



Council of the
European Union

Brussels, 16 February 2024
(OR. en)

6156/24

LIMITE

PHARM 21
SAN 65
MI 120
COMPET 121
CODEC 284

Interinstitutional File:
2024/0021(COD)

'I' ITEM NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee (Part 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 a gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain *in vitro* diagnostic medical devices
- Confirmation of the final compromise text with a view to agreement

I. INTRODUCTION

1. On 23 January 2024, the Commission submitted a proposal to the Council and to the European Parliament for a Regulation amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the a gradual roll-out Eudamed, information obligation in case of interruption of supply and the transitional provisions of certain *in vitro* diagnostic medical devices.¹
2. The proposal is based on Article 114 and Article 168(4), point (c) of the Treaty on the Functioning of the European Union. The ordinary legislative procedure is applicable.

¹ 5712/24.

3. The proposed Regulation aims to amend the Medical Devices Regulation (MDR) and the In vitro Diagnostic Medical Devices Regulation (IVDR) to further mitigate the risk of shortages of medical devices on the market by:
- Extending the transitional period for certain in vitro diagnostic medical devices (IVDs) under certain conditions;
 - obliging manufacturers to inform competent national authorities in case of their intention to interrupt/withdraw the supply of certain critical medical devices and IVDs; and
 - implementing in a step-wise manner the EUDAMED database, through mandatory use of those modules that have been audited and declared functional instead of waiting for the full platform to be operational.
4. Consultation of the European Economic and Social Committee and the Committee of the Regions is compulsory, as this proposal concerns public health. Both Committees are being consulted and invited to deliver their opinion as quickly as possible.

II. WORK IN THE COUNCIL AND THE EUROPEAN PARLIAMENT

1. On 14 February 2024, the Permanent Representatives' Committee agreed on the text of the Commission proposal without amendments as a mandate² for the Presidency to enter into negotiations with the European Parliament.
2. At the European Parliament, the Committee on the Environment, Public Health and Food Safety (ENVI) is responsible for the file.
3. Following informal contacts with the European Parliament, it is expected that the European Parliament will vote on the text of the Commission proposal without amendments as its position at first reading during a plenary session in April 2024, through an urgency procedure and subject to legal-linguistic revision of the text.

² 6067/24.

III. CONCLUSION

4. In light of the above, the Permanent Representatives Committee is invited to:

- confirm agreement on the final compromise text as set out in the annex to this note with a view to reaching an agreement at first reading with the European Parliament;

and
- authorise the Chair of the Permanent Representatives Committee to send a letter to inform the Chair of the European Parliament's ENVI Committee that, should the European Parliament adopt its position at first reading on the text of the proposal in the exact form as set out in the annex to this note, and subject to revision of that text by the lawyer-linguists of both institutions, the Council will approve the European Parliament's position and the act will be adopted in the wording which corresponds to the European Parliament's position.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of
Eudamed, information obligation in case of interruption of supply and the transitional
provisions for certain *in vitro* diagnostic medical devices

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (c), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee³,

Having regard to the opinion of the Committee of the Regions⁴,

Acting in accordance with the ordinary legislative procedure,

³ OJ C , , p. .

⁴ OJ C , , p. .

Whereas:

- (1) Regulations (EU) 2017/7455 and (EU) 2017/7466 of the European Parliament and of the Council establish a regulatory framework to ensure the smooth functioning of the internal market as regards medical devices and *in vitro* diagnostic medical devices, taking as a base a high level of protection of health for patients and users. At the same time, Regulations (EU) 2017/745 and (EU) 2017/746 set high standards of quality and safety for medical devices and *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such devices. Furthermore, both Regulations significantly reinforce key elements of the previous regulatory framework set out in Council Directives 90/385/EEC⁷ and 93/42/EEC⁸ and Directive 98/79/EC⁹ of the European Parliament and of the Council, such as the supervision of notified bodies, risk classification, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, and require the setting up of the European database on medical devices ('Eudamed') to enable transparency and traceability in respect of medical devices and *in vitro* diagnostic medical devices.

⁵ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>).

⁶ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176, ELI: <http://data.europa.eu/eli/reg/2017/746/oj>).

⁷ Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17, ELI: <http://data.europa.eu/eli/dir/1990/385/oj>).

⁸ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1, ELI: <http://data.europa.eu/eli/dir/1993/42/oj>).

⁹ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1, ELI: <http://data.europa.eu/eli/dir/1998/79/oj>).

- (2) Regulations (EU) 2017/745 and (EU) 2017/746 require the Commission to set up, maintain and manage Eudamed, which includes seven interconnected electronic systems. The development of four electronic systems has been completed and the completion of two further electronic systems is expected in 2024. However, the development of the electronic system on clinical investigations and performance studies is significantly delayed, due to the technical complexity of requirements and workflows to be implemented.
- (3) Pursuant to Regulations (EU) 2017/745 and (EU) 2017/746, the obligations and requirements that relate to Eudamed are to apply from a certain date after the Commission has verified the full functionality of Eudamed and published a notice to that effect. The delayed development of the last electronic system therefore holds back the mandatory use of the electronic systems that are available.
- (4) The use of the electronic systems that are completed or that are about to be completed would largely support the effective and efficient implementation of Regulations (EU) 2017/745 and (EU) 2017/746, decreasing the administrative burden for economic operators. A gradual roll-out of the individual electronic systems of Eudamed should therefore be allowed once their functionality has been verified in accordance with the procedure laid down in Regulation (EU) 2017/745.
- (5) Having regard to the gradual roll-out of Eudamed's electronic systems and to avoid overlapping periods of registration in national databases and in Eudamed, the dates of application of the obligations and requirements that relate to Eudamed and the dates of application of the corresponding national registration requirements based on Directives 90/385/EEC, 93/42/EEC and 98/79/EC should be aligned.
- (6) Due to the delay of the development of the electronic system on clinical investigations and performance studies, the timeline for the application of the coordinated assessment for clinical investigations and performance studies should also be adapted, keeping the approach that Member States should first have the possibility to opt-in before participation in the coordinated assessment becomes mandatory for all Member States.

- (7) Despite the increase in the number of notified bodies designated in accordance with Regulation (EU) 2017/746, the overall capacity of notified bodies is still not sufficient to ensure the certification of the large number of devices which are to undergo conformity assessment involving a notified body under that Regulation.
- (8) The number of applications for conformity assessment submitted by manufacturers and the number of certificates issued by notified bodies to date show that transition to the Regulation (EU) 2017/746 has not progressed in a way to ensure a smooth transition to the new rules.
- (9) It is very likely that many safe and critical *in vitro* diagnostic medical devices, which are essential for medical diagnosis and treatment of patients would not be certified in accordance with Regulation (EU) 2017/746 before the end of the transitional periods. This leads to a risk of shortages especially of highest-risk (class D) devices by the end of the current transitional period on 26 May 2025. It is therefore necessary to ensure that there is an uninterrupted market supply of *in vitro* diagnostic medical devices in the Union.
- (10) In order to ensure a high level of protection of public health and patient safety, while safeguarding the smooth functioning of the internal market, as well as to provide legal certainty and avoid potential market disruption, it is therefore necessary to extend further the transitional periods laid down in Regulation (EU) 2017/746 for devices covered by certificates issued by notified bodies in accordance with Directive 98/79/EC and for devices which are to undergo conformity assessment involving a notified body for the first time under Regulation (EU) 2017/746. To achieve those objectives, the extended transitional period should concern all device classes so as to guarantee a manageable distribution of workload on notified bodies across time and avoid any impediment to the certification process.
- (11) The extension should be of sufficient duration to give manufacturers and notified bodies the time necessary to carry out the required conformity assessments. The extension should aim to ensure a high level of public health protection, including patient safety and an avoidance of shortages of *in vitro* diagnostic medical devices needed for the smooth functioning of healthcare services, without lowering current quality or safety requirements.

- (12) The extension should be subject to certain conditions to ensure that only devices that are safe and for which the manufacturers have taken certain steps to transition towards compliance with Regulation (EU) 2017/746 are to benefit from the additional period.
- (13) To ensure a progressive transition to Regulation (EU) 2017/746, the appropriate surveillance regarding devices benefiting from the transitional period should be transferred from the notified body that issued the certificate in accordance with Directive 98/79/EC to a notified body designated under Regulation (EU) 2017/746. For reasons of legal certainty, the notified body designated under Regulation (EU) 2017/746 should not be responsible for conformity assessment and surveillance activities carried out by the notified body that issued the certificate.
- (14) As regards the periods needed to allow manufacturers and notified bodies to carry out the conformity assessment in accordance with Regulation (EU) 2017/746 of *in vitro* diagnostic medical devices that are covered by a certificate or a declaration of conformity that was issued in accordance with Directive 98/79/EC, a balance should be struck between the limited available capacity of notified bodies and ensuring a high level of patient safety and public health protection. Therefore, the length of the transitional period should depend on the risk class of the medical devices concerned, so that the period is shorter for devices belonging to a higher risk class and longer for devices belonging to a lower risk class.

- (15) Having regard to the impact that shortages of certain medical devices may have on patient safety and public health, a prior notice mechanism should be introduced to enable in particular competent authorities and health institutions to take mitigating measures where necessary to ensure patient health and safety. Therefore, where manufacturers for any reason anticipate the interruption of supply of medical devices or *in vitro* diagnostic medical devices and it is reasonably foreseeable that the interruption may result in serious harm or a risk of serious harm to patients or public health in one or more Member States, the manufacturer should notify the relevant competent authorities as well as the economic operators to whom they directly supply the device and, where applicable, the health institutions or healthcare professionals to whom they directly supply the device, thereof. The risk of serious harm to patients or public health may, for example, be due to the relevance of the device for ensuring essential healthcare services in one or more Member States, the dependency of patient health and safety on the continuous availability of the device in one or more Member States, or the absence of suitable alternatives, also considering the expected length of the supply interruption, the quantities of devices already made available on the market and available stocks or timelines for procuring alternative devices. The information should be provided by the manufacturer and other economic operators in the downstream supply chain until it reaches the relevant health institutions or healthcare professionals. As the risk of shortages is particularly relevant during the transition from Directives 90/385/EEC, 93/42/EEC and 98/79/EC to Regulations (EU) 2017/745 and (EU) 2017/746, the prior notice mechanism should also apply to devices placed on the market in accordance with the transitional provisions laid down in Article 120 of Regulation (EU) 2017/745 and Article 110 of Regulation (EU) 2017/746.
- (16) Regulations (EU) 2017/745 and (EU) 2017/746 should therefore be amended accordingly.

- (17) Since the objectives of this Regulation, namely to address risks of shortages of *in vitro* diagnostic medical devices in the Union and the timely roll-out of Eudamed, cannot be sufficiently achieved by the Member States but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union ('TEU'). In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives. This Regulation is being adopted in view of the exceptional circumstances arising from an imminent risk of shortages of *in vitro* diagnostic medical devices and the associated risk of a public health crisis, as well as the significant delay in the development of the last electronic system of Eudamed. In order to attain the intended effect of amending Regulations (EU) 2017/745 and (EU) 2017/746 and to ensure availability of devices whose certificates have already expired or are due to expire before 26 May 2025, to provide legal certainty for economic operators and healthcare providers, and for reasons of consistency as regards the amendments to both Regulations, this Regulation should enter into force as a matter of urgency. For the same reasons, it is also considered to be appropriate to invoke the exception to the eight-week period provided for in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the TEU, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community.
- (18) To allow manufacturers and other economic operators time to adapt to the obligation to provide notice of an anticipated interruption of supply of certain devices, it is appropriate to defer the application of the provisions related to such obligation,

HAVE ADOPTED THIS REGULATION:

Article 1
Amendments to Regulation (EU) 2017/745

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

- (1) the following Article 10a is inserted:

‘Article 10a

Obligations in case of interruption of supply of certain devices

1. Where a manufacturer anticipates an interruption of the supply of a device, other than a custom-made device, and where it is reasonably foreseeable that this interruption may result in serious harm or a risk of serious harm to patients or public health in one or more Member States, the manufacturer shall inform the competent authority of the Member State where it or its authorised representative is established, as well as the economic operators, health institutions and healthcare professionals to whom the manufacturer directly supplies the device, of the anticipated interruption.

The information referred to in the first subparagraph shall, other than in exceptional circumstances, be provided at least six months before the anticipated interruption. The information provided to the competent authority shall specify the reasons for the interruption.

2. The competent authority that has received the information referred to in paragraph 1 shall inform without undue delay the competent authorities of the other Member States and the Commission of the anticipated interruption.
3. The economic operators who have received the information from the manufacturer in accordance with paragraph 1, shall inform without undue delay any other economic operators, health institutions and healthcare professionals to whom they directly supply the device of the anticipated interruption.’

(2) Article 34 is amended as follows:

- (a) in paragraph 1, the third sentence is deleted;
- (b) paragraph 2 is replaced by the following:

‘2. The Commission shall inform the MDCG when, on the basis of independent audit reports, it has verified that one or more of the electronic systems referred to in Article 33(2) are functional and meet the functional specifications drawn up pursuant to paragraph 1 of this Article.’;

(3) in Article 78, paragraph 14 is replaced by the following:

‘14. All Member States shall be required to apply the procedure set out in this Article from the date corresponding to five years after the date of publication of the notice referred to in Article 34(3) informing that the electronic system referred to in Article 33(2), point (e), is functional and meets the functional specifications drawn up pursuant to Article 34(1).

Before that date and at the earliest six months after the date of publication of the notice referred to in the first subparagraph, the procedure set out in this Article shall be applied only by those Member States in which the clinical investigation is to be conducted which have agreed to apply it.’;

(4) Article 120 is amended as follows:

- (a) paragraph 8 is deleted;
- (b) the following paragraph 13 is added:

‘13. Article 10a shall apply also to devices referred to in paragraphs 3, 3a and 3b of this Article.’;

(5) in Article 122, first paragraph, the first, second, third and fourth indents are replaced by the following:

- ‘- Articles 8 and 10, Article 10b(1), points (b) and (c), Article 10b(2) and (3) of Directive 90/385/EEC and Article 10, Article 14a(1), points (c) and (d), Article 14a(2) and (3) and Article 15 of Directive 93/42/EEC, and the obligations relating to vigilance and clinical investigations provided for in the corresponding Annexes to those Directives, which are repealed, as applicable, with effect from the date referred to in Article 123(3), point (d), of this Regulation in respect of the application of the obligations and requirements that relate to the electronic systems referred to in Article 33(2), points (e) and (f), respectively;
- Article 10a, Article 10b(1), point (a), and Article 11(5) of Directive 90/385/EEC and Article 14(1) and (2), Article 14a(1), points (a) and (b), and Article 16(5) of Directive 93/42/EEC, and the obligations relating to registration of devices and economic operators, and to certificate notifications, provided for in the corresponding Annexes to those Directives, which are repealed, as applicable, with effect from the date referred to in Article 123(3), point (d), of this Regulation in respect of the application of the obligations and requirements that relate to the electronic systems referred to in Article 33(2), points (a), (c) and (d), respectively;’;

(6) Article 123(3) is amended as follows:

(a) point (d) is amended as follows:

(i) in the first paragraph, the first sentence of the introductory wording is replaced by the following:

‘without prejudice to the obligations of the Commission pursuant to Article 34, the obligations and requirements that relate to any of the electronic systems referred to in Article 33(2) shall apply from the date corresponding to six months after the date of publication of the notice referred to in Article 34(3) informing that the relevant electronic system is functional and meets the functional specifications drawn up pursuant to Article 34(1).’;

(ii) after the twelfth indent, the following indent is inserted:

‘- Article 56(5),’;

(iii) the fourteenth indent is replaced by the following:

‘- Article 78(1) to (13), without prejudice to Article 78(14),’;

(iv) the second paragraph is replaced by the following:

‘Until the date of application of the provisions referred to in the first paragraph of this point, the corresponding provisions of Directives 90/385/EEC and 93/42/EEC regarding information on vigilance reporting, clinical investigations, registration of devices and economic operators, and certificate notifications shall continue to apply.’;

(b) point (e) is replaced by the following:

‘(e) no later than 6 months after the date referred to in point (d) of this paragraph, manufacturers shall ensure that the information to be entered in Eudamed in accordance with Article 29 is entered in the electronic system referred to in Article 33(2), point (a), also regarding the following devices, provided that the same devices are placed on market also from the date referred to in point (d) of this paragraph:

- (i) devices, other than custom-made devices, for which the manufacturer has undertaken a conformity assessment in accordance with Article 52;
- (ii) devices, other than custom-made devices, placed on the market pursuant to Article 120(3), (3a) or (3b), unless the device, for which the manufacturer has undertaken a conformity assessment in accordance with Article 52, is already registered in Eudamed;’;

(c) the following points are inserted after point (e):

‘(ea) no later than 12 months after the date referred to in point (d) of this paragraph, notified bodies shall ensure that the information to be entered in Eudamed in accordance with Article 56(5) is entered in the electronic system referred to in Article 33(2), point (d), also regarding devices referred to in point (e), (i), of this paragraph. For those devices, only the latest relevant certificate and, if applicable, any decision taken by the notified body related to such certificate shall be entered;

- (eb) by way of derogation from the first paragraph of point (d) of this paragraph, the obligations to upload the summary of safety and clinical performance in accordance with Article 32(1) and to notify competent authorities in accordance with Article 55(1), through the electronic system referred in Article 33(2), point (d), shall apply to devices referred to in point (e) of this paragraph when the certificate is entered in Eudamed in accordance with point (ea) of this paragraph;
- (ec) without prejudice to the first paragraph of point (d) of this paragraph, when a manufacturer has to submit a PSUR in accordance with Article 86(2) or report a serious incident, a field safety corrective action in accordance with Article 87 or submit a trend report in accordance with Article 88 through the electronic system referred to in Article 33(2), point (f), it shall also register the device, which is subject of the PSUR or the vigilance report, in the electronic system referred to in Article 33(2), point (a), except if such device was placed on the market in accordance with Directive 90/385/EEC or Directive 93/42/EEC;’;

(d) point (h) is deleted.

Article 2

Amendments to Regulation (EU) 2017/746

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

(1) the following Article 10a is inserted:

‘Article 10a

Obligations in case of interruption of supply of certain devices

1. Where a manufacturer anticipates an interruption of the supply of a device and where it is reasonably foreseeable that this interruption may result in serious harm or a risk of serious harm to patients or public health in one or more Member States, the manufacturer shall inform the competent authority of the Member State where it or its authorised representative is established, as well as the economic operators, health institutions and healthcare professionals to whom it directly supplies the device, of the anticipated interruption.

The information referred to in the first subparagraph shall, other than in exceptional circumstances, be provided at least six months before the anticipated interruption. The information provided to the competent authority shall specify the reasons for the interruption.

2. The competent authority that has received the information referred to in paragraph 1 shall inform without undue delay the competent authorities of the other Member States and the Commission of the anticipated interruption.
3. The economic operators who have received the information from the manufacturer in accordance with paragraph 1, shall inform without undue delay any other economic operators, health institutions and healthcare professionals to whom they directly supply the device of the anticipated interruption.’

(2) in Article 74, paragraph 14 is replaced by the following:

- ‘14. All Member States shall be required to apply the procedure set out in this Article from the date corresponding to 5 years after the date of publication of the notice referred to in Article 34(3) of Regulation (EU) 2017/745 informing that the electronic system referred to in Article 33(2), point (e), of that Regulation is functional and meets the functional specifications drawn up pursuant to Article 34(1) of that Regulation.

Before that date and at the earliest six months after the date of publication of the notice referred to in the first subparagraph, the procedure set out in this Article shall be applied only by those Member States in which the performance study is to be conducted which have agreed to apply it.’;

(3) Article 110 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Certificates issued by notified bodies in accordance with Directive 98/79/EC from 25 May 2017 that were still valid on 26 May 2022 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until 31 December 2027. Certificates issued by notified bodies in accordance with that Directive from 25 May 2017 that were still valid on 26 May 2022 and that have expired before [*OP: please insert the date = date of entry into force of this amending Regulation*] shall be considered to be valid until 31 December 2027 only if one of the following conditions is fulfilled:

- (a) before the date of expiry of the certificate, the manufacturer and a notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device;
- (b) a competent authority of a Member State has granted a derogation from the applicable conformity assessment procedure in accordance with Article 54(1) of this Regulation or has required the manufacturer, in accordance with Article 92(1) of this Regulation, to carry out the applicable conformity assessment procedure.’;

(b) paragraph 3 is replaced by the following:

‘3. By way of derogation from Article 5 and provided the conditions set out in paragraph 3c of this Article are met, devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates set out in those paragraphs.’;

(c) the following paragraphs 3a to 3e are inserted:

- ‘3a. Devices which have a certificate that was issued in accordance with Directive 98/79/EC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until 31 December 2027.
- 3b. Devices for which the conformity assessment procedure pursuant to Directive 98/79/EC did not require the involvement of a notified body, for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with that Directive, and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, may be placed on the market or put into service until the following dates:
- (a) 31 December 2027, for class D devices;
 - (b) 31 December 2028, for class C devices;
 - (c) 31 December 2029, for class B devices and for class A devices placed on the market in sterile condition.
- 3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:
- (a) those devices continue to comply with Directive 98/79/EC;
 - (b) there are no significant changes in the design and intended purpose;
 - (c) the devices do 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;
 - (d) no later than 26 May 2025, the manufacturer has put in place a quality management system in accordance with Article 10(8);
 - (e) the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, no later than:
 - (i) 26 May 2025, for devices referred to in paragraph 3a and paragraph 3b, point (a);
 - (ii) 26 May 2026, for devices referred to in paragraph 3b, point (b);
 - (iii) 26 May 2027, for devices referred to in paragraph 3b, point (c);

- (f) the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII no later than:
- (i) 26 September 2025, for devices referred to in paragraph 3b, point (a);
 - (ii) 26 September 2026, for devices referred to in paragraph 3b, point (b);
 - (iii) 26 September 2027, for devices referred to in paragraph 3b, point (c).
- 3d. By way of derogation from paragraph 3, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply to devices referred to in the paragraphs 3a and 3b of this Article, instead of the corresponding requirements in Directive 98/79/EC.
- 3e. Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in paragraph 3a shall continue to be responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices it has certified, unless the manufacturer has agreed with a notified body designated in accordance with Article 42 that the latter shall carry out such surveillance.

No later than 26 September 2025, the notified body that has signed the written agreement referred to in paragraph 3c, point (f), shall become responsible for the surveillance in respect of the devices covered by the written agreement. Where the written agreement covers a device intended to substitute a device which has a certificate that was issued in accordance with Directive 98/79/EC, the surveillance shall be conducted in respect of the device that is being substituted.

The arrangements for the transfer of the surveillance from the notified body that issued the certificate to the notified body designated in accordance with Article 38 shall be clearly defined in an agreement between the manufacturer and the notified body designated in accordance with Article 42 and, where practicable, the notified body that issued the certificate. The notified body designated in accordance with Article 42 shall not be responsible for conformity assessment activities carried out by the notified body that issued the certificate.’;

(d) paragraph 8 is deleted;

(e) the following paragraph 11 is added:

‘11. Article 10a shall apply also to devices referred to in paragraphs 3, 3a and 3b of this Article.’;

(4) Article 112 is amended as follows:

(a) the first paragraph is replaced by the following:

‘Without prejudice to Article 110(3) to (3e) and (4), and without prejudice to the obligations of the Member States and manufacturers as regards vigilance and to the obligations of manufacturers as regards the making available of documentation, under Directive 98/79/EC, that Directive is repealed with effect from 26 May 2022, with the exception of:

(a) Article 11, Article 12(1), point (c), and Article 12(2) and (3) of Directive 98/79/EC, and the obligations relating to vigilance and performance studies provided for in the corresponding Annexes to that Directive, which are repealed, as applicable, with effect from the date referred to in Article 113(3), point (f), of this Regulation in respect of the application of the obligations and requirements that relate to the electronic systems referred to in, respectively, Article 33(2), points (e) and (f), of Regulation (EU) 2017/745;

(b) Article 10, Article 12(1), points (a) and (b), and Article 15(5) of Directive 98/79/EC, and the obligations relating to registration of devices and economic operators, and certificate notifications provided for in the corresponding Annexes to that Directive, which are repealed, as applicable, with effect from the date referred to in Article 113(3), point (f), of this Regulation in respect of the application of the obligations and requirements that relate to the electronic systems referred to in, respectively, Article 33(2), points (a), (c) and (d), of Regulation (EU) 2017/745.’;

(b) the second paragraph is replaced by the following:

‘As regards the devices referred to in Article 110(3) to (3e) and (4) of this Regulation, Directive 98/79/EC shall continue to apply to the extent necessary for the application of those paragraphs.’;

(5) Article 113(3) is amended as follows:

(a) point (a) is deleted;

(b) point (f) is amended as follows:

(i) the first paragraph is amended as follows:

(1) the first sentence of the introductory wording is replaced by the following:

‘without prejudice to the obligations of the Commission pursuant to Article 34 of Regulation (EU) 2017/745, the obligations and requirements that relate to any of the electronic systems referred to in Article 33(2) of that Regulation shall apply from the date corresponding to six months after the date of publication of the notices referred to in Article 34(3) of that Regulation informing that the relevant electronic system is functional and meets the functional specifications drawn up pursuant to Article 34(1) of that Regulation.’;

(2) after the tenth indent, the following indent is inserted:

‘ - Article 51(5),’;

- (3) the twelfth indent is replaced by the following:
‘- Article 74(1) to (13), without prejudice to Article 74(14),’;
- (4) the last indent is replaced by the following:
‘- Article 110(3d).’;
- (ii) the second paragraph is replaced by the following:
‘Until the date of application of the provisions referred to in the first paragraph of this point, the corresponding provisions of Directive 98/79/EC regarding information on vigilance reporting, performance studies, registration of devices and economic operators, and certificate notifications shall continue to apply.’;
- (c) the following points are inserted after point (f):
- ‘(fa) no later than 6 months after the date referred to in point (f) of this paragraph, manufacturers shall ensure that the information to be entered in Eudamed in accordance with Article 26 is entered in the the electronic system referred to in Article 33(2), point (a), of Regulation (EU) 2027/745 also regarding the following devices , provided that the same devices are placed on market also from the date referred to in point (f) of this paragraph:
- (i) devices for which the manufacturer has undertaken a conformity assessment in accordance with Article 48;
- (ii) devices placed on the market pursuant to Article 110(3), (3a) or (3b), unless the device, for which the manufacturer has undertaken a conformity assessment in accordance with Article 48, is already registered in Eudamed;
- (fb) no later than 12 months after the date referred to in point (f) of this paragraph, notified bodies shall ensure that the information to be entered in Eudamed in accordance with Article 51(5) of this Regulation is entered in the electronic system referred to in Article 33(2), point (d), of Regulation (EU) 2027/745 also regarding devices referred to in point (fa), (i), of this paragraph. For those devices, only the latest relevant certificate and, if applicable, any decision taken by the notified body related to such certificate shall be entered;

- (fc) by way of derogation from the first paragraph of point (f) of this paragraph, the obligations to upload the summary of safety and performance in accordance with Article 29(1) of this Regulation and to notify competent authorities in accordance with Article 50(1) of this Regulation, through the electronic system referred in Article 33(2), point (d), of Regulation (EU) 2017/745 shall apply to devices referred to in point (fa) of this paragraph when the certificate is entered in Eudamed in accordance with point (fb) of this paragraph;
- (fd) without prejudice to the first paragraph of point (f) of this paragraph, when a manufacturer has to submit a PSUR in accordance with Article 81(2) or report a serious incident, a field safety corrective action in accordance with Article 82 or submit a trend report in accordance with Article 83 through the electronic system referred to in Article 33(2), point (f), of Regulation (EU) 2017/745, it shall also register the device, which is subject of the PSUR or the vigilance report, in the electronic system referred to in Article 33(2), point (a), of that Regulation, except if such device was placed on the market in accordance with Directive 98/79/EC;’;
- (d) point (g) is deleted;
- (e) in point (j), the date ‘26 May 2028’ is replaced by ‘31 December 2030’.

Article 3

Entry into force

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Article 1, point (1), and Article 2, point (1), shall apply from [*OP: please insert the date = 6 months after entry into force of this amending Regulation*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament

The President

For the Council

The President