Council of the European Union

Brussels, 28 August 2026
(OR. en)

12272/26

Interinstitutional File:
2025/0404 (COD)

LIMITE

SAN 620
PHARM 144
MI 817
COMPET 995
CODEC 1518

PUBLIC

WORKING DOCUMENT

From:	Presidency
To:	Delegations
No. prev. doc.:	7255/26; 7252/26
No. Cion doc.:	16919/25 + ADD 1
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I *- Exchange of views*

Delegations will find in Annex the first Presidency compromise text on Qualification and classification (MDR Article 4, 4a, 51, 51a, 51b, and IVDR Articles 3, 3a, 47, 47a and 47b) as well as Market Surveillance (MDR Articles 93-98, and IVDR Articles 88-93) to be discussed at the meetings of the Working Party on Pharmaceuticals and Medical Devices on 10-11 September 2026.

Changes compared to the Commission proposal are indicated in ~~strikethrough~~ for deletions and **bold** for new text. Text from the MDR or IVDR not included in the Commission proposal and added to this compromise text is indicated in *italics*. Changes to that text are indicated in ~~***strikethrough***~~ for deletions and ***bold*** for new text.

ANNEX

PUBLIC

Regulation (EU) 2017/745 is amended as follows:

(3) Articles 3 and 4 are replaced by the following:

(…)

'Article 4

Regulatory status of products

1. The competent authorities of the Member States shall**, when necessary, exchange experience, cooperate and** coordinate their activities**, with the support of the Agency as referred to in Article 106b (1) point (a),** when determining whether a specific product, or category, or group of products, falls within the definition of 'medical device' set out in Article 2, point (1), or the definition of 'accessory for a medical device' set out in Article 2, point (2), or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex.

2. The Member States shall**, when necessary,** ensure an appropriate level of consultation of the relevant competent authorities of the Member States in the fields of in vitro diagnostic medical devices, medicinal products, substances of human origin (SoHO), biocides, food products, cosmetics or other products subject to Union legislation, where the determination of whether a product has the regulatory status of a device involves aspects concerning the borderline with any of those types of products. ~~If that is the case, Member States~~ **As part of providing its support as referred to in Article 106b (1) point (a), the Agency** shall ~~also~~**, where necessary,** ensure an appropriate level of consultation of the relevant advisory or regulatory bodies established in the relevant Union legislation, such as ~~the European Medicines Agency (EMA),~~ the SoHO Coordination Board, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA).

3. Where a competent authority of a Member State, ~~after having performed an evaluation in accordance with Article 94~~**as part of its market surveillance activities**, considers that a product that is CE marked in accordance with Article 20, does not fall within the scope of this Regulation, it shall consult the competent authorities of the other Member States regarding its envisaged ~~measure~~**decision** determining the regulatory status of the product in question.

4. Where a competent authority of a Member State raises a substantiated disagreement regarding the envisaged **decision on the status of the product** ~~measure~~ referred to in paragraph 3, the ~~consulting~~ **initiating** authority shall refer the matter to **the MDCG for an opinion.**

When necessary, the MDCG may seek the advice of an expert panel as referred to in Article 106**. The expert panel shall provide the requested advice to the MDCG within 30 days. The MDCG shall provide its opinion within 30 days of receiving the advice from the expert panel.**

The initiating competent authority shall ~~and~~ give utmost consideration to the opinion of ~~that expert panel~~**the MDCG and shall, where applicable, conduct an evaluation in accordance with Article 94**.

5. The ~~results~~ **outcomes** of the coordination activities of the competent authorities in accordance with this Article ~~and~~**,** the opinions **of the MDCG, and the advice** of the expert panel delivered in accordance with paragraph 4 of this Article and Article 4a(2) shall be made publicly available, without disclosing any confidential information as referred to in Article 109.

6. ~~The Commission may, by means of implementing acts, lay down the procedure, including timelines, for the application of paragraphs 1 to 4 of this Article and of Article 4a. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).~~';

PUBLIC

(4) the following Article 4a is inserted:

'Article 4a

Opinion on and determination of the regulatory status of a product

1. A competent authority, a notified body, a manufacturer**, an authorised representative**, a developer of a product or the Commission may submit a substantiated request for an opinion from ~~an expert panel~~**the competent authorities, in accordance with the coordination activities of the competent authorities** referred to in Article ~~106~~ **4(1),** on the question whether a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory for a medical device', or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex. Where, in such a request, the requester considers that the product in question is a device, the request shall also specify the proposed classification of the device in accordance with Article 51 and Annex VIII.

Requests by a notified body may only be submitted with regards to the product of an applicant.

1a. A manufacturer, an authorised representative or a developer of a product may submit a substantiated request as referred to in paragraph 1 only if they have requested from the competent authority of the Member State, in which they are established, advice on the same matter and have not received any advice within a period of three months.

2. **Where necessary, the competent authorities may request the advice of an expert panel referred to in Article 106.** The expert panel shall provide its **advice to the competent authorities within 30 days. The competent authorities shall provide their** opinion ~~without undue delay.~~ **within 30 days of receiving the advice from the expert panel. The time limits provided for in this subparagraph shall be suspended for the duration of any consultation of relevant Union bodies.**

The requester shall give utmost consideration to the opinion of the ~~expert panel~~**competent authorities**.

3. Having regard to the ~~expert panel~~ opinion referred to in paragraph 2 or in Article 4(4), a Member State may submit a substantiated request to the Commission to determine whether a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory for a medical device', or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex.

The Commission shall decide on the substantiated request of the Member State or on its own initiative, by means of implementing acts, **within 180 days,** which shall be adopted in accordance with the examination procedure referred to in Article 114(3).

The Commission may ask the expert panel **or the competent authorities** for clarifications or refer the opinion back ~~to the expert panel~~ for further consideration, including in cases where a Member State's substantiated request raises new questions of a scientific or technical nature.

4. This Article shall not apply where within the framework of another Union legislation the regulatory status of the product, or category or group of products concerned has been determined as falling within the scope of that other Union legislation, or where a procedure for the determination of the regulatory status is ongoing within the framework of another Union legislation.

4a. The Commission may, after consulting the MDCG, by means of implementing acts, lay down the procedure, for the application of paragraphs 1 to 5 of Article 4 and of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';

PUBLIC

(41) Article 51 is amended as follows:

(a) paragraph 2 is replaced by the following:

‘2. The competent authorities **of the Member States** shall**, when necessary, exchange experience, cooperate and** coordinate their activities **with the support of the Agency as referred to in Article 106b(1) point (a),** when determining the classification of a device, or a category or group of devices. The results of the coordination activities of the competent authorities, including the results of any decision or measure adopted by a competent authority in accordance with Articles 51a or 51b and any opinion issued by an expert panel in relation to classification, shall be made publicly available, without disclosing any confidential information as referred to in Article 109.’;

(b) in paragraph 3, point (b) is replaced by the following:

‘(b) that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII, taking into consideration the principle of proportionality and classification of devices at international level.’;

(c) in paragraph 5, the first sentence is replaced by the following:

‘In order to ensure the uniform application of the rules set out in Annex VIII, and taking account of the relevant scientific opinions of the relevant scientific committees or expert panels, the Commission is empowered to adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.’;

(d) the following paragraph 7 is added:

‘7. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend Annex VIII in order to adapt it to technical or scientific progress or to take into account developments regarding classification of devices at international level.’;

PUBLIC

(42) the following Articles 51a and 51b are inserted:

'Article 51a

Classification in the event of a dispute between manufacturer and notified body

1. A manufacturer or a notified body may refer any dispute between them arising from the application of Annex VIII to the competent authority of the Member State in which the manufacturer has its registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State in which the authorised representative referred to in Section 2.2, second paragraph, point (b), last indent, of Annex IX has its registered place of business.

2. Within ~~30 days~~ **60 days** of receipt of the referral referred to in paragraph 1, the competent authority shall consult the other ~~Member States~~ **competent authorities in accordance with the coordination activities referred to in Article 51(2)** regarding its draft classification decision.

   The authority may within these 60 days ask for clarification or additional information about the referral, and the 60-day clock will stop until all relevant information has been received.

   At the time of consultation of the competent authorities, the initiating competent authority may request the opinion of an expert panel with the support of the Agency.

   If the requisite information is not provided within 60 days of it being requested by the authority, the referral may be considered as lapsed.

3. Where, within 30 days of ~~receipt of~~ **sending** the consultation referred to in the paragraph 2, no substantiated disagreement has been raised ~~by a Member State~~, the competent authority shall adopt its decision within ~~90~~**30** days of ~~receipt~~**the expiry** of the ~~referral~~**deadline of the consultation** referred to in paragraph ~~1~~**2**.

4. Where, within 30 days of ~~receipt~~ **sending** of the consultation referred to in paragraph 2, a substantiated disagreement has been raised ~~by a Member State~~ regarding the draft classification decision, the matter shall be referred to **the relevant** ~~an~~ expert panel as referred to in Article 106. That expert panel shall deliver **a technical or scientific** ~~an~~ opinion on the ~~classification of the device~~ **matter** within 30 days **to be used by the competent authority to resolve the dispute between the notified body and the manufacturer**. The competent authority may ask the expert panel for clarifications on its opinion.

5. Within 30 days of receipt of the expert panel opinion, or any requested clarification, referred to in paragraph 4, the competent authority shall adopt its decision, giving utmost consideration to the expert panel opinion. It shall notify the other Member States and the Commission of its decision without undue delay.

6. ~~The Commission may, by means of implementing acts, lay down further details of the procedure for the application of this Article and of Article 51b. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).~~

Article 51b

Challenges to the classification of CE marked devices

1. Where a competent authority, ~~after having performed an evaluation in accordance with Article 94,~~ **as part of its market surveillance activities** considers that a device that is CE marked in accordance with Article 20, is not classified in accordance with Annex VIII, it shall consult the other ~~Member States~~ **competent authorities in accordance with the coordination activities referred to in Article 51(2)** regarding its envisaged ~~measure~~ **decision** on the classification of the device.

2. Where, within 30 days of ~~receipt of~~ **sending** the consultation referred to in paragraph 1, no substantiated disagreement is raised ~~by a Member State~~, the competent authority may ~~adopt the measure~~**decide** on the classification of the device in question and shall notify the other Member States and the Commission of its decision giving the reasons for the decision.

3. Where, within 30 days of ~~receipt~~ **sending** of the consultation referred to in paragraph 1, a substantiated disagreement is raised ~~by a Member State~~ regarding the envisaged measure on the classification, the matter shall be referred to an expert panel referred to in Article 106, which shall deliver an opinion on the classification of the device within 30 days. The competent authority may ask the expert panel for clarifications on its opinion.

4. The competent authority shall give utmost consideration to the expert panel opinion. **The competent authority shall, where necessary, conduct an evaluation in accordance with Article 94.** Where the competent authority adopts a measure on the classification, it shall notify the other Member States and the Commission of its measure without undue delay.

4a. The Commission may, after consulting the MDCG, by means of implementing acts, lay down further details of the procedure for the application of Article 51a and of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';

(74) Article 93 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices and on the compliance of economic operators with the obligations set out in this Regulation including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.';

PUBLIC

(b) the following paragraph 1a is inserted:

‘1a. Member States shall ensure that their national competent authorities are provided with adequate and sufficient technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation.’;

(c) paragraph 2 is replaced by the following:

‘2. The competent authorities shall draw up annual surveillance activity plans, taking into account the European market surveillance programme, which shall be developed and maintained by the MDCG, and local circumstances.’;

(d) the following paragraph 12 is added:

‘12. **The competent authorities may exchange information in relation to their market surveillance activities and, where relevant, engage with the authorities responsible for notified bodies and the authorities responsible for vigilance.**

Where appropriate, the competent authorities may also cooperate and exchange relevant information with other authorities, including in the fields of cybersecurity, artificial intelligence, and other areas where regulatory interplay exists, whose responsibilities are relevant to the performance of their market surveillance activities.

In respect of devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689, the competent authorities shall cooperate with market surveillance authorities of their Member State designated in accordance with Article 70 of Regulation (EU) 2024/1689.’;

PUBLIC

(75) Article 94 is replaced by the following:

'Article 94

Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

The competent authorities of a Member State shall, alone or in cooperation with the competent authorities of other Member States, carry out an evaluation of a device ~~of of an economic operator~~ covering all the relevant requirements laid down in this Regulation relating to the risk presented by the device, or to any other non-compliance of the device ~~or of the economic operator~~, where they, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe either of the following:

(a) the device may present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

(b) the device ~~or the economic operator~~ concerned otherwise does not comply with the requirements laid down in this Regulation.

The relevant economic operators and, where applicable and requested, the notified body that issued a certificate for the device in question shall cooperate with the competent authorities.

The competent authorities of the Member States may request any economic operator or notified body to submit documentation available to them, where access to such documentation is needed in the interest of public health or patient safety or health.';

PUBLIC

(76) Article 95 is amended as follows:

(a) paragraph 3 is replaced by the following:

‘3. The economic operators as referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken, within the period referred to in paragraph 1, throughout the Union in respect of all the devices concerned that they have made available on the market.’;

(b) paragraph 7 is amended as follows:

(i) the first subparagraph is replaced by the following:

‘Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of the notified measures taken by a Member State, those measures shall be deemed to be justified.’;

(ii) ~~in~~ the second subparagraph~~,~~ **is replaced by** the following ~~sentence is added~~:

‘~~Paragraph 4 shall not apply to such measuresadopted by the other Member States.~~

In that case, all Member States shall ensure that corresponding appropriate restrictive or prohibitive measures, including withdrawing, recalling or limiting the availability of the device on their national market, are taken without delay in respect of the device concerned.

Corresponding measures adopted by the other Member States pursuant to this paragraph shall be based on the notification referred to in paragraph 4. Those measures shall not be subject to the procedure referred to in paragraph 4.’;

PUBLIC

(77) Article 96 is amended as follows:

(a) ~~in paragraph 1, the third sentence is deleted;~~

(b) in paragraph 2, the second sentence of the first subparagraph is replaced by the following:

'If the Commission considers that the national measure is unjustified, the Member State concerned, as well as any Member State that has taken corresponding restrictive or prohibitive measures, shall withdraw the measure.';

(78) Article 97 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Where, having performed an evaluation pursuant to Article 94, the competent authorities of a Member State find that a device or an economic operator does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.';

(b) in paragraph 2, the first sentence is replaced by the following:

'Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1, the Member State concerned shall, without delay, take all appropriate measures to restrict or prohibit the product being made available on the national market or to ensure that it is recalled or withdrawn from the national market.';

PUBLIC

(c) the following paragraph 2a is inserted:

‘2a. The economic operator shall take any appropriate corrective action pursuant to paragraph 1 ~~or 2~~ throughout the Union in respect of all the devices concerned that they have made available on the market, unless a competent authority takes other appropriate measures.’;

(79) ~~in Article 98(3), the fourth sentence is deleted;~~

PUBLIC

Regulation (EU) 2017/746 is amended as follows:

(3) Article 3 is replaced by the following

'Article 3

Regulatory status of products

1. The competent authorities of the Member States shall**, when necessary, exchange experience, cooperate and** coordinate their activities**, with the support of the Agency as referred to in Article 106b(1) point (a) of Regulation (EU) 2017/745,** when determining whether a specific product, or category**,** or group of products, falls within the definition of an 'in vitro diagnostic medical device' or of an 'accessory for an in vitro diagnostic medical device'.

2. The Member States shall**, when necessary,** ensure an appropriate level of consultation of the relevant competent authorities of the Member States in the fields of medical devices, medicinal products, substances of human origin (SoHO), biocides, food, cosmetics or other products subject to Union legislation, where the determination of the regulatory status of a product involves aspects concerning the borderline with any of those types of products. **As part of providing its support as referred to in Article 106b(1) point (a) of Regulation (EU) 2017/745, the Agency**~~In that case, Member States~~ shall ~~also~~**, where necessary,** ensure an appropriate level of consultation of the relevant advisory or regulatory bodies established in the relevant Union legislation, such as ~~the European Medicines Agency (EMA),~~ the SoHO Coordination Board, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA).

3. Where a competent authority of a Member State, ~~after having performed an evaluation in accordance with Article 89~~ **as part of its market surveillance activities**, considers that a product that is CE marked in accordance with Article 18, does not fall within the scope of this Regulation, it shall consult the competent authorities of the other Member States regarding ~~its~~ envisaged ~~measure~~**decision** determining the regulatory status of the product in question.

4. Where a competent authority of a Member State raises a substantiated disagreement regarding the envisaged **decision on the status of the product** ~~measure~~ referred to in paragraph 3, the ~~consulting~~ **initiating** authority shall refer the matter to **the MDCG for an opinion. When necessary, the MDCG may seek the advice of an** ~~an~~ expert panel as referred to in Article 106 **of Regulation (EU) 2017/745.**

The expert panel shall provide the requested advice to the MDCG within 30 days. The MDCG shall provide its opinion within 30 days of receiving the advice from the expert panel.

The initiating competent authority ~~of Regulation (EU) 2017/745 and~~ shall give utmost consideration to the opinion of ~~that expert panel~~**the MDCG and shall, where necessary, conduct an evaluation in accordance with Article 94**.

5. The ~~results~~**outcomes** of the coordination activities of the competent authorities in accordance with this Article ~~and~~**,** the opinions **of the MDCG, and the advice** of the expert panel delivered in accordance with paragraph 4 of this Article and Article 3a(2) shall be made publicly available, without disclosing any confidential information as referred to in Article 102.

6. ~~The Commission may, by means of implementing acts, lay down the procedure, including timelines, for the application of paragraphs 1 to 4 of this Article and of Article 3a. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).~~';

PUBLIC

(4) the following Article 3a is inserted:

'Article 3a

Opinion on and determination of the regulatory status of products at Union level

1. A competent authority, a notified body, a manufacturer**, an authorised representative**, a developer of a product or the Commission may submit a substantiated request for an opinion from ~~an expert panel~~**the competent authorities, in accordance with the coordination activities of the competent authorities** referred to in Article ~~106 of Regulation (EU) 2017/745~~**3(1)** on the question whether a specific product, or category or group of products, falls within the definitions of 'in vitro diagnostic medical device' or 'accessory for an in vitro diagnostic medical device'. Where, in such a request, the requester considers that the product in question is an in vitro diagnostic medical device, the request shall also specify the proposed classification of the device in accordance with Article 47 and Annex VIII.

Requests by a notified body may only be submitted with regards to the product of an applicant.

1a. A manufacturer or an authorised representative may submit a substantiated request as referred to in paragraph 1 only if they have requested from the competent authority of the Member State, in which they are established, advice on the same matter and have not received any advice within a period of three months.

2. **Where necessary, the competent authorities may request the advice of an expert panel referred to in Article 106 of Regulation (EU) 2017/745.** The expert panel shall provide its **advice to the competent authorities within 30 days. The competent authorities shall provide their** opinion ~~without undue delay.~~**within 30 days of receiving the advice from the expert panel. The time limits provided for in this subparagraph shall be suspended for the duration of any consultation of relevant Union bodies.**

The requester shall give utmost consideration to the opinion of the ~~expert panel~~ **competent authorities**.

3. Having regard to the ~~expert panel~~ opinion referred to in paragraph 2 or in Article 3(4), a Member State may submit a substantiated request to the Commission to determine whether a specific product, or category or group of products, falls within the definition of 'in vitro diagnostic medical device' or of 'accessory for an in vitro diagnostic medical device'.

The Commission shall decide on the substantiated request of the Member State, or on its own initiative, by means of implementing acts, **within 180 days,** which shall be adopted in accordance with the examination procedure referred to in Article 107(3).

The Commission may ask the expert panel **or the competent authorities** for clarifications or refer the opinion back to the ~~expert panel for~~ **competent authorities for** further consideration, including in cases where a Member State's substantiated request raises new questions of a scientific or technical nature.

4. This Article shall not apply where within the framework of another Union legislation the regulatory status of the product, or category or group of products concerned has been determined as falling within the scope of that other Union legislation, or where a procedure for the determination of the regulatory status is ongoing within the framework of another Union legislation.

4a. The Commission shall, after consulting with MDCG, by means of implementing acts, lay down the procedure for the application of paragraphs 1 to 5 of Article 3 and of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).';

PUBLIC

(27) Article 47 is amended as follows:

(a) paragraph 2 is replaced by the following:

‘2. The competent authorities **of the Member States** shall**, when necessary, exchange experience, cooperate and** coordinate their activities**, with the support of the Agency as referred to in Article 106b(1) point (a) of Regulation (EU) 2017/745,** when determining the classification of a device, or a category or group of devices. The results of the coordination activities of the competent authorities, including the result of any decision or measure adopted by a competent authority in accordance with Article 47a or 47b and any opinion issued by an expert panel in relation to classification shall be made publicly available, without disclosing any confidential information as referred to in Article 102.’;

(b) in paragraph 3, point (b), is replaced by the following:

‘(b) that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII, taking into consideration the principle of proportionality and classification of devices at international level.’;

(c) paragraph 5 is replaced by the following:

‘5. In order to ensure the uniform application of the rules set out in Annex VIII, and taking account of the relevant scientific opinions of the relevant scientific committees or expert panels, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.’;

PUBLIC

(d) the following paragraph 7 is added:

'7. The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend Annex VIII in order to adapt it to technical or scientific progress or to take into account developments regarding classification of devices at international level.';

(28) the following Articles 47a and 47b are inserted:

'Article 47a

Classification in the event of a dispute between manufacturer and notified body

1. A manufacturer or a notified body may refer any dispute between them arising from the application of Annex VIII to the competent authority of the Member State in which the manufacturer has its registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State in which the authorised representative referred to in Section 2.2., second paragraph, point (b), last indent, of Annex IX has its registered place of business.

The competent authority of the Member State in which the manufacturer has its registered place of business shall notify the MDCG and the Commission of its decision. The decision shall be made available upon request.

2. Within ~~30 days~~ **60 days** of receipt of the referral referred to in paragraph 1, the competent authority shall consult the other ~~Member States~~ **competent authorities in accordance with the coordination activities referred to in Article 47(2)** regarding its draft classification decision.

The authority may within these 60 days ask for clarification or additional information about the referral, and the 60-day clock will stop until all relevant information has been received.

At the time of consultation of the competent authorities, the initiating competent authority may request the opinion of an expert panel with the support of the Agency.

If the requisite information is not provided within 60 days of it being requested by the authority, the referral may be considered as lapsed.

3. Where, within 30 days of ~~receipt of~~ **sending** the consultation referred to in the paragraph 2, no substantiated disagreement is raised ~~by a Member State~~, the competent authority shall adopt its decision within ~~90~~**30** days of ~~receipt~~**the expiry** of the ~~referral~~**deadline of the consultation** referred to in paragraph ~~1~~**2**.

4. Where, within 30 days of ~~receipt of~~ **sending** the consultation referred to in paragraph 2, a substantiated disagreement ~~is~~**has been** raised ~~by a Member State~~ regarding the ~~notified envisaged decision on the~~ **draft** classification **decision**, the matter shall be referred to **the relevant** ~~an~~ expert panel as referred to in Article 106 of Regulation (EU) 2017/745. That expert panel shall deliver ~~an~~**a technical or scientific** opinion on the ~~classification of the device~~ **matter** within 30 days **to be used by the competent authority to resolve the dispute between the notified body and the manufacturer**. The competent authority may ask the expert panel for clarifications on its opinion.

5. Within 30 days of receipt of the expert panel opinion, or any requested clarification, the competent authority shall adopt its decision, giving utmost consideration to the expert panel opinion. It shall notify the other Member States and the Commission of its decision without undue delay.

6. ~~The Commission may, by means of implementing acts, lay down further details of the procedure for the application of this Article and of Article 47b. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).~~

PUBLIC

Article 47b

Challenges to the classification of CE marked devices

1. Where a competent authority, ~~after having performed an evaluation in accordance with Article 89,~~ **as part of its market surveillance activities** considers that a device that is CE marked in accordance with Article 18, is not classified in accordance with Annex VIII, it shall consult the other ~~Member States~~ **competent authorities in accordance with the coordination activities referred to in Article 47(2)** regarding its envisaged ~~measure~~ **decision** on the classification of the device.

2. Where, ~~within~~**after** 30 days of ~~receipt~~ **sending** of the consultation referred to in paragraph 1, no substantiated disagreement **has been** ~~is~~ raised by **a competent authority of** a Member State, the **initiating** competent authority may ~~adopt the measure~~**decide** on the classification of the device in question and shall notify the other Member States and the Commission of its decision giving the reasons for the decision.

3. Where, within 30 days of ~~receipt~~ **sending** of the consultation referred to in paragraph 1, a substantiated disagreement is raised ~~by a Member State~~ regarding the notified envisaged measure on the classification, the matter shall be referred to an expert panel referred to in Article 106 of Regulation (EU) 2017/745, which shall deliver an opinion on the classification of the device within 30 days. The competent authority may ask the expert panel for clarifications on its opinion.

4. The competent authority shall give utmost consideration to the expert panel opinion. **The competent authority shall, where necessary, conduct an evaluation in accordance with Article 94.** Where the competent authority adopts a measure on the classification, it shall notify the other Member States and the Commission of its measure without undue delay.

4a. The Commission may, after consulting the MDCG, by means of implementing acts, lay down further details of the procedure for the application of Article 47a and of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';

PUBLIC

(60) Article 88 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices and on the compliance of economic operators with the obligations set out in this Regulation including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.’;

(b) the following paragraph 1a is inserted:

‘1a. Member States shall ensure that their national competent authorities are provided with adequate and sufficient technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation.’;

(c) paragraph 2 is replaced by the following:

‘2. The competent authorities shall draw up annual surveillance activity plans, taking into account the European market surveillance programme, which shall be developed and maintained by the MDCG, and local circumstances.’;

(d) the following paragraph 12 is added:

‘12. **The competent authorities may exchange information in relation to their market surveillance activities and, where relevant, engage with the authorities responsible for notified bodies and the authorities responsible for vigilance.**

PUBLIC

Where appropriate, the competent authorities may also cooperate and exchange relevant information with other authorities, including in the fields of cybersecurity, artificial intelligence, and other areas where regulatory interplay exists, whose responsibilities are relevant to the performance of their market surveillance activities.

In respect of devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689, the competent authorities shall cooperate with market surveillance authorities of their Member State designated in accordance with Article 70 of Regulation (EU) 2024/1689.'

(61) Article 89 is replaced by the following:

'Article 89

Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

The competent authorities of a Member State, either alone or in cooperation with the competent authorities of other Member States, shall carry out an evaluation of a device ~~or of an economic operator~~ covering the relevant requirements laid down in this Regulation relating to the risk presented by the device or to any other non-compliance of the device ~~or of the economic operator~~, where they, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe either of the following:

(a) a device may present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

(b) a device ~~or an economic operator~~ otherwise does not comply with the requirements laid down in this Regulation.

The relevant economic operators and, where applicable and requested, the notified body that issued a certificate for the device in question shall cooperate with the competent authorities.';

(62) Article 90 is amended as follows:

(a) paragraph 3 is replaced by the following:

‘3. The economic operators referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken within the period referred to in that paragraph throughout the Union in respect of all the devices concerned that they have made available on the market.’;

(b) paragraph 7 is ~~amended as follows~~**replaced by the following**:

(i) ~~the first sentence is replaced by the following:~~

‘Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of the notified measures taken by a Member State, those measures shall be deemed to be justified.

In that case, all Member States shall ensure that corresponding appropriate restrictive or prohibitive measures, including withdrawing, recalling or limiting the availability of the device on their national market are taken without delay in respect of the device concerned.

Corresponding measures adopted by the other Member States pursuant to this paragraph shall be based on the notification referred to in paragraph 4. Those measures shall not be subject to the procedure set out in paragraph 4.’;

(ii) ~~the following subparagraph is added:~~

~~‘Paragraph 4 shall not apply to such measures adopted by the Member States.’;~~

PUBLIC

(63) Article 91 is amended as follows:

(a) ~~in paragraph 1, the third sentence is deleted;~~

(b) in paragraph 2, the **second sentence of the** first subparagraph is replaced by the following:

‘~~Where the Commission considers the national measure to be justified as referred to in paragraph 1 of this Article, Article 90(7), second sentence, shall apply.~~ If the Commission considers the national measure to be unjustified, the Member State concerned, as well as any Member State that has taken corresponding restrictive or prohibitive measures, shall withdraw the measure.’;

(64) Article 92 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Where, having performed an evaluation pursuant to Article 89, the competent authorities of a Member State find that a device or an economic operator does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.’;

(b) in paragraph 2, the first sentence is replaced by the following:

‘Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1, the Member State concerned shall, without delay, take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the national market.’;

PUBLIC

(c) the following paragraph 2a is inserted:

‘2a. The economic operator shall take any appropriate corrective action pursuant to paragraph 1 ~~or paragraph 2~~ throughout the Union in respect of all the devices concerned that they have made available on the market, unless a competent authority takes other appropriate measures.’;

(65) ~~in Article 93(3), the fourth sentence is deleted;~~

PUBLIC