diagnostic Medical Devices shall be responsible for drawing up the opinion of the Agency on any matter concerning the admissibility of applications submitted in accordance with the centralised procedure.
	3. Each application for the devices referred to in Article 39a (1) shall include

the particulars and documents as referred to in Annexes VII, VIII, IX and X, as relevant.

4. The application shall be accompanied by the fee payable to the Agency for examining the application.

5. The Agency shall ensure that the opinion of the Committee for the Authorisation of In Vitro Diagnostic Medical Devices is issued within 210 days from receipt of a valid application. The Committee for the Authorisation of In Vitro Diagnostic Medical Devices shall be given at least 80 days from receipt of an application for analysing the scientific data in the documentation accompanying an application for a marketing authorisation. On the basis of a duly reasoned request, from the Committee for the Authorisation of In Vitro Diagnostic Medical Devices, the Agency may extend that period.

6. The Committee may only once request the manufacturer to submit additional information that for scientifically valid grounds is necessary for the assessment of the application for marketing authorisation. Where such a request has been made, the period referred to in paragraph 5 shall be suspended until the additional information requested has been supplied.

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

8. Where the Committee for the Authorisation of In Vitro Diagnostic Medical Devices considers it necessary in order to complete its examination of an application, it may require the applicant to undergo a specific inspection of the manufacturing site of the in vitro diagnostic medical device concerned.

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

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

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

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

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

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

10. Within 15 days of receipt of the opinion referred to in paragraph 9, the applicant may notify the Agency in writing of his intention to request a reexamination of the opinion. In such a case, the applicant shall transmit to the Agency the detailed grounds for such a request within 60 days of receipt of the opinion. Within 60 days following receipt of the grounds for the request, the Committee for the Authorisation of In Vitro Diagnostic Medical Devices shall re-examine its opinion. The Committee for the Authorisation of In Vitro Diagnostic Medical Devices shall appoint a different rapporteur and, where necessary, a different co-rapporteur from those

appointed for the initial opinion. The re-examination procedure may deal only with the points of the opinion initially identified by the applicant and may be based only on the scientific data available when the Committee for the Authorisation of In Vitro Diagnostic Medical Devices adopted the initial opinion. The applicant may request that the Committee for the Authorisation of In Vitro Diagnostic Medical Devices consult a scientific advisory group in connection with the re-examination.

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

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

13. Within 15 days of receipt of the opinion referred to in paragraph 11, the Commission shall prepare a draft of the decision to be taken in respect of the application. Where the draft decision diverges from the opinion of the Agency, the Commission shall annex a detailed explanation of the reasons for the differences. The draft decision shall be transmitted to the Member States and the applicant. Member States shall have 22 days to submit their written observations

on the draft decision to the Commission. However, if a decision has to be taken urgently, a shorter time-limit may be set by the Chairperson of the Committee on In Vitro Diagnostic Medical Devices according to the degree of urgency involved. This time-limit shall not, otherwise than in exceptional circumstances, be shorter than 5 days;

14. Member States may request in writing that the draft decision referred to in paragraph 13 be discussed by a plenary meeting of the Committee on In Vitro Diagnostic Medical Devices, stating their reasons in detail. Where, in the opinion of the Commission, a Member State's written observations raise important new questions of a scientific or technical nature which the opinion delivered by the Agency has not addressed, the Chairperson of the Committee on In Vitro Diagnostic Medical Devices shall suspend the procedure and refer the application back to the Agency for further consideration.

15. The Commission shall take a final decision within 30 days from the end of the examination procedure referred to in Article [...].

16. The refusal of a marketing authorisation shall constitute a prohibition on the placing on the market of the devices referred to in Article 39a(1) throughout the Union.

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

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

economic grounds in this respect.

Or. en

Amendment 253
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 39 d (new)

Text proposed by the Commission	*Amendment*
	Article 39 d
	Committee for the Authorisation of In Vitro Diagnostic Medical Devices
	1. The Committee for the Authorisation of In Vitro Diagnostic Medical Devices shall be composed of the following:
	(a) one member and one alternate member appointed by each Member State, in accordance with paragraph 3 of this Article;
	(b) six members appointed by the Commission, with a view to ensuring that the relevant expertise in the field of medical devices is available within the Committee, on the basis of a public call for expressions of interest;
	(c) one member and one alternate member appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent healthcare professionals;
	(d) one member and one alternate member appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent patient organisations. The alternate members shall represent and vote for the members in their absence. The alternate members

referred to in point (a) may be appointed to act as rapporteurs in accordance with Article 62 of Regulation (EC) 726/2004.

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

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

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

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

6. The mandate of the Committee for the Authorisation of In Vitro Diagnostic Medical Devices shall cover all aspects of the evaluation of medical devices in the scope of the procedures under Articles 39c;

Or. en

Amendment 254
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 39 e (new)

Text proposed by the Commission	*Amendment*
	Article 39 e
	The actors in the Committee for the Authorisation of In Vitro Diagnostic Medical Devices shall undertake to act independently in the public interest. Prior to taking up their duties, they 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 255
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 39 f (new)

Text proposed by the Commission	*Amendment*
	Article 39 f
	Variation to a marketing authorisation
	1. Any application by the marketing authorization holder to vary a marketing authorization which has been granted in accordance with the provisions of Article

41c shall be submitted to the Commission. The Commission shall, in consultation with the Agency, be empowered to adopt delegated acts in accordance with Article 89 of this Regulation in order to adopt the appropriate arrangements for the examination of variations to the terms of a marketing authorization.

2. Where a Member State considers that the variation of a marketing authorization which has been granted in accordance with the provisions of this Chapter or its suspension or withdrawal is necessary for the protection of public health, the Member State concerned may request a discussion by a plenary meeting of the Committee on In Vitro Diagnostic Medical Devices, stating their reasons in detail. In exceptional cases where, in the opinion of the Commission, a Member State's written observations raise important new questions of a scientific or technical nature which the authorisation delivered has not addressed, the Chairperson of the Committee on In Vitro Diagnostic Medical Devices shall suspend the authorization and refer the application to the Agency for further consideration.

Or. en

Amendment 256
Margrete Auken
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
Manufacturers of devices classified as class D, other than devices for performance evaluation, shall be subject to a ***conformity assessment based on full quality***	Manufacturers of devices classified as class D, other than devices for performance evaluation, shall be subject to a ***centralised marketing authorisation procedure***.

assurance, design dossier examination and batch verification, as specified in Annex VIII. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX, coupled with a conformity assessment based on production quality assurance including batch verification, as specified in Annex X.

Or. en

Amendment 257
Dagmar Roth-Behrendt

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

Text proposed by the Commission	*Amendment*
Manufacturers of devices classified as class D, other than devices for performance evaluation, shall be subject to a ***conformity assessment*** based on full quality assurance, design dossier examination and batch verification, as specified in Annex VIII. Alternatively, the manufacturer may choose to apply a ***conformity assessment*** based on type examination as specified in Annex IX, coupled with a ***conformity assessment*** based on production quality assurance including batch verification, as specified in Annex X.	Manufacturers of devices classified as class D, other than devices for performance evaluation, shall be subject to a ***marketing authorisation*** based on full quality assurance, design dossier examination and batch verification, as specified in Annex VIII. Alternatively, the manufacturer may choose to apply a ***marketing authorisation*** based on type examination as specified in Annex IX, coupled with a ***marketing authorisation*** based on production quality assurance including batch verification, as specified in Annex X.

Or. en

Amendment 258
Dagmar Roth-Behrendt

Proposal for a regulation
Article 40 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
In addition, where a reference laboratory is designated in accordance with Article 78, the ***notified body performing the conformity assessment*** shall request that reference laboratory to verify compliance of the device with the applicable CTS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as specified in Section 5.4 of Annex VIII and in Section 3.5 of Annex IX.	In addition, where a reference laboratory is designated in accordance with Article 78, the ***Committee for the Authorisation of In Vitro Diagnostic Medical Device referred to in Article 39c, or the national authority,*** shall request that reference laboratory to verify compliance of the device with the applicable CTS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as specified in Section 5.4 of Annex VIII and in Section 3.5 of Annex IX.

Or. en

Amendment 259
Peter Liese, Margrete Auken, Paolo Bartolozzi, Anne Delvaux, Anna Rosbach, Thomas Ulmer, Zofija Mazej Kukovič, Renate Sommer, Miroslav Mikolášik

Proposal for a regulation
Article 40 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
In addition, where a reference laboratory is designated in accordance with Article 78, the notified body performing the conformity assessment shall request that reference laboratory to verify compliance of the device with the applicable CTS, ***when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as specified in Section 5.4 of Annex VIII and in Section 3.5 of Annex IX***.	In addition, where a reference laboratory is designated in accordance with Article 78, the notified body performing the conformity assessment shall request that reference laboratory to verify ***by laboratory testing*** compliance of the device with the applicable CTS, ***as specified in Section 5.4 of Annex VIII and in Section 3.5 of Annex IX. Laboratory tests performed by a reference laboratory shall focus on in particular analytic sensitivity and specificity using reference materials and diagnostic sensitivity and specificity using specimens from early and established infection***.

Or. en

Justification

Experiences with the current legislation call for a clear description that the involvement of reference laboratories means to perform testings and not paper investigations.

Amendment 260
Anna Rosbach

Proposal for a regulation
Article 40 – paragraph 2 – subparagraph 3

Text proposed by the Commission	*Amendment*
For companion diagnostics ***intended to be used to assess the patient eligibility for treatment with a specific medicinal product, the notified body shall consult one of the competent authorities*** designated ***by the Member States*** in accordance with ***Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use or the European Medicines Agency (EMA) in accordance*** with the ***procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX***.	For companion diagnostics ***where a reference laboratory has been*** designated in accordance with ***Article 78, the notified body performing the conformity assessment shall request that reference laboratory to verify compliance of the device*** with the ***applicable CTS, when available***.

Or. en

Justification

This will change the path for companion Diagnostics to co-development of CTS between EMA and IVD experts from Notified bodies and competent authorities for IVD medical devices.

Amendment 261
Dagmar Roth-Behrendt

Proposal for a regulation
Article 40 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
Manufacturers of devices classified as class C, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality assurance, as specified in Annex VIII, with assessment of the design documentation within the technical documentation on a representative basis. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination, as specified in Annex IX coupled with conformity assessment based on production quality assurance, as specified in Annex X.	***By way of derogation from Article 39a,*** manufacturers of devices classified as class C, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality assurance, as specified in Annex VIII, with assessment of the design documentation within the technical documentation on a representative basis. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination, as specified in Annex IX coupled with conformity assessment based on production quality assurance, as specified in Annex X.

Or. en

Amendment 262
Anna Rosbach

Proposal for a regulation
Article 40 – paragraph 3 – subparagraph 3

Text proposed by the Commission	*Amendment*
For companion diagnostic ***intended to be used to assess the patient eligibility to a treatment with a specific medicinal product***, the notified body ***shall consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the European Medicines Agency (EMA) in accordance*** with the ***procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX***.	For companion diagnostic ***where a reference laboratory is designated in accordance with Article 78***, the notified body ***performing the conformity assessment shall request that reference laboratory to verify compliance of the device*** with the ***applicable CTS, when available***.

Or. en

Justification

This will change the path for companion Diagnostics to co-development of CTS between EMA and IVD experts from Notified bodies and competent authorities for IVD medical devices

Amendment 263
Dagmar Roth-Behrendt

Proposal for a regulation
Article 40 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
Manufacturers of devices classified as class B, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality assurance, as specified in Annex VIII.	***By way of derogation from Article 39a,*** manufacturers of devices classified as class B, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality assurance, as specified in Annex VIII.

Or. en

Amendment 264
Dagmar Roth-Behrendt

Proposal for a regulation
Article 40 – paragraph 5 – subparagraph 1

Text proposed by the Commission	*Amendment*
Manufacturers of devices classified as class A, other than devices for performance evaluation, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 15, after drawing up the technical documentation set out in Annex II.	***By way of derogation from Article 39a,*** manufacturers of devices classified as class A, other than devices for performance evaluation, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 15, after drawing up the technical documentation set out in Annex II.

Or. en

Amendment 265
Dagmar Roth-Behrendt

Proposal for a regulation
Article 40 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Manufacturers may choose to apply a conformity assessment procedure applicable to devices of a higher class than the device in question.	6. Manufacturers may choose to apply a ***marketing authorisation or a*** conformity assessment procedure applicable to devices of a higher class than the device in question.

Or. en

Amendment 266
Dagmar Roth-Behrendt

Proposal for a regulation
Article 40 – paragraph 9 – subparagraph 1 – indent 3

Text proposed by the Commission	*Amendment*
– the frequency of samples of the manufactured devices or batches of devices classified as class D to be sent to a reference laboratory designated under Article 78 in accordance with Section 5.7 of Annex VIII and Section 5.1 of Annex X, or	***deleted***

Or. en

Amendment 267
Dagmar Roth-Behrendt

Proposal for a regulation
Article 41 – title

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

Or. en

Amendment 268
Dagmar Roth-Behrendt

Proposal for a regulation
Article 41 – paragraph 1

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

Or. en

Amendment 269
Milan Cabrnoch

Proposal for a regulation
Article 42

Text proposed by the Commission	*Amendment*
	Article deleted

Or. cs

Amendment 270
Anja Weisgerber

Proposal for a regulation
Article 42

Text proposed by the Commission	*Amendment*
	Article deleted

Or. de

Justification

If the safety of medical devices is to be enhanced, it is particularly vital that the role of notified bodies should be strengthened. The use of the scrutiny procedure may mean that highly innovative medical devices become available to patients only after a considerable delay.

Amendment 271
Dagmar Roth-Behrendt

Proposal for a regulation
Article 42

Text proposed by the Commission	*Amendment*
	deleted

Or. en

Amendment 272
Christofer Fjellner, Anna Rosbach

Proposal for a regulation
Article 42

Text proposed by the Commission	*Amendment*
	deleted

Or. en

Justification

The proposal counteracts with the basic principles of the CE marking of products, in which the manufacturer is responsible for ensuring that the product meets the applicable requirements and is properly CE marked. Article 42 introduce a review process in which agencies should examine products in the highest risk category, Class D, before they are CE marked and placed on the market. This form of pre-approval shifts responsibility from the manufacturer of the product to the authorities. A pre-approval system for in vitro medical devices will also increase the administrative burden for manufacturers, notified bodies, authorities and the Commission, without ensuring an actual increase in the safety for patients.

Amendment 273
Alda Sousa

Proposal for a regulation
Article 42 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Notified bodies shall notify the Commission of applications for conformity assessments for devices classified as class D, with the exception of applications to supplement or renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and performance referred to in Article 24. In its notification the notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the MDCG.	1. Notified bodies shall notify the Commission of applications for conformity assessments for devices classified as class D ***and for devices classified as class C which fulfil the definition of novelty set out in Article 2(12a)***, with the exception of applications to supplement or renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and performance referred to in Article 24. In its notification the notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the MDCG.

Or. en

Amendment 274
Milan Cabrnoch

Proposal for a regulation
Article 43 – paragraph 1

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

Or. cs

Amendment 275
Dagmar Roth-Behrendt

Proposal for a regulation
Article 44 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. ***In cases*** where a manufacturer ***terminates*** his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the modalities of the change of notified body shall be clearly defined in an agreement between the manufacturer, the outgoing notified body and the incoming notified body. This agreement shall address at least the following aspects:	1. Where a manufacturer ***decides to terminate*** his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, ***it shall inform its national authority responsible for the notified bodies of this change.*** The modalities of the change of notified body shall be clearly defined in an agreement between the manufacturer, the outgoing notified body and the incoming notified body. This agreement shall address at least the following aspects:

Or. en

Amendment 276
Jolanta Emilia Hibner

Proposal for a regulation
Article 45 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Upon request by a Member State and where this is in the interest of public health or patient safety in more than one Member State, the Commission may, by means of implementing acts, extend for a determined period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	***deleted***
On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 84(4).	

Or. pl

Justification

Art. 45 ust. 3 wskazuje, że Komisja może rozszerzyć na cały obszar EU decyzję państwa członkowskiego, które wyraziło zgodę na wprowadzenie na swoim terytorium wyrobu nie spełniającego wymagań określonych w rozporządzeniu. Jest to kwestia ściśle polityczna, bowiem państwo członkowskie jest odpowiedzialne za bezpieczeństwo swoich obywateli i jeżeli w innym kraju specjalnie powołane do tego celu organy uznają, że będą tolerowały ryzyko stosowania takich wyrobów i wydania zezwolenia, aby na ich terytorium były obecne wyroby nie spełniające wymagań, to ponoszą ryzyko na własną odpowiedzialność. Z drugiej strony, jeżeli którykolwiek kraj Wspólnoty dowie się, że inne państwo członkowskie wydało taką decyzję, to może samodzielnie wydać decyzję podobną i nie musi to być decyzja Komisji Europejskiej. Przedmiotowy przepis narusza zasadę propocjonalności i subsydiarności. Wystarczające dla osiągnięcia celu regulacji są tu działania na poziomie państw członkowskich.

Amendment 277
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 6 – title

Text proposed by the Commission	*Amendment*
Chapter ***VI***	Chapter ***V***
Clinical evidence	Clinical evidence

Or. en

Amendment 278
Dagmar Roth-Behrendt

Proposal for a regulation
Article 48 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) to verify ***that devices achieve*** the intended benefits to the patient ***as specified by the manufacturer***;	(b) to verify ***the clinical safety and efficacy of the device, including*** the intended benefits to the patient***, when used for the intended purpose, in the target population and in accordance with the instructions of use***;

Or. en

Amendment 279
Dagmar Roth-Behrendt

Proposal for a regulation
Article 48 – paragraph 4

Text proposed by the Commission	*Amendment*
4. All clinical performance studies shall be designed and conducted in a way that the rights, safety and well-being of the subjects participating in such clinical performance studies are protected and that the clinical data generated in the clinical performance study are going to be reliable and robust.	4. All clinical performance studies shall be designed and conducted in a way that the rights, safety and well-being of the subjects participating in such clinical performance studies are protected***, in accordance with Article 48 a (3),*** and that the clinical data generated in the clinical performance study are going to be reliable and robust.

Or. en

Amendment 280
Dagmar Roth-Behrendt

Proposal for a regulation
Article 48 a (new)

Text proposed by the Commission	*Amendment*
	Article 48 a
	Involvement of Ethics Committee
	1. Authorisation to conduct a clinical performance study may only be granted if an independent ethics committee has previously submitted a positive evaluation of that performance study.
	2. The statement of the Ethics Committee shall cover in particular the medical justification, the consent of the test subjects participating in the clinical performance study following the provision of full information about the clinical performance study and the suitability of the investigators and investigation facilities.
	3. The Ethics Committee shall ensure that the rights, safety and well-being of subjects participating in a clinical performance study are protected.
	4. It shall be independent of the researcher, independent of the sponsor, and free of any other undue influence. It shall act in accordance with the laws and regulations of the country or countries in which the research is to be conducted and must abide by all relevant international norms and standards.
	5. The Ethics Committee shall consist of a clearly defined number of members and substitutes which include healthcare professionals, laypersons and at least one well-experienced, knowledgeable patient or patient representative, who collectively

possess the relevant qualifications and experience to be able to review and evaluate the scientific, medical and ethical aspects of the proposed clinical performance study.

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

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

Or. en

Amendment 281
Dagmar Roth-Behrendt

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

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

Or. en

Amendment 282
Peter Liese, Margrete Auken, Paolo Bartolozzi, Anne Delvaux, Anna Rosbach, Thomas

Ulmer, Renate Sommer, Miroslav Mikolášik

Proposal for a regulation
Article 49 – paragraph 2 – subparagraph 1 a (new)

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

Or. en

Justification

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

Amendment 283
Dagmar Roth-Behrendt

Proposal for a regulation
Article 49 – paragraph 3 – subparagraph 1

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

Or. en

Amendment 284
Dagmar Roth-Behrendt

Proposal for a regulation
Article 49 – paragraph 3 – subparagraph 3

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

Or. en

Amendment 285
Dagmar Roth-Behrendt

Proposal for a regulation
Article 49 – paragraph 5 – point c

Text proposed by the Commission	*Amendment*
(c) after the expiry of ***35*** days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.	(c) after the expiry of ***60*** days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.

Or. en

Amendment 286
Dagmar Roth-Behrendt

Proposal for a regulation
Article 50 – paragraph 1 – point g a (new)

Text proposed by the Commission	*Amendment*
	(g a) the methodology to be used, the number of subjects involved and the intended result of the study.

Or. en

Amendment 287
Dagmar Roth-Behrendt

Proposal for a regulation
Article 50 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Upon completion of the clinical performance study, the sponsor shall enter in the electronic system referred to in Article 51 a summary of its results drawn up in a way that is easy for a lay person to understand.

Or. en

Amendment 288
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 50 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. The information shall be accessible to the public, through the electronic system referred to in Article 51***, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:***	3. The information shall be ***fully*** accessible to the public, through the electronic system referred to in Article 51**.**

Or. en

Amendment 289
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 50 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) protection of personal data in accordance with Regulation (EC) No 45/2001,	***deleted***

Or. en

Justification

The protection of personal data is already ensured in point number 4 stating that "No personal data of subjects participating in the clinical performance study shall be accessible to the public."

Amendment 290
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 50 – paragraph 3 – point b

Text proposed by the Commission	*Amendment*
(b) protection of commercially sensitive information,	***deleted***

Or. en

Justification

For effective transparency and to ensure access for independent researchers to do randomised performance studies and meta-analysis, the database should be publicly accessible.

Amendment 291
Alda Sousa

Proposal for a regulation
Article 50 – paragraph 3 – point b

Text proposed by the Commission	*Amendment*
(b) protection of commercially sensitive information,	***deleted***

Or. en

Amendment 292
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 50 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) effective supervision of the conduct of the clinical performance study by the Member State(s) concerned.	***deleted***

Or. en

Justification

The effective supervision of performance studies should not be clouded but transparent and subject to public scrutiny.

Amendment 293
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 51 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system on interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies to create the single identification numbers for such clinical performance studies referred to in Article 49(1) and to collate and process the following information:	1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system on interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies***. The existence of this database will allow the public to be able to search for specific performance studies and citizens and professionals to make informed decisions about in-vitro devices. To ensure this, the electronic system will help*** to create the single identification numbers for such clinical performance studies referred to in Article 49(1) and to collate and process the following information:

Or. en

Justification

The database should be set up with the intent of providing both citizens, doctors and independent researchers with information that enables them to make informed decisions about the use of in-vitro devices.

Amendment 294
Rebecca Taylor

Proposal for a regulation
Article 51 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(c a) the clinical performance study reports submitted by sponsors in Article 56(5);

Or. en

Justification

It should be clarified that Clinical Performance Study Reports shall be part of the information

available to the public and healthcare professionals. These amendments ensure that a degree of coherency can be found with the likely outcome of the Clinical Trials negotiations.

Amendment 295
Dagmar Roth-Behrendt

Proposal for a regulation
Article 51 – paragraph 2

Text proposed by the Commission	*Amendment*
2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article […] of Regulation (EU) No [Ref. of future Regulation on clinical trials]. With the exception of the information referred to in Article 50, the information collated and processed in the electronic system shall be accessible ***only*** to the Member States and to the Commission.	2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article […] of Regulation (EU) No [Ref. of future Regulation on clinical trials]. With the exception of the information referred to in Article 50, the information collated and processed in the electronic system shall be accessible to the Member States and to the ***Commission. The*** Commission ***shall also ensure that healthcare professionals have access to the electronic system***.

Or. en

Amendment 296
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 51 – paragraph 2

Text proposed by the Commission	*Amendment*
2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article […] of Regulation	2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article […] of Regulation

(EU) No [Ref. of future Regulation on clinical trials]. ***With the exception of the information referred to in Article 50,*** the information collated and processed in the electronic system shall be accessible ***only*** to the Member States ***and*** to the ***Commission.***	(EU) No [Ref. of future Regulation on clinical trials]. The information collated and processed in the electronic system shall be accessible to the Member States***, to the Commission, and the Commission shall also ensure that healthcare professionals and patients have access*** to the ***electronic system***

Or. en

Amendment 297
Dagmar Roth-Behrendt

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

Text proposed by the Commission	*Amendment*
	2a. Upon a reasoned request, all information on a specific in vitro diagnostic medical device available in the electronic system shall be made accessible to the party requesting it, save where the confidentiality of all or parts of the information is justified on any of the following grounds:
	(a) protection of personal data in accordance with Regulation (EC) No 45/2001;
	(b) protection of commercially sensitive information;
	(c) effective supervision of the conduct of the clinical performance study by the Member State(s) concerned.

Or. en

Amendment 298
Dagmar Roth-Behrendt

Proposal for a regulation
Article 54 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where a Member State has refused, suspended or terminated a clinical performance study, or has called for a substantial modification or temporary halt of a clinical performance study, or has been notified by the sponsor of the early termination of a clinical performance study on safety grounds, that Member State shall communicate its decision and the grounds ***therefor*** to all Member States and the Commission by means of the electronic system referred to in Article 51.	1. Where a Member State has refused, suspended or terminated a clinical performance study, or has called for a substantial modification or temporary halt of a clinical performance study, or has been notified by the sponsor of the early termination of a clinical performance study on safety ***or efficacy*** grounds, that Member State shall communicate its decision and the grounds ***for that decision*** to all Member States and the Commission by means of the electronic system referred to in Article 51.

Or. en

Amendment 299
Dagmar Roth-Behrendt

Proposal for a regulation
Article 55 – paragraph 1

Text proposed by the Commission	*Amendment*
1. If the sponsor has temporarily halted a clinical performance study on safety grounds, he shall inform the Member States concerned within 15 days of the temporary halt.	1. If the sponsor has temporarily halted a clinical performance study on safety ***or efficacy*** grounds, he shall inform the Member States concerned within 15 days of the temporary halt.

Or. en

Amendment 300
Dagmar Roth-Behrendt

Proposal for a regulation
Article 55 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
The sponsor shall notify each Member	The sponsor shall notify each Member

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

Or. en

Amendment 301
Dagmar Roth-Behrendt

Proposal for a regulation
Article 55 – paragraph 2 – subparagraph 2

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

Or. en

Amendment 302
Rebecca Taylor

Proposal for a regulation
Article 55 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Within one year from the end of the clinical performance study, the sponsor shall submit to the Member States concerned ***a summary of*** the results of the clinical performance study in form of a clinical performance study report referred to in Section 2.3.3 of Part A of Annex XII. Where, for scientific reasons, it is not possible to submit the clinical performance study report within one year, it shall be submitted as soon as it is available. In this case, the clinical performance study protocol referred to in Section 2.3.2 of Part A of Annex XII shall specify when the results of the clinical performance study are going to be submitted, together with an explanation.	3. Within one year from the end of the clinical performance study, the sponsor shall submit to the Member States concerned the results of the clinical performance study in form of a clinical performance study report referred to in Section 2.3.3 of Part A of Annex XII. Where, for scientific reasons, it is not possible to submit the clinical performance study report within one year, it shall be submitted as soon as it is available. In this case, the clinical performance study protocol referred to in Section 2.3.2 of Part A of Annex XII shall specify when the results of the clinical performance study are going to be submitted, together with an explanation.

Or. en

Justification

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

Amendment 303
Dagmar Roth-Behrendt

Proposal for a regulation
Article 56 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In the single application, the sponsor shall propose one of the Member States concerned as coordinating Member State. If that Member State does not wish to be the coordinating Member State, it shall agree, within six days of submission of the single application, with another Member	2. In the single application, the sponsor shall propose one of the Member States concerned as coordinating Member State. ***The reporting Member State shall be chosen from among the Member States concerned in which most of the subjects participating in the clinical performance***

State concerned that the latter shall be the coordinating Member State. If no other Member State accepts to be the coordinating Member State, the Member State proposed by the sponsor shall be the coordinating Member State. If another Member State than the one proposed by the sponsor becomes coordinating Member State, the deadlines referred to in Article 49(2) shall start on the day following the acceptance.	***study in question live.*** If that Member State does not wish to be the coordinating Member State, it shall agree, within six days of submission of the single application, with another Member State concerned that the latter shall be the coordinating Member State. If no other Member State accepts to be the coordinating Member State, the Member State proposed by the sponsor shall be the coordinating Member State. If another Member State than the one proposed by the sponsor becomes coordinating Member State, the deadlines referred to in Article 49(2) shall start on the day following the acceptance.

Or. en

Amendment 304
Antonyia Parvanova

Proposal for a regulation
Article 57 – paragraph 2 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) ***a serious*** adverse event that has a causal relationship with the device for performance evaluation, the comparator or the study procedure or where such causal relationship is reasonably possible;	(a) ***any*** adverse event that has a causal relationship with the device for performance evaluation, the comparator or the study procedure or where such causal relationship is reasonably possible;

Or. en

Amendment 305
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 7 – title

Text proposed by the Commission	*Amendment*
Chapter ***VII***	Chapter ***VIII***

Vigilance and market surveillance	Vigilance and market surveillance

Or. en

Amendment 306
Dagmar Roth-Behrendt

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

Text proposed by the Commission	*Amendment*
(a) any serious incident in respect of devices made available on the Union market;	(a) any serious incident ***,including date and place of incident,*** in respect of devices made available on the Union market; ***where available, the manufacturer shall include information on the patient or user and healthcare professional involved in the incident;***

Or. en

Amendment 307
Antonyia Parvanova

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

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

Or. en

Amendment 308
Dagmar Roth-Behrendt

Proposal for a regulation
Article 59 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Member States shall take all appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1. They shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall ***take the necessary steps to*** ensure that the ***manufacturer of the device concerned is informed of the*** incident***. The manufacturer shall ensure the appropriate follow-up***.	The Member States shall take all appropriate measures***, including targeted information campaigns,*** to encourage healthcare professionals, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1. They shall record such reports centrally at national level. Where a competent authority of a Member State obtains such reports, it shall ***inform the manufacturer of the device concerned without delay. The manufacturer shall*** ensure ***the appropriate follow-up.*** ***Where a competent authority of a member State ascertains*** that the ***reports received pursuant to the first subparagraph relate to a serious*** incident ***it shall notify those reports to the electronic system referred to in Article 60 without delay, unless the same incident has already been reported by the manufacturer***.

Or. en

Amendment 309
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 59 – paragraph 3 – subparagraph 1

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

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

Or. en

Justification

This provision reflects the approach taken in the Pharmacovigilance Directive.

Amendment 310
Rebecca Taylor

Proposal for a regulation
Article 59 – paragraph 3 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The reporting of suspected serious incidents shall take into account whether parts or components have been replaced, as specified in Article 19.

Or. en

Justification

Reporting the use of replacement parts or components should allow competent authorities to identify problems originating from replacement parts or components quickly

Amendment 311
Dagmar Roth-Behrendt

Proposal for a regulation
Article 59 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
The Member States ***shall coordinate between them the development of standard web-based structured*** forms for	***The Commission, in cooperation with*** the Member States ***and in consultation with relevant partners including patient and***

reporting of serious incidents by healthcare professionals, users and patients.	***consumer organisations, shall develop standard*** forms for ***electronic and non-electronic*** reporting of serious incidents by healthcare professionals, users and patients.

Or. en

Amendment 312
Rebecca Taylor, Marina Yannakoudakis

Proposal for a regulation
Article 60 – paragraph 1 – point f a (new)

Text proposed by the Commission	*Amendment*
	(f a) the reports by competent authorities on serious incidents and field safety corrective actions taken within Health Institutions involving devices referred to in Article 4(4)

Or. en

Justification

The in-house exemption for devices manufactured and used within a single Health Institution should be subject to reporting requirements. The European Commission, when reviewing legislation in this field in the future, will benefit from access to this information.

Amendment 313
Rebecca Taylor

Proposal for a regulation
Article 60 – paragraph 2

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

	consultation with the Medical Devices Coordination Group, shall provide an overview of this information, every 6 months, for the public and healthcare professionals. This information shall be accessible through the European databank in Article 25.

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 314
Dagmar Roth-Behrendt

Proposal for a regulation
Article 60 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission ***and*** to the notified bodies.	2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission***, to the Agency,*** to the notified bodies ***and healthcare professionals.***.

Or. en

Amendment 315
Dagmar Roth-Behrendt

Proposal for a regulation
Article 60 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall ensure that ***healthcare professionals and*** the public	3. The Commission shall ensure that the public ***has an*** appropriate ***level*** of access to

have appropriate ***levels*** of access to the electronic system.	the electronic system. ***In particular, it shall ensure that, in case information is requested on a specific in vitro diagnostic medical device, it is made available without delay and within 15 days.***

Or. en

Amendment 316
Dagmar Roth-Behrendt

Proposal for a regulation
Article 61 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
If in the case of reports received in accordance with Article 59(3) the competent authority ascertains that the reports relate to a serious incident it shall notify without delay those reports to the electronic system referred to in Article 60, unless the same incident has already been reported by the manufacturer.	***deleted***

Or. en

Amendment 317
Rebecca Taylor

Proposal for a regulation
Article 66 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States and to the Commission.	2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States and to the Commission. ***The Commission, in consultation with the Medical Devices Coordination Group, shall provide an overview of this information, every 6 months, for the***

public and healthcare professionals. This information shall be accessible through the European databank in Article 25.

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 318
Dagmar Roth-Behrendt

Proposal for a regulation
Article 66 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States and to the Commission.	2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States***, to the Commission, to the Agency*** and to ***healthcare professionals.*** The Commission ***shall also ensure that the public has an appropriate level of access to the electronic system. In particular, it shall ensure that, in case information is requested on a specific in vitro diagnostic medical device, it is made available without delay and within 15 days.***.

Or. en

Amendment 319
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 8 – title

Text proposed by the Commission	*Amendment*
Chapter ***VIII***	Chapter ***IX***
Cooperation between Member States, Medical Device Coordination Group, EU reference laboratories, device registers	Cooperation between Member States, Medical Device Coordination Group, EU reference laboratories, device registers

Or. en

Amendment 320
Dagmar Roth-Behrendt

Proposal for a regulation
Article 77 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) to examine questions related to the mutual recognition procedure in accordance with provisions under Article 39e;

Or. en

Amendment 321
Rebecca Taylor

Proposal for a regulation
Article 77 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) to oversee the coordination group of Notified Bodies as specified in Article 39;

Or. en

Justification

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

Amendment 322
Christofer Fjellner, Anna Rosbach

Proposal for a regulation
Article 77 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 42;	***deleted***

Or. en

Amendment 323
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 77 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 42;	***deleted***

Or. en

Justification

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

Amendment 324
Rebecca Taylor

Proposal for a regulation
Article 77 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) to act as an arbitration forum for disputes concerning Chapter IV on the competences of Notified Bodies.

Or. en

Justification

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

Amendment 325
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 77 – paragraph 1 – point c

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

Or. en

Justification

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

Amendment 326
Rebecca Taylor

Proposal for a regulation
Article 77 – paragraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) to assist the Commission in providing an overview of vigilance data and market surveillance activities, including any preventive health protection measures taken, on a 6-monthly basis. This information shall be accessible through the European databank in Article 75;

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 327
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 77 – paragraph 1 – point e

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

Or. en

Justification

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

Amendment 328
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 77 – paragraph 1 – point f

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

Or. en

Justification

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

Amendment 329
Anja Weisgerber, Thomas Ulmer

Proposal for a regulation
Article 77 – paragraph 1 – points f a to f k (new)

Text proposed by the Commission	*Amendment*
	(fa) to continuously monitor the technical progress in particular in the field of implantable devices and assess whether the essential requirements on safety and performance provided within this Regulation are appropriate to ensure safety and performance of medical devices and identify the need to amend Annex I;
	(fb) to develop guidelines on clinical trials of certain medical devices
	(fc) to contribute to the development of medical devices standards;
	(fd) to contribute to the development of Common Technical Specifications (CTS)
	(fe) to develop and maintain a framework for a European market surveillance

program;

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

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

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

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

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

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

Or. en

Justification

The MDCG is a crucial part of the regulatory framework. Its competences should therefore be described in a more detailed way.

Amendment 330
Dagmar Roth-Behrendt

Proposal for a regulation
Article 77 a (new)

Text proposed by the Commission	*Amendment*
	Article 77a
	Advisory Committee

The Advisory Committee established in accordance with the conditions and modalities defined in Article 78a of Regulation (EU) [Ref. of future Regulation on medical devices] shall carry out the tasks assigned to it by this Regulation.

Or. en

Amendment 331
Peter Liese

Proposal for a regulation
Article 78 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) to carry out appropriate tests on samples of manufactured class D devices or batches of class D devices, as provided for in the Section 5.7 of Annex VIII and in Section 5.1 of Annex X;	(b) to carry out appropriate ***laboratory*** tests on samples of manufactured class D devices or batches of class D devices, as provided for in the Section 5.7 of Annex VIII and in Section 5.1 of Annex X;

Or. en

Justification

Clarification that it has to be laboratory testing and not only a "paper test"

Amendment 332
Anna Rosbach

Proposal for a regulation
Article 78 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) to carry out appropriate tests on samples of manufactured class D devices ***or batches of class D devices, as provided for in the Section 5.7 of Annex VIII and in Section 5.1 of*** Annex ***X***;	(b) to carry out appropriate tests on samples of manufactured class D devices ***on request of competent authorities on samples collected during market surveillance activities under article 65 and***

of notified bodies on samples collected during unannounced inspections under Annex ***VIII section 4.4***;

Or. en

Justification

Batch release testing on samples chosen by the manufacturer is according to the impact assessment of no practical value in ensuring patient safety. The control by effective testing of samples on the market, outside of the manufacturer's facilities, would be cost-effective and not needing additional resources. This shift from batch release control to unannounced post-market control will better detect fraud, counterfeit and defective products and ensure a cost-efficient system of control.

Amendment 333
Peter Liese

Proposal for a regulation
Article 78 – paragraph 2 – point d

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

Or. en

Justification

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

Amendment 334
Peter Liese

Proposal for a regulation
Article 78 – paragraph 2 – point f

Text proposed by the Commission	*Amendment*
(f) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures ***and*** market surveillance;	(f) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures***, in particular for batch verification of class D devices and for*** market surveillance;

Or. en

Justification

The task of Reference Laboratories to be responsible also for batch verification of class D IVD has to be described in Article 78.

Amendment 335
Peter Liese, Nora Berra

Proposal for a regulation
Article 78 – paragraph 2 – point i

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

Or. en

Justification

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

Amendment 336
Peter Liese

Proposal for a regulation
Article 78 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) to have appropriately qualified staff with adequate knowledge and experience in the field of the in vitro diagnostic medical devices for which they are designated;	(a) to have appropriately qualified staff with adequate knowledge and experience in the field of the in vitro diagnostic medical devices for which they are designated; ***appropriate knowledge and experience shall be based on*** ***- experience of assessing high-risk IVDs and of carrying out the relevant laboratory tests;*** ***- in-depth knowledge of high-risk in-vitro diagnostic medical devices and relevant technologies;*** ***- proven laboratory experience in one of the following areas: testing or calibration laboratory, supervisory authority or institution, national reference laboratory for class D devices, quality control of in-vitro diagnostic medical devices, development of reference materials for IVDs, calibration of diagnostic medical devices; laboratories or blood banks which experimentally assess and use high-risk IVDs or, where applicable, manufacture them in-house;*** ***- knowledge and experience of product or batch testing, quality checks, design, manufacture and use of IVDs;*** ***- knowledge of the health risks faced by patients, their partners and recipients of blood/organ/tissue donations/preparations associated with the use and, in particular, malfunctioning of high-risk IVDs;*** ***- knowledge of this Regulation and of applicable laws, rules and guidelines, knowledge of the Common Technical Specifications (CTS), applicable harmonized standards, product-specific requirements and relevant guidance documents;*** ***- participation in relevant external and***

	internal quality assessment schemes organised by international or national organisations.

Or. en

Justification

Requirements on reference laboratories have to be clearly described.

Amendment 337
Peter Liese

Proposal for a regulation
Article 78 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they ***may*** be required to pay fees to wholly ***or partially*** cover the costs incurred by that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions.	5. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they ***shall*** be required to pay fees to wholly cover the costs incurred by that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions.

Or. en

Justification

The fees should fully cover the costs to avoid distortion of competition between the reference laboratories

Amendment 338
Dagmar Roth-Behrendt

Proposal for a regulation
Article 79 – paragraph 1

Text proposed by the Commission	*Amendment*
The Commission and the Member States shall take all appropriate measures to ***encourage*** the establishment of registers for ***specific types of*** devices to gather post-market experience related to the use of such devices. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices.	The Commission and the Member States shall take all appropriate measures to ***ensure*** the establishment of registers for ***in vitro diagnostic*** devices to gather post-market experience related to the use of such devices***. registers for class C and D shall be systematically established***. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices.

Or. en

Amendment 339
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 9 – title

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

Or. en

Amendment 340
Dagmar Roth-Behrendt

Proposal for a regulation
Article 82 – paragraph 1

Text proposed by the Commission	*Amendment*
This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles. They	This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is ***comparable and*** set in a transparent manner and on the basis of cost recovery

shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted.	principles. They shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted.

Or. en

Amendment 341
Antonyia Parvanova

Proposal for a regulation
Article 83 – paragraph 1

Text proposed by the Commission	*Amendment*
The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive. The Member States shall notify those provisions to the Commission by [3 months prior to the date of application of this Regulation] and shall notify it without delay of any subsequent amendment affecting them.	The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented ***and sufficiently dissuasive***. The penalties provided for shall be effective, proportionate, and dissuasive. The Member States shall notify those provisions to the Commission by [3 months prior to the date of application of this Regulation] and shall notify it without delay of any subsequent amendment affecting them.

Or. en

Amendment 342
Andrés Perelló Rodríguez

Proposal for a regulation
Article 83 – paragraph 1

Text proposed by the Commission	*Amendment*
The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures	The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures

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

Or. es

Justification

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

Amendment 343
Dagmar Roth-Behrendt

Proposal for a regulation
Chapter 10 – title

Text proposed by the Commission	*Amendment*
Chapter ***X***	Chapter ***XI***
Final provisions	Final provisions

Or. en

Amendment 344
Dagmar Roth-Behrendt

Proposal for a regulation
Article 90 – paragraph 2

Text proposed by the Commission	*Amendment*
2. It shall apply from [***five*** years after entry	2. It shall apply from [***three*** years after

into force].	entry into force].

Or. en

Amendment 345
Alda Sousa

Proposal for a regulation
Annex 1 – part II – point 6 – point 6.1 – point b

Text proposed by the Commission	*Amendment*
(b) the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive and negative predictive value, likelihood ratio, expected values in normal or affected populations.	(b) the clinical performance, ***including measures of clinical validity*** such as diagnostic sensitivity, diagnostic specificity, positive and negative predictive value, likelihood ratio, expected values in normal or affected populations***; and, where appropriate, measures of clinical utility. In the case of companion diagnostics, evidence of the clinical utility of the device for the intended purpose (selection of patients with a previously diagnosed condition or predisposition eligible for a targeted therapy) is required. For a companion diagnostic, the manufacturer should supply clinical evidence relating to the impact of a positive or negative test on (1) patient care; and (2) health outcomes, when used as directed with the stated therapeutic intervention***.

Or. en

Amendment 346
Daciana Octavia Sârbu, Cătălin Sorin Ivan

Proposal for a regulation
Annex 1 – part II – point 7 – point 7.3

Text proposed by the Commission	*Amendment*
7.3. The devices shall be designed and manufactured in such a way as to reduce as	7.3. The devices shall be designed and manufactured in such a way as to reduce as

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

Or. en

Justification

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

Amendment 347
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Annex 1 – part II – point 16 a (new)

Text proposed by the Commission	*Amendment*
	16 a. The devices intended for self-testing help consumers access information about their health. However, lack of proper

counselling regarding the use of self-testing devices - such as the sampling, reading and interpreting results - can lead to traumatic events and may harm users. Therefore, Member States should ensure appropriate counselling conducted by persons admitted to the medical profession under the applicable national legislation before the use of such self-testing devices that are manufactured to test for chronic and transmittable diseases.

Or. en

Justification

Sampling, reading and interpreting results are procedures which allow for faulty handling and defective manoeuvres when they are carried out by lay persons. Self-tests only make sense if they are part of coherent multidisciplinary management of a medical condition. Without proper counselling by doctor, some people may consider that the information made available by the self-testing devices is exact. Proper counselling can also help reduce the possible risk of abuse for example pressure or coercion by a partner or an employer.

Amendment 348
Alda Sousa

Proposal for a regulation
Annex 1 – part III – point 17 – point 17.1 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
Each device shall be accompanied by the information needed to identify the device and its manufacturer, and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, taking into account the following:	Each device shall be accompanied by the information needed to identify the device and its manufacturer, and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, ***and must be made available on the manufacturer's website*** taking into account the following:

Or. en

Justification

The current definition of a label does not 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 349
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 1 – part III – point 17 – point 17.2 – paragraph 1 – point xv

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

Or. en

Amendment 350
Alda Sousa

Proposal for a regulation
Annex 1 – part III – point 17 – point 17.3 – point 17.3.1 – point ii – indent 2

Text proposed by the Commission	*Amendment*
– its function (e.g. screening, monitoring, diagnosis or aid to diagnosis);	– its function (e.g. screening, monitoring, diagnosis or aid to diagnosis***, prognosis, companion diagnostic***);

Or. en

Amendment 351
Alda Sousa

Proposal for a regulation
Annex 1 – part III – point 17 – point 17.3 – point 17.3.1 – point ii – indent 7 a (new)

Text proposed by the Commission	*Amendment*
	- for companion diagnostics, the relevant target population and directions for use with associated therapeutic(s).

Or. en

Amendment 352
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 1 – part III – point 17 – point 17.3 – point 17.3.1 – point xii – indent 5

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

Or. en

Amendment 353
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 1 – part III – point 17 – point 17.3 – point 17.3.1 – point xii – indent 6

Text proposed by the Commission	*Amendment*
– if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilization. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material	– if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging***, the maximum number of allowable reuses*** and, where appropriate, the validated method of re-sterilization. Information shall be provided to identify when the device should no

degradation ***or the maximum number of allowable reuses***.	longer be reused, e.g. signs of material degradation.

Or. en

Amendment 354
Alda Sousa

Proposal for a regulation
Annex 2 – point 1 – point 1.1 – point c – point ii

Text proposed by the Commission	*Amendment*
(ii) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis);	(ii) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis***, prognosis, companion diagnosis***);

Or. en

Amendment 355
Alda Sousa

Proposal for a regulation
Annex 2 – point 1 – point 1.1 – point c – point viii a (new)

Text proposed by the Commission	*Amendment*
	(viii a) for companion diagnostics, the relevant target population and directions for use with the associated therapeutic(s).

Or. en

Amendment 356
Rebecca Taylor

Proposal for a regulation
Annex 2 – point 6 – paragraph 2 – point 6.1 – point 6.2 – paragraph 2

Text proposed by the Commission	*Amendment*
The clinical evidence report referred to in	The clinical evidence report referred to in

Section 3 of Annex XII shall be included and***/or*** fully referenced in the technical documentation.	Section 3 of Annex XII shall be included and fully referenced in the technical documentation.

Or. en

Justification

The Clinical Evidence Study Report should be included in the technical documentation in full

Amendment 357
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Annex 2 – point 7 (new)

Text proposed by the Commission	*Amendment*
	7. Public access to technical documentation
	The technical documentation and clinical evidence submitted by manufacturers to notified bodies must be made publicly available.

Or. en

Justification

Full disclosure of technical documentation and clinical evidence is necessary to ensure that products are safe and well-functioning.

Amendment 358
Peter Liese

Proposal for a regulation
Annex 3 – point 7

Text proposed by the Commission	*Amendment*
7. References to the relevant harmonised	***deleted***

standards or CTS used in relation to which conformity is declared;

Or. en

Justification

The reference to the harmonized standards and the applied parts of standards is made in the technical documentation and can be examined by the public authorities with all the items of evidence. The continuous need for changes by updating the standards in the declaration of conformity would be immense - without generating any extra value concerning patient safety or safety of the devices in general. It is a huge burden for the manufacturers and should therefore be deleted to avoid overburden bureaucracy.

Amendment 359
Margrete Auken
on behalf of the Verts/ALE Group

Proposal for a regulation
Annex 5 – section 1 – paragraph 1 – point 18 a (new)

Text proposed by the Commission	*Amendment*
	18 a. Full technical documentation and the clinical performance report.

Or. en

Amendment 360
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 6 – point 1 – point 1.1 – point 1.1.4 – paragraph 1

Text proposed by the Commission	*Amendment*
The organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel with influence upon the performance and results of the conformity assessment activities shall be clearly documented.	The organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel with influence upon the performance and results of the conformity assessment activities shall be clearly documented. ***This information shall be***

made publicly available.

Or. en

Amendment 361
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 6 – point 1 – point 1.2 – point 1.2.3 a (new)

Text proposed by the Commission	*Amendment*
	1.2.3 a. The notified body shall provide evidence to the national authority that there are no conflicts of interest in compliance with point 1.2.3. The national authority shall report to the Commission twice a year in full transparency.

Or. en

Amendment 362
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 6 – point 1 – point 1.2 – point 1.2.6

Text proposed by the Commission	*Amendment*
1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity of its conformity assessment activities.	1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity of its conformity assessment activities. ***The notified body shall provide evidence to the national authority of its compliance with this point.***

Or. en

Amendment 363
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 6 – point 1 – point 1.3 – paragraph 1

Text proposed by the Commission	*Amendment*
The personnel of a notified body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation to the national authorities responsible for notified bodies, competent authorities or the Commission. Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.	The personnel of a notified body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, ***only in justified cases and*** except in relation to the national authorities responsible for notified bodies, competent authorities or the Commission. Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place. ***Where information and data are requested by the public or healthcare professionals, the notified body shall make publicly available the reasons for such information being subject to non-disclosure.***

Or. en

Amendment 364
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 6 – point 1 – point 1.6 – point 1.6.1

Text proposed by the Commission	*Amendment*
1.6.1. The notified body shall participate in, or ensure that its assessment personnel is informed of the relevant standardisation activities and the activities of the notified body coordination group and that its assessment and decision making personnel are informed of all relevant legislation, guidance and best practice documents adopted in the framework of this Regulation.	1.6.1. The notified body shall participate in, or ensure that its assessment personnel is informed of the relevant standardisation activities and the activities of the notified body coordination group and that its assessment and decision making personnel are informed of all relevant legislation, guidance and best practice documents adopted in the framework of this Regulation. ***The notified body shall keep a record of the actions it takes to inform its***

personnel.

Or. en

Amendment 365
Dagmar Roth-Behrendt

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

Text proposed by the Commission	*Amendment*
This presupposes the availability within its organisation of sufficient scientific personnel who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Regulation and, in particular, those set out in Annex I.	This presupposes the ***permanent*** availability within its organisation of sufficient scientific personnel who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Regulation and, in particular, those set out in Annex I.

Or. en

Amendment 366
Dagmar Roth-Behrendt

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

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

data.	assessment of clinical data.

Or. en

Amendment 367
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 6 – point 3 – point 3.1 – point 3.1.3 a (new)

Text proposed by the Commission	*Amendment*
	3.1.3 a. The notified body shall make available the list of its personnel and their expertise to the Commission and, upon request, to other parties. That list shall be kept up to date.

Or. en

Amendment 368
Dagmar Roth-Behrendt

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

Text proposed by the Commission	*Amendment*
	- at least three years' appropriate experience in the field of conformity assessments within a notified body,

Or. en

Amendment 369
Dagmar Roth-Behrendt

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

Text proposed by the Commission	*Amendment*
3.2.4. Notified bodies shall have available personnel with clinical ***expertise***. This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:	3.2.4. ***Clinical experts:*** notified bodies shall have available***, on a permanent basis,*** personnel with ***expertise in*** clinical ***investigation design, medical statistics, clinical patient management, Good Clinical Practice in the field of clinical performance studies and pharmacology***. This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:

Or. en

Amendment 370
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.4 – indent 1

Text proposed by the Commission	*Amendment*
– identify when specialist input is required for the assessment of the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;	– identify when specialist input is required for the assessment of the clinical ***performance studies plans and the clinical*** evaluation conducted by the manufacturer and identify appropriately qualified experts;

Or. en

Amendment 371
Dagmar Roth-Behrendt

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

Text proposed by the Commission	*Amendment*
– be able to discuss the clinical ***data contained within the manufacturer's clinical evaluation*** with the manufacturer	– be able to discuss the ***rationale of the planned study design, the*** clinical ***performance study plans and the selection***

and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;	***of the control intervention*** with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;

Or. en

Amendment 372
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.4 – indent 4

Text proposed by the Commission	*Amendment*
– be able to scientifically challenge the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;	– be able to scientifically challenge the clinical ***performance study plans and the clinical*** data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;

Or. en

Amendment 373
Dagmar Roth-Behrendt

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

Text proposed by the Commission	*Amendment*
	- provide an understanding of active substances.

Or. en

Amendment 374
Dagmar Roth-Behrendt

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

Text proposed by the Commission	*Amendment*
3.2.5. The personnel responsible for carrying out product related review (e.g. design dossier review, technical documentation review or type examination including aspects such as clinical evaluation, sterilisation, software validation) shall have the following proven qualification:	3.2.5. ***Product assessors:*** the personnel responsible for carrying out product related review (e.g. design dossier review, technical documentation review or type examination including aspects such as clinical evaluation, sterilisation, software validation) shall have the following proven qualification:

Or. en

Amendment 375
Radvilė Morkūnaitė-Mikulėnienė

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

Text proposed by the Commission	*Amendment*
3.2.5. The personnel responsible for carrying out product related review (e.g. design dossier review, technical documentation review or type examination including aspects such as clinical evaluation, sterilisation, software validation) shall have the following proven qualification:	3.2.5. The personnel responsible for carrying out product related review (e.g. design dossier review, technical documentation review or type examination including aspects such as clinical evaluation, sterilisation, software validation) shall have ***an appropriate qualification certified by a competent authority of a Member State. Appropriate qualifications are, for example:***:

Or. lt

Amendment 376
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.6 – introductory part

Text proposed by the Commission	*Amendment*
3.2.6. The personnel responsible for	3.2.6. ***Auditors:*** the personnel responsible

carrying out audits of the manufacturer's quality management system shall have the following proven qualification:	for carrying out audits of the manufacturer's quality management system shall have the following proven qualification:

Or. en

Amendment 377
Radvilė Morkūnaitė-Mikulėnienė

Proposal for a regulation
Annex 6 – point 3 – point 3.2 – point 3.2.6 – introductory part

Text proposed by the Commission	*Amendment*
3.2.6. The personnel responsible for carrying out audits of the manufacturer's quality management system shall have the following proven qualification:	3.2.6. The personnel responsible for carrying out audits of the manufacturer's quality management system shall have ***an appropriate qualification certified by a competent authority of a Member State. Appropriate qualifications are, for exampl***::

Or. lt

Amendment 378
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 6 – point 3 – point 3.3 – point 3.3.1

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

assessment activities.

Or. en

Amendment 379
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 6 – point 3 – point 3.3 – point 3.4 – point 3.4.1

Text proposed by the Commission	*Amendment*
	3.4.(-1). Notified body shall have permanent "in house" competent personnel and expertise, not only in technical fields linked with the assessment of the performance of the devices, but also in the medical sector. They shall have the capacity to evaluate "in house" the quality of subcontractors. By derogation, the following paragraphs apply.
3.4.1. Without prejudice to the limitations emanating from Section 3.2., the notified bodies may subcontract clearly defined parts of the conformity assessment ***activities***. The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed.	3.4.1. Without prejudice to the limitations emanating from Section 3.2., the notified bodies may subcontract clearly defined parts of the conformity assessment ***activities to public entities. Contracts can also be awarded to external experts for the assessment of innovative medical devices or technologies where clinical expertise is limited***. The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed.

Or. en

Amendment 380
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 6 – point 3 – point 3.3 – point 3.4 – point 3.4.2

Text proposed by the Commission	*Amendment*
3.4.2. Where a notified body subcontracts conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place. Any subcontracting or consultation of external experts shall be properly documented and be subject to a written agreement covering, among others, confidentiality and conflict of interests.	3.4.2. Where a notified body subcontracts conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place. Any subcontracting or consultation of external experts shall be properly documented***, be publicly available*** and be subject to a written agreement covering, among others, confidentiality and conflict of interests.

Or. en

Amendment 381
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 6 – point 3 – point 3.3 – point 3.4 – point 3.4.4 a (new)

Text proposed by the Commission	*Amendment*
	3.4.4 a. The policy and procedures under points 3.4.2 and 3.4.4 shall be communicated to the national authority before any subcontracting takes place.

Or. en

Amendment 382
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 6 – point 3 – point 3.3 – point 3.5 – point 3.5.2

Text proposed by the Commission	*Amendment*
3.5.2. It shall review the competence of its personnel and identify training needs in order to maintain the required level of qualification and knowledge.	3.5.2. It shall review the competence of its personnel and identify training needs ***and ensure that necessary measures are taken accordingly,*** in order to maintain the

required level of qualification and knowledge.

Or. en

Amendment 383
Dagmar Roth-Behrendt

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

Text proposed by the Commission	*Amendment*
4.3. The notified body shall have in place documented procedures covering at least:	4.3. The notified body shall have in place documented procedures ***that are publicly available*** covering at least:

Or. en

Amendment 384
Dagmar Roth-Behrendt

Proposal for a regulation
Annex 6 – point 4 – point 4.3 – indent 2

Text proposed by the Commission	*Amendment*
– the processing of the application, including the verification of the completeness of the documentation, the qualification of the product as in vitro diagnostic medical device and its classification,	– the processing of the application, including the verification of the completeness of the documentation, the qualification of the product as in vitro diagnostic medical device and its classification, ***as well as the minimum time for its audit assessments,***

Or. en

Amendment 385
Alda Sousa

Proposal for a regulation
Annex 7 – part 1 – point 1.1

Text proposed by the Commission	*Amendment*
1.1. Application of the classification rules shall be governed by the intended purpose of the devices.	1.1. Application of the classification rules shall be governed by the intended purpose***, novelty, complexity and inherent risk*** of the devices.

Or. en

Amendment 386
Alda Sousa

Proposal for a regulation
Annex 7 – part 2 – point 2.3 – paragraph 1 – point f – point i

Text proposed by the Commission	*Amendment*
(i) Devices intended to be used as companion diagnostics***; or***	(i) Devices intended to be used as companion diagnostics ***are classified as a Class C, except when intended to identify patients at risk of life-threatening adverse event, or where the selection decision may lead to the withholding of a potentially life-saving treatment, in which case they are Class D***

Or. en

Amendment 387
Alda Sousa

Proposal for a regulation
Annex 7 – part 2 – point 2.3 – paragraph 1 – point f – point ii

Text proposed by the Commission	*Amendment*
(ii) Devices intended to be used for disease staging; or	(ii) Devices intended to be used for disease staging ***or prognosis***; or

Or. en

Justification

Disease prognosis is an increasingly common application in the molecular diagnostic sector, exemplified by tests such as Agendia's Mammaprint and Genomic Health's Oncotype Dx, which are both used to give prognostic scores for likelihood of disease recurrence in breast cancer after surgery. Because prognosis is a form of patient selection, we believe that such devices should explicitly be included under Rule 3.

Amendment 388
Alda Sousa

Proposal for a regulation
Annex 7 – part 2 – point 2.3 – paragraph 1 – point j a (new)

Text proposed by the Commission	*Amendment*
	(j a) IVDs for the detection and identification of antibodies directed against erythrocytes, platelets, or leucocytes.

Or. en

Amendment 389
Alda Sousa

Proposal for a regulation
Annex 7 – part 2 – point 2.6 – paragraph 1

Text proposed by the Commission	*Amendment*
Devices not covered by the above-mentioned classification rules are classified as class B.	Devices not covered by the above-mentioned classification rules are classified as class B. ***However, novel class B devices will be classified as class C.***

Or. en

Amendment 390
Peter Liese

Proposal for a regulation
Annex 8 – section 2 – point 5 – point 5.7

Text proposed by the Commission	*Amendment*
5.7. To verify conformity of manufactured devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer***, in regular intervals,*** shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate tests. The reference laboratory shall inform the notified body about its findings.	5.7. To verify conformity of manufactured devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate tests. The reference laboratory shall inform the notified body about its findings.

Or. en

Justification

It should not be done in regular intervals but in each and every case.

Amendment 391
Anna Rosbach

Proposal for a regulation
Annex 8 – section 2 – point 6 – point 6.2 – point c

Text proposed by the Commission	*Amendment*
(c) ***For companion diagnostic intended to be used to assess the patient eligibility to a treatment with a specific medicinal product***, the notified body shall ***consult***	(c) ***Before issuing an EU design-examination certificate***, the notified body shall ***request a reference laboratory, where designated in accordance with***

before issuing an EU design-examination certificate and on the basis of the draft summary of safety and performance and the draft instructions for use, one of the competent authorities designated by the ***Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA') established by the Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, regarding the suitability of the device in relation*** to the ***medicinal product concerned. Where the medicinal product falls exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA***.

Article 78, to verify compliance of the device with the CTS, when available, or with other solutions chosen by the ***manufacturer to ensure a level of safety and performance that is at least equivalent. The reference laboratory shall provide a scientific opinion within 30 days. The scientific opinion of the reference laboratory and any possible updates shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration*** to the ***views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable***.

Or. en

Justification

This shifts the consultation process to the development of Common Technical Specifications for companion diagnostics, setting up minimal performance requirements for those tests; these 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 392
Anna Rosbach

Proposal for a regulation
Annex 8 – section 2 – point 6 – point 6.2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(c a) Changes to the approved design shall

receive further approval from the notified body which issued the EU design-examination certificate, wherever the changes could affect conformity with the general safety and performance requirements of this Regulation or with the conditions prescribed for use of the device. The applicant shall inform the notified body which issued the EU design-examination certificate of any planned changes to the approved design. The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU design-examination report. Where the changes could affect compliance with the CTS or with other solutions chosen by the manufacturer which were approved through the EU design examination certificate, the notified body shall consult the reference laboratory that was involved in the initial consultation, in order to confirm that compliance with the CTS or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent are maintained. The reference laboratory shall provide a scientific opinion within 30 days. The approval of any change to the approved design shall take the form of a supplement to the EU design-examination certificate.

Or. en

Justification

This shifts the consultation process to the development of Common Technical Specifications for companion diagnostics, setting up minimal performance requirements for those tests; these 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 393
Peter Liese

Proposal for a regulation
Annex 8 – section 2 – point 6 – point 6.2 – point e

Text proposed by the Commission	*Amendment*
(e) The notified body shall give due consideration to the opinion, if any, expressed by the medicinal products competent authority concerned or the EMA when making its decision. It shall ***convey its final*** decision to the medicinal products competent authority concerned or to the EMA. The design-examination certificate shall be delivered in accordance with point (d) of Section 6.1.	(e) The notified body shall give due consideration to the opinion, if any, expressed by the medicinal products competent authority concerned or the EMA ***on the scientific suitability of the companion diagnostic*** when making its decision. ***If the notified body deviates from that position,*** it shall ***justify its*** decision to the medicinal products competent authority concerned or to the EMA. ***If no agreement is reached, the notified body shall inform the MDCG thereof.*** The design-examination certificate shall be delivered in accordance with point (d) of Section 6.1.

Or. en

Justification

The Proposal states that the notified body shall give "due consideration" to the opinion expressed by the EMA. This leaves ample room for interpretation and, while the notified body is under no obligation to follow the EMA's opinion, it seems rather unlikely that they disregard it. We thus need a definition of what happens if the assessments of the EMA and notified body are inconsistent.

Amendment 394
Anna Rosbach

Proposal for a regulation
Annex 9 – point 3 – paragraph 1 – point 3.5

Text proposed by the Commission	*Amendment*
3.5. in the case of devices classified as class D, request a reference laboratory, where designated in accordance with Article 78, to verify compliance of the	3.5. in the case of devices classified as class D, ***or for companion diagnostics,*** request a reference laboratory, where designated in accordance with Article 78,

device with the CTS or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent. The reference laboratory shall provide a scientific opinion within 30 days. The scientific opinion of the reference laboratory and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable;	to verify compliance of the device with the CTS or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent. The reference laboratory shall provide a scientific opinion within 30 days. The scientific opinion of the reference laboratory and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable;

Or. en

Justification

This shifts the consultation process to the development of Common Technical Specifications for companion diagnostics, setting up minimal performance requirements for those tests; these 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 395
Anna Rosbach

Proposal for a regulation
Annex 9 – point 3 – paragraph 1 – point 3.6

Text proposed by the Commission	*Amendment*
3.6. For companion diagnostic intended to be used to assess the patient eligibility to a treatment with a specific medicinal product, seek the opinion, on the basis of the draft summary of safety and performance and the draft instructions for use, of a one of the competent authorities designated by the Member States in	***deleted***

accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA') on the suitability of the device in relation to the medicinal product concerned. Where the medicinal product falls exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA. The medicinal products authority or the European Medicines Agency shall deliver its opinion, if any, within 60 days upon receipt of the valid documentation. This 60-day period may be extended only once for a further 60 days on scientifically valid grounds. The opinion of the medicinal products authority or of the EMA and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the opinion, if any, expressed by the medicinal products competent authority concerned or the EMA when making its decision. It shall convey its final decision to the medicinal products competent authority concerned or to the EMA.

Or. en

Justification

This shifts the consultation process to the development of Common Technical Specifications for companion diagnostics, setting up minimal performance requirements for those tests; these 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 396
Anna Rosbach

Proposal for a regulation
Annex 9 – point 5 – point 5.4

Text proposed by the Commission	*Amendment*
5.4. Where the changes affect a companion diagnostic approved through the EU type-examination certificate with regard to its suitability in relation to a medicinal product, the notified body shall consult the medicinal products competent authority that was involved in the initial consultation or the EMA. The medicinal products competent authority or the EMA shall give its opinion, if any, within 30 days after receipt of the valid documentation regarding the changes. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.	***deleted***

Or. en

Justification

This shifts the consultation process to the development of Common Technical Specifications for companion diagnostics, setting up minimal performance requirements for those tests; these 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 397
Peter Liese

Proposal for a regulation
Annex 10 – point 5 – point 5.1

Text proposed by the Commission	*Amendment*
5.1. In the case of devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each	5.1. In the case of devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each

batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer***, in regular intervals,*** shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate tests. The reference laboratory shall inform the notified body about its findings	batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate ***laboratory*** tests. The reference laboratory shall inform the notified body about its findings

Or. en

Justification

Clarification that it has to be laboratory testing and not only a "paper test"

Amendment 398
Alda Sousa

Proposal for a regulation
Annex 12 – section 1 – point 1 – point 1.2.2 – point 1.2.2.6 – indent 2

Text proposed by the Commission	*Amendment*
– For devices classified as class C according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion ***and*** the relevant details of the study protocol***;***	– For devices classified as class C ***and class D*** according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion***,*** the relevant details of the study protocol ***and the individual data points.***

Or. en

Amendment 399
Alda Sousa

Proposal for a regulation
Annex 12 – section 1 – point 1 – point 1.2.2 – point 1.2.2.6 – indent 3

Text proposed by the Commission	*Amendment*
– For devices classified as class D according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion, the relevant details of the study protocol and the individual data points.	***deleted***

Or. en