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NOTE

From:	General Secretariat of the Council
To:	Delegations
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Subject:	Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices *- Analysis of the final compromise text with a view to agreement*

I. INTRODUCTION

1. On 6 January 2023, 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 transitional provisions for certain medical devices and 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.

3. The proposed Regulation aims to amend the Medical Devices Regulation (MDR) and the *In vitro* Diagnostic Medical Devices Regulation (IVDR) to mitigate the risk of shortages of medical devices on the market.

[1] 5139/2

It aims at extending the existing transitional period for medical devices covered by a notified body certificate or manufacturer's declaration of conformity issued before 26 May 2021, in a staggered and conditional manner until 31 December 2027 for higher risk devices and until 31 December 2028 for medium and lower risk devices. Furthermore, the proposal aims to introduce a transition period until 26 May 2026 for class III implantable custom-made devices, subject to the application of the manufacturer for a conformity assessment before 26 May 2024. The validity of certificates that were valid on 26 May 2021 is also extended. Finally, it is proposed to remove the "sell-off" date currently established in the MDR and IVDR.

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 have been consulted and invited to deliver their opinion as quickly as possible.

II. WORK IN THE COUNCIL AND THE EUROPEAN PARLIAMENT

5. On 25 January 2023, the Permanent Representatives' Committee agreed on the text of the Commission proposal without amendments as a mandate[2] for the Presidency to enter into negotiations with the European Parliament. DK has a parliamentary scrutiny reservation.

6. At the European Parliament, the Committee on the Environment, Public Health and Food Safety (ENVI) is responsible for the file.

7. 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 the plenary session of 13-16 February 2023, through an urgency procedure and subject to legal-linguistic revision of the text.

[2] 5369/23

III. CONCLUSION

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

– to approve the text set out in Annex, which is identical to the Commission proposal,

and

– to mandate the Presidency to send a letter to the Chair of the ENVI Committee of the European Parliament confirming that, should the Parliament adopt its position at first reading in accordance with Article 294(3) TFEU and in the exact form set out in annex to this note - subject to legal-linguistic revision - the Council would, in accordance with Article 294(4) TFEU, approve the European Parliament's position and the act would be adopted in the wording which corresponds to the European Parliament's position.

ANNEX

2023/0005 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *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,

After consulting the European Economic and Social Committee,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Regulations (EU) 2017/745[3] and (EU) 2017/746[4] of the European Parliament and of the Council establish a new 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 in Council Directives 90/385/EEC[5] and 93/42/EEC[6] and Directive 98/79/EC of the European Parliament and of the Council[7], such as the supervision of notified bodies, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, whilst introducing provisions ensuring transparency and traceability regarding medical devices and *in vitro* diagnostic medical devices.

(2) Due to the impact of the COVID-19 pandemic, the date of application of Regulation (EU) 2017/745 has been postponed by one year to 26 May 2021 by Regulation (EU) 2020/561 of the European Parliament and of the Council[8], while the date of 26 May 2024 was maintained as end of the transition period by which certain devices that continue to comply with Directive 90/385/EEC or Directive 93/42/EEC may be placed on the market or put into service.

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3 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).

4 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).

5 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).

6 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

7 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).

8 Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (OJ L 130, 24.4.2020, p. 18).

(3) Also due to the impact of the COVID-19 pandemic, the transition period provided for in Regulation (EU) 2017/746 has already been extended by Regulation (EU) 2022/112 of the European Parliament and of the Council[9].

(4) Despite the steady increase in the number of notified bodies designated in accordance with Regulation (EU) 2017/745, the overall capacity of notified bodies is still not sufficient to ensure the conformity assessment of the large number of devices covered by certificates issued under Directive 90/385/EEC or Directive 93/42/EEC before 26 May 2024. It appears that a large number of manufacturers, especially small and medium-sized enterprises, are not sufficiently prepared to demonstrate compliance with the requirements of Regulation (EU) 2017/745, taking into account also the complexity of those new requirements. Therefore, it is very likely that many devices that may be placed on the market in accordance with the transitional provisions provided for in Regulation (EU) 2017/745 are not going to be certified in accordance with that Regulation before the end of the transition period, which leads to the risk of shortages of medical devices in the Union.

(5) In light of reports from healthcare professionals about the imminent risk of shortages of devices, it is necessary, as a matter of urgency, to extend the validity of certificates issued under Directives 90/385/EEC and 93/42/EEC and to extend the transition period during which devices that are in conformity with those Directives can be placed on the market. The extension should be sufficiently long to give notified bodies the time needed to carry out the conformity assessments required of them. The extension aims at ensuring a high level of public health protection, including patient safety and an avoidance of shortages of medical devices needed for the smooth functioning of health services, without lowering current quality and safety requirements.

(6) The extension should be subject to certain conditions to ensure that only devices that are safe and for which the manufacturers have taken steps to transition towards compliance with Regulation (EU) 2017/745 will benefit from the additional time.

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9 Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and the deferred application of conditions for in-house devices (OJ L 19, 28.1.2022, p. 3).

(7) To ensure progressive transition to Regulation (EU) 2017/745, the appropriate surveillance regarding devices benefiting from the transition period should eventually pass over from the body that has issued the certificate in accordance with Directive 90/385/EEC or Directive 93/42/EEC to a notified body designated under Regulation (EU) 2017/745. For reasons of legal certainty it should be provided that the notified body should not be responsible for conformity assessment and surveillance activities carried out by the outgoing body.

(8) As regards the period of time needed to allow manufacturers and notified bodies to carry out the conformity assessment in accordance with Regulation (EU) 2017/745 of medical devices that had been CE marked in accordance with Directive 90/385/EEC or Directive 93/42/EEC, 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 transition 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.

(9) Contrary to Directives 90/385/EEC and 93/42/EEC, Regulation (EU) 2017/745 requires the involvement of a notified body in the conformity assessment of class III custom-made implantable devices. Having regard to insufficient notified body capacity and the fact that manufacturers of custom-made devices are often small or medium-sized enterprises that did not have access to a notified body under Directives 90/385/EEC and 93/42/EEC, a transition period should be provided during which class III custom-made implantable devices may be placed on the market or put into service without a certificate issued by a notified body.

(10) Article 120(4) of Regulation (EU) 2017/745 and Article 110(4) of Regulation (EU) 2017/746 prohibit the further making available of devices which are placed on the market by the end of the applicable transition period and which are still in the supply chain one year after the end of that transition period. To prevent unnecessary disposal of safe medical devices and *in vitro* diagnostic medical devices that are still in the supply chain, thus adding to the imminent risk of shortages of devices, such further making available of devices should be unlimited in time.

(11) The adoption of this Regulation takes place due to exceptional circumstances arising from an imminent risk of shortages of medical devices and the associated risk of a public health crisis. In order to attain the intended effect of the amendments to 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 2024, to provide legal certainty for economic operators and healthcare providers, and for reasons of consistency as regards the amendments to both Regulations, it is necessary for this Regulation to enter into force as soon as possible. For the same reasons it is also considered appropriate to provide for an exception to the eight-week period referred to in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the Treaty on European Union, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community,

HAVE ADOPTED THIS REGULATION:

Article 1

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

(1) Article 120 is amended as follows:

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

‘Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC as from 25 May 2017 that were valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the dates set out in paragraph 3b for the relevant risk class of the devices. Certificates referred to in the first sentence that have expired before [*OP please insert the date – date of entry into force of this Regulation*] shall be considered to be valid until the dates set out in paragraph 3b 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 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 59(1) or has required the manufacturer, in accordance with Article 97(1), to carry out the applicable conformity assessment procedure';

(b) paragraph 3 is replaced by the following:

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

3b. Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates:

(a) 31 December 2027, for class III devices and for class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;

(b) 31 December 2028, for class IIb devices other than those covered by point (a), for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

3c. Devices for which the conformity assessment procedure pursuant to Directive 93/42/EEC did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 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 31 December 2028.

3d. Devices may be placed on the market or put into service until the dates referred to in paragraphs 3b and 3c of this Article only if the following conditions are met:

(a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;

(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 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);

(e) no later than 26 May 2024, the manufacturer, or an authorised representative, has lodged a formal application in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraphs 3b and 3c of this Article or in respect of a device intended to substitute that device, and no later than 26 September 2024 the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

3e. By way of derogation from paragraph 3a, 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 paragraphs 3b and 3c of this Article in place of the corresponding requirements in Directives 90/385/EEC and 93/42/EEC.

3f. Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in paragraph 3b of this Article 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 that surveillance.

No later than 26 September 2024, the notified body that has signed the written agreement referred to in paragraph 3d, point (e), shall be 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 90/385/EEC or Directive 93/42/EEC, 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 42 shall be defined in an agreement between the manufacturer, 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.

3g. By way of derogation from Article 5, class III custom-made implantable devices may be placed on the market or put into service until 26 May 2026 without a certificate issued by a notified body in accordance with the conformity assessment procedure referred to in Article 52(8), second subparagraph, provided that no later than 26 May 2024, the manufacturer, or the authorised representative of the manufacturer, has lodged a formal application in accordance with Section 4.3, first subparagraph, of Annex VII for the applicable conformity assessment, and no later than 26 September 2024 the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.’;

(c) paragraph 4 is replaced by the following:

‘4. Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2021, and devices placed on the market from 26 May 2021 pursuant to paragraphs 3a, 3b, 3c and 3g of this Article, may continue to be made available on the market or put into service.’

(2) Article 122 is amended as follows:

(1) in the first paragraph, the introductory wording is replaced by the following:

‘Without prejudice to Article 120(3a) to (3f) and (4) of this Regulation, 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 Directives 90/385/EEC and 93/42/EEC, those Directives are repealed with effect from 26 May 2021, with the exception of:’;

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

‘As regards the devices referred to in Article 120(3a) to (3f) and (4) of this Regulation, the Directives referred to in the first paragraph shall continue to apply to the extent necessary for the application of those paragraphs.’;

(3) In Article 123(3), point (d), the twenty-fourth indent is replaced by the following:

‘- Article 120(3e).’.

Article 2

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

(1) in Article 110, paragraph 4 is replaced by the following:

‘4. Devices lawfully placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022, and devices lawfully placed on the market from 26 May 2022 pursuant to paragraph 3 of this Article may continue to be made available on the market or put into service.’;

(2) in Article 112, the second paragraph is replaced by the following:

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

Article 3

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

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

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*