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INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices - Outcome of the European Parliament's first reading (Strasbourg, 13-16 December 2021)

I. INTRODUCTION

On 24 November 2021, the Permanent Representatives Committee confirmed that should the European Parliament approve the abovementioned Commission's proposal without amendments, the Council would approve the European Parliament's position.

In this context, the Committee on Environment, Public Health and Food Safety tabled the Commission's proposal for a Regulation. No amendments were presented.

II. VOTE

The Parliament adopted its first-reading position on 15 December 2021 by taking over the Commission proposal. This position is contained in its legislative resolution.

The Council should therefore be in a position to approve the European Parliament's position as set out in the Annex hereto, thus bringing to a close the first reading for both Institutions.

The legislative act would then be adopted in the wording which corresponds to the European Parliament's position.

P9_TA(2021)0498

Transitional provisions for certain *in vitro* diagnostic medical devices and deferred application of requirements for in-house devices ***I

European Parliament legislative resolution of 15 December 2021 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and deferred application of requirements for in-house devices (COM(2021)0627 – C9-0381/2021 – 2021/0323(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2021)0627),

– having regard to Article 294(2) and Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0381/2021),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 8 December 2021[1],

– after consulting the Committee of the Regions,

– having regard to the undertaking given by the Council representative by letter of 24 November 2021 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

– having regard to Rules 59 and 163 of its Rules of Procedure,

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

[1] Not yet published in the *Official Journal*.

P9_TC1-COD(2021)0323

Position of the European Parliament adopted at first reading on 15 December 2021 with a view to the adoption of Regulation (EU) 2021/… of the European Parliament and of the Council 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

(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 Committee[2],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[3],

[2] Opinion of 8 December 2021 (not yet published in the *Official Journal*).
[3] Position of the European Parliament of 15 December 2021.

Whereas:

(1) Regulation (EU) 2017/746 of the European Parliament and of the Council[4] establishes a new regulatory framework to ensure the smooth functioning of the internal market as regards *in vitro* diagnostic medical devices covered by that Regulation, taking as a base a high level of protection of health for patients and users, and taking into account the small and medium-sized enterprises that are active in this sector. At the same time, Regulation (EU) 2017/746 sets high standards of quality and safety for *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such devices. Furthermore, Regulation (EU) 2017/746 significantly reinforces key elements of the existing regulatory approach in Directive 98/79/EC of the European Parliament and of the Council[5], such as the supervision of notified bodies, risk classification, conformity assessment procedures, performance evaluation and performance studies, vigilance and market surveillance, whilst introducing provisions ensuring transparency and traceability regarding *in vitro* diagnostic medical devices.

[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] 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).

(2) The COVID-19 pandemic and the associated public health crisis presented and continues to present an unprecedented challenge to Member States and constitutes an immense burden for national authorities, health institutions, Union citizens, notified bodies and economic operators. The public health crisis has created extraordinary circumstances that demand substantial additional resources, as well as the increased availability of vitally important *in vitro* diagnostic medical devices, which could not reasonably have been anticipated at the time of adoption of Regulation (EU) 2017/746. Those extraordinary circumstances have a significant impact on various areas covered by that Regulation, such as the designation and work of notified bodies and the placing on the market and making available on the market of *in vitro* diagnostic medical devices in the Union.

(3) *In vitro* diagnostic medical devices are essential to the health and safety of Union citizens, and SARS-CoV-2 tests, in particular, are vital in the fight against the pandemic. Therefore, it is necessary to ensure that there is an uninterrupted market supply of such devices in the Union.

(4) Given the unprecedented magnitude of the current challenges, the additional resources needed by Member States, health institutions, notified bodies, economic operators and other relevant parties in order to fight the COVID-19 pandemic and the currently limited capacity of notified bodies, and taking into account the complexity of Regulation (EU) 2017/746, it is very likely that Member States, health institutions, notified bodies, economic operators and other relevant parties will not be in a position to ensure the proper implementation and full application of that Regulation from 26 May 2022 as laid down therein.

(5) Moreover, the current transitional period provided for in Regulation (EU) 2017/746 regarding the validity of certificates issued by notified bodies for *in vitro* diagnostic medical devices under Directive 98/79/EC will end on the same date as the transitional period provided for in Regulation (EU) 2017/745 of the European Parliament and of the Council[6] regarding the validity of certain EC declarations of conformity and certificates issued by notified bodies for medical devices under Council Directives 90/385/EEC[7] and 93/42/EEC[8], that is on 26 May 2024. This puts a strain on actors who deal with both medical devices and *in vitro* diagnostic medical devices.

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6 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).

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).

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

(6) In order to ensure the smooth functioning of the internal market and a high level of protection of public health and patient safety, as well as to provide legal certainty and avoid potential market disruption, it is necessary to extend 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. For the same reasons, it is also necessary to provide a sufficient transitional period for devices which are to undergo conformity assessment involving a notified body for the first time under Regulation (EU) 2017/746.

(7) As regards the period of time needed to expand the capacity of notified bodies, a balance should be struck between the limited available capacity of such bodies and ensuring a high level of public health protection. Therefore, the transitional periods for *in vitro* diagnostic medical devices that are to undergo conformity assessment involving a notified body for the first time under Regulation (EU) 2017/746 should be such as to allow differentiation between higher-risk and lower-risk devices. The length of the transitional period should depend on the risk class of the device 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.

(8) In order to allow *in vitro* diagnostic medical devices which have been lawfully placed on the market in accordance with the transitional provisions laid down in this Regulation sufficient time to continue to be made available on the market, including to be supplied to end users, or to be put into service, the sell-off date of 27 May 2025 provided for in Regulation (EU) 2017/746 should be adapted to take into account the additional transitional periods provided for in this Regulation.

(9) Having regard to the resources required by health institutions in the fight against the COVID-19 pandemic, those institutions should be given additional time to prepare to meet the specific conditions for the manufacture and use of devices within the same health institution ('in-house devices') laid down in Regulation (EU) 2017/746. The application of those conditions should therefore be deferred. As the health institutions need a complete overview of CE-marked *in vitro* diagnostic medical devices available on the market, the condition obliging the health institution to justify that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance, by an equivalent device available on the market should not become applicable until the transitional periods laid down in this Regulation have ended.

(10) Regulation (EU) 2017/746 should therefore be amended accordingly.

(11) Since the objectives of this Regulation, namely to extend the transitional periods set out in Regulation (EU) 2017/746, to introduce additional transitional provisions in that Regulation and to defer the application of the provisions of that Regulation concerning in-house devices, 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.

(12) The adoption of this Regulation takes place under exceptional circumstances arising from the COVID-19 pandemic and the associated public health crisis. To attain the intended effect of amending Regulation (EU) 2017/746 as regards the transitional periods, the additional transitional provisions and the application of the provisions concerning in-house devices, in particular with a view to providing legal certainty for economic operators, it is necessary for this Regulation to enter into force before 26 May 2022. It is therefore considered to be 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 TEU, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community.

(13) In light of the overriding need to immediately address the public health crisis associated with the COVID-19 pandemic, this Regulation should enter into force as a matter of urgency on the day of its publication in the *Official Journal of the European Union*,

HAVE ADOPTED THIS REGULATION:

Article 1

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

(1) Article 110 is amended as follows:

(a) paragraph 2 is amended as follows:

(i) in the first subparagraph, the date ‘27 May 2024’ is replaced by ‘27 May 2025’;

(ii) in the second subparagraph, the date ‘27 May 2024’ is replaced by ‘27 May 2025’;

(b) paragraphs 3 and 4 are replaced by the following:

‘3. By way of derogation from Article 5 of this Regulation, the devices referred to in the second and third subparagraphs of this paragraph may be placed on the market or put into service until the dates set out in those subparagraphs, provided that, from the date of application of this Regulation, those devices continue to comply with Directive 98/79/EC, and provided that there are no significant changes in the design and intended purpose of those devices.

Devices with a certificate that was issued in accordance with Directive 98/79/EC and which is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until 26 May 2025.

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) 26 May 2025, for class D devices;

(b) 26 May 2026, for class C devices;

(c) 26 May 2027, for class B devices;

(d) 26 May 2027, for class A devices placed on the market in sterile condition.

By way of derogation from the first subparagraph of this paragraph, 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 second and third subparagraphs of this paragraph instead of the corresponding requirements in Directive 98/79/EC.

Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in the second subparagraph of this paragraph shall continue to be responsible for the appropriate surveillance in respect of all applicable requirements relating to the devices it has certified.

4. Devices lawfully placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022 may continue to be made available on the market or put into service until 26 May 2025.

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 until the following dates:

(a) 26 May 2026 for devices referred to in paragraph 3, second subparagraph, or in paragraph 3, third subparagraph, point (a);

(b) 26 May 2027 for devices referred to in paragraph 3, third subparagraph, point (b);

(c) 26 May 2028 for devices referred to in paragraph 3, third subparagraph, points (c) and (d).’;

(2) in Article 112, second paragraph, the date ‘27 May 2025’ is replaced by ‘26 May 2028’;

(3) in Article 113(3), the following points are added:

‘(i) Article 5(5), points (b) and (c) and (e) to (i), shall apply from 26 May 2024;

(j) Article 5(5), point (d), shall apply from 26 May 2028.’.

Article 2

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 ...,

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