Council of the European Union

Brussels, 7 April 2020
(OR. en)

7180/20

Interinstitutional File: 2020/0060 (COD)

PHARM 8
SAN 122
MI 102
COMPET 142
CODEC 245

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions *- Mandate for negotiations with the European Parliament*

Introduction

1. On 3 April 2020, the Commission submitted its proposal ("The proposal") for a Regulation amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions.

2. Regulation (EU) 2017/745 establishes a new regulatory framework to ensure the smooth functioning of the internal market as regards medical devices. It replaces Council Directive 90/385/EEC[1] on active implantable medical devices and Council Directive 93/42/EEC[2] concerning medical devices. In order to create a smooth transition, it has since 26 November 2017 been possible to designate Notified Bodies[3] that meet the requirements of the Regulation and it is also already now allowed to place devices which comply with the Regulation on the market.

[1] OJ L 189, 20.7.1990, p. 17–36.
[2] OJ L 169, 12.7.1993, p. 1–43.
[3] Notified Bodies are organisations designated by an EU Member State to assess the conformity of products, *e.g.* medical devices, before they can be placed on the market.

3. The proposal has two aims:
   - to prolong the transitional period that started in 2017 by one year, by postponing from 26 May 2020 to 26 May 2021 the application of most of the provisions of Regulation (EU) 2017/745 and, for the same reason, to defer the repeal of most of the provisions of the two Directives until 26 May 2021.
   - to make it possible to adopt Union-wide derogations from the normal conformity assessment procedures for specific devices when this is in the interest of public health.

4. Both aims are directly related to the ongoing outbreak of COVID-19. While many devices are already certified under the Regulation, the prolonged transitional period aims to prevent potential shortages of devices that comply with the Directives but have not yet been certified under the Regulation. The Union-wide derogations aim to make specific vitally important medical devices available faster than would otherwise have been possible.

5. It is necessary to adopt the Regulation amending Regulation (EU) 2017/745 before 26 May since the two Directives will otherwise be repealed from that date and desirable to adopt it even earlier in order to establish the procedure for Union-wide derogations as early as possible. Such swift adoption presupposes an agreement at first reading between the Council and the European Parliament.

Preparation of the negotiation mandate

6. The Presidency has examined the proposal and discovered a need for introducing a few corrections/technical changes. They are included in the negotiation mandate set out in Annex I. In order to facilitate understanding, Annex II contains explanations of these changes and also sets out the Commission proposal together with the relevant parts of the consolidated text of Regulation (EU) 2017/745 as resulting from the second corrigendum[4] published in December 2019.

[4] OJ L 334, 27.12.2019, p. 165–166.

7. The negotiation mandate was circulated[5] to delegations on 6 April together with explanations for the changes introduced by the Presidency and comments on other elements of the proposal. In addition, the Presidency informally contacted all delegations to discuss the proposal in its entirety, including the Presidency changes to the text. In those contacts, particular attention was paid to points 6(aa) and 8(b)(iii). One delegation informally circulated written suggestions[6] for an additional change to Article 120(1) and to point 6(aa). Based on these consultations, the Presidency believes that a large majority of delegations can support it.

8. The outbreak of COVID-19 and the resulting public health crisis present an unprecedented challenge to health care systems in the Member States. In this situation, the Presidency deems it imperative to secure supply of safe medical devices for the treatment of European patients. To this aim, shortages due to regulatory reasons of any already approved medical devices must be prevented. It is also desirable to make vitally important new medical devices available as fast as possible.

9. The Presidency therefore recommends to adopt the proposed Regulation amending Regulation (EU) 2017/745 without delay.

Future steps

10. The Permanent Representatives Committee is invited to agree on a mandate based on the Presidency text set out in Annex I at its meeting on 8 April. The mandate will be transmitted to the European Parliament in a letter in which the Chair of the Committee informs the Parliament about the Council intention to reach an agreement at first reading.

11. The European Parliament is expected to vote its position at first reading already at its plenary on 16 April.

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5 WK 3580/2020 of 6 April 2020. This document in addition contains the consolidated text of the relevant parts of Regulation (EU) 2017/745.

6 The written comments were formalised in document WK 3625/2020 of 7 April.

12. After the vote in the European Parliament, the Permanent Representatives Committee will be invited to examine the Parliament's position and agree if it corresponds to the Council mandate. Should that be the case, a written procedure will be used to invite the Council:
    - to approve the Parliament's position, and
    - to agree to derogate from the eight-week period foreseen for scrutiny by the national parliaments[7].

13. It is noted that consultation of the European Economic and Social Committee and the Committee of the Regions is compulsory, as this proposal concerns public health. Both consultations must be finished before the Regulation amending Regulation (EU) 2017/745 is adopted. Both Committees have been contacted with the aim of speeding up the consultation.

CONCLUSION

14. The Permanent Representatives Committee is invited to:
    - agree on the amended text of the proposal for a Regulation amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions, as set out in Annex I to this note;
    - authorise the Presidency to send a letter to the Chair of the ENVI Committee confirming that, should the European Parliament adopt its position at first reading, in accordance with Article 294 paragraph 3 of the Treaty, in the form set out in the text contained in Annex I (subject to revision by the lawyer-linguists of both institutions), the Council would, in accordance with Article 294, paragraph 4 of the Treaty, approve the European Parliament's position and the act shall be adopted in the wording which corresponds to the European Parliament's position;
    - authorise the Presidency to request to the European Parliament the use of the urgent procedure.

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[7] The eight week period is provided for in Article 4 of Protocol 1 on the role of national Parliaments in the EU.

ANNEX I

Negotiation mandate

This Annex sets out the text of the amending Regulation to be proposed by the Permanent Representatives Committee for adoption y the European Parliament and the Council. Changes to the Commission proposal are indicated as follows:

New text is set out in ***bold italics***.

Deletions are set out in ~~strike-through~~.

(1) in Article 1(2), the second subparagraph is amended as follows:

(a) in the first sentence, ’26 May 2020’ is replaced by ’26 May 2021’,

(b) in the second sentence, ’26 May 2020’ is replaced by ’26 May 2021’;

(2) Article 17 is amended as follows:

(a) paragraph 5 is amended as follows:

(i) in the first sentence, ‘26 May 2020’ is replaced by ‘26 May 2021’,

(ii) in the third sentence, ‘26 May 2020’ is replaced by ‘26 May 2021’,

(b) in paragraph 6, ‘26 May 2020’ is replaced by ‘26 May 2021’;

(3) in Article 34(1), ‘25 March 2020’ is replaced by ’25 March 2021’;

(4) Article 59 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. By way of derogation from Article 52 of this Regulation or, for the period from [insert date – date of entry into force of this Regulation] to 25 May 2021, by way of derogation from Article 9(1) and (2) of Directive 90/385/EEC or from Article 11(1) to (6) of Directive 93/42/EEC, any competent authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific device for which the applicable procedures referred to in those Articles have not been carried out but use of which is in the interest of public health or patient safety or health.’,

(b) in paragraph 2, the following subparagraph is added:
'The Member State may inform the Commission and the other Member States of any authorisation granted in accordance with Article 9(9) of Directive 90/385/EEC or Article 11(13) of Directive 93/42/EEC before [insert date – date of entry into force of this Regulation].',

(c) in paragraph 3, the first subparagraph is replaced by the following:
'Following a notification pursuant to paragraph 2 of this Article, the Commission, in exceptional cases relating to public health or patient safety or health, may, by means of implementing acts, extend for a limited period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 of this Article or, when granted before [insert date – date of entry into force of this Regulation], in accordance with Article 9(9) of Directive 90/385/EEC or Article 11(13) of Directive 93/42/EEC to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';

(5) in Article 113, '25 February 2020' is replaced by '25 February 2021';

(6) Article 120 is amended as follows:

(a) in paragraph 1, '26 May 2020' is replaced by '26 May 2021',

(aa) paragraph 3 is replaced by the following:

'3. By way of derogation from Article 5 of this Regulation, a device which is a class I device pursuant to Directive 93/42/EEC, 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, or which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2021 it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.',

(b) 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 paragraph 3 of this Article, may continue to be made available on the market or put into service until 26 May 2025.’,

(c) in paragraph 5, ‘26 May 2020’ is replaced by ‘26 May 2021’,

(d) paragraph 6 is ~~amended as follows~~ ***replaced by the following***:

~~(i) in the first sentence, ‘26 May 2020’ is replaced by ‘26 May 2021’,~~

~~(ii) in the second sentence, ‘26 May 2020’ is replaced by ‘26 May 2021’,~~

‘6. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified prior to 26 May 2021. Notified bodies which are designated and notified in accordance with this Regulation may carry out the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation prior to 26 May 2021. ’,

(e) ~~in~~ paragraph 10~~, ‘26 May 2020’~~ is replaced by ~~‘26 May 2021’,~~ ***the following:***

‘10. Devices falling within the scope of this Regulation in accordance with point (g) of Article 1(6) which have been legally placed on the market or put into service in accordance with the rules in force in the Member States prior to 26 May 2021 may continue to be placed on the market and put into service in the Member States concerned.’,

(f) paragraph 11 is amended as follows:

(i) in the first sentence, ‘26 May 2020’ is replaced by ‘26 May 2021’,

(ii) in the second sentence, ‘26 May 2020’ is replaced by ‘26 May 2021’;

(7) in Article 122, the first paragraph is amended as follows

(a) in the introductory sentence, ’26 May 2020’ is replaced by ’26 May 2021’;

(b) the following indent is added:

“– Article 11(13) of Directive 93/42/EEC and Article 9(9) of Directive 90/385/EEC which are repealed with effect from [insert date – date of entry into force of this Regulation]”;

(8) Article 123 is amended as follows:

(a) in paragraph 2, ‘26 May 2020’ is replaced by ‘26 May 2021’,

(b) paragraph 3 is amended as follows:

(i) in point (a), ‘26 May 2020’ is replaced by ‘26 May 2021’,

(ii) in the first sentence of point (d), ‘26 May 2020’ is replaced by ‘26 May 2021’,

~~(iii) point (f) is replaced by the following:~~

~~‘(f) Article 27(4) shall apply to class IIa and class IIb devices from 26 May 2023 and to class I devices from 26 May 2025;’,~~

(iv) point (g) is replaced by the following:

‘(g) with regard to reusable devices that are required to bear the UDI carrier on the device itself, Article 27(4) shall apply to:

(i) implantable devices and class III devices from 26 May 2023;

(ii) class IIa and class IIb devices from 26 May 2025;

(iii) class I devices from 26 May 2027;’

(v) the following point (j) is added:

“(j) Article 59 shall apply from [insert date – date of entry into force of this Regulation]’;

(9) in point (h) of point 5.1 of Annex IX,’26 May 2020’ is replaced by ’26 May 2021’.

ANNEX II

Commission proposal and Presidency comments and changes

This Annex sets out the relevant parts of the consolidated text of Regulation (EU) 2017/745 as resulting from the second corrigendum[8] published in December 2019 together with the Commission proposal and comments and Presidency proposals for changes to the proposal.

Consolidated text Reg. (EU) 2017/745	**Commission proposal**	**Comment/ Presidency change**
	(1) in Article 1(2), the second subparagraph is amended as follows:	
The necessary common specifications shall be adopted by 26 May 2020. They shall apply as from six months after the date of	(a) in the first sentence, '26 May 2020' is replaced by '26 May 2021',	*General change of date of application*
their entry into force or from 26 May 2020, whichever is the latest.	(b) in the second sentence, '26 May 2020' is replaced by '26 May 2021';	*General change of date of application*
	(2) Article 17 is amended as follows:	
	(a) paragraph 5 is amended as follows:	
5. The Commission shall adopt, in accordance with Article 9(1), the necessary CS referred to in point (b) of paragraph 3 by 26 May 2020. Those CS shall be consistent with the latest scientific evidence and shall address the application of the general requirements on safety and performance laid down in in this Regulation. In the event that	(i) in the first sentence, '26 May 2020' is replaced by '26 May 2021',	*General change of date of application. Consistent with change in Article 1(2)*
those CS are not adopted by 26 May 2020, reprocessing shall be performed in accordance with any relevant harmonised standards and national provisions that cover the aspects outlined in point (b) of paragraph 3. Compliance with CS or, in the absence of CS, with any relevant harmonised standards and national provisions, shall be certified by a notified body.	(ii) in the third sentence, '26 May 2020' is replaced by '26 May 2021',	*General change of date of application. Consistent with change in Article 1(2)*
6. Only single-use devices that have been placed on the market in accordance with this Regulation, or prior to 26 May 2020 in accordance with Directive 93/42/EEC, may be reprocessed.	(b) in paragraph 6, '26 May 2020' is replaced by '26 May 2021';	*General change of date of application.*

[8] OJ L 334, 27.12.2019, p. 165–166.

1. The Commission shall, in collaboration with the MDCG, draw up the functional specifications for Eudamed. The Commission shall draw up a plan for the implementation of those specifications by 26 May 2018. That plan shall seek to ensure that Eudamed is fully functional at a date that allows the Commission to publish the notice referred to in paragraph 3 of this Article by 25 March 2020 and that all other relevant deadlines laid down in Article 123 of this Regulation and in Article 113 of Regulation (EU) 2017/746 are met.	(3) in Article 34(1), '25 March 2020' is replaced by '25 March 2021';	*This change is a result of the general change of date of application.*
Article 59 **Derogation from the conformity assessment procedures**	(4) Article 59 is amended as follows: (a) paragraph 1 is replaced by the following:	
1. By way of derogation from Article 52, any competent authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific device for which the procedures referred to in that Article have not been carried out but use of which is in the interest of public health or patient safety or health.	'1. By way of derogation from Article 52 of this Regulation or, for the period from [insert date – date of entry into force of this Regulation] to 25 May 2021, by way of derogation from Article 9(1) and (2) of Directive 90/385/EEC or from Article 11(1) to (6) of Directive 93/42/EEC, any competent authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific device for which the applicable procedures referred to in those Articles have not been carried out but use of which is in the interest of public health or patient safety or health.',	*Article 52 of 2017/745 can be used for conformity assessments during the transitional period* i.e. *before 26 May 2021 by virtue of Article 120(5) that allow devices compliant with 2017/745 to be placed on the market.*

2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.	(b) in paragraph 2, the following subparagraph is added: 'The Member State may inform the Commission and the other Member States of any authorisation granted in accordance with Article 9(9) of Directive 90/385/EEC or Article 11(13) of Directive 93/42/EEC before [insert date – date of entry into force of this Regulation].',	*Not compulsory to inform under the Directives. But information from MS needed for the purpose of para 3.*
3. Following a notification pursuant to paragraph 2 of this Article, the Commission, in exceptional cases relating to public health or patient safety or health, may, by means of implementing acts, extend for a limited period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 of this Article to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 114(4).	(c) in paragraph 3, the first subparagraph is replaced by the following: 'Following a notification pursuant to paragraph 2 of this Article, the Commission, in exceptional cases relating to public health or patient safety or health, may, by means of implementing acts, extend for a limited period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 of this Article or, when granted before [insert date – date of entry into force of this Regulation], in accordance with Article 9(9) of Directive 90/385/EEC or Article 11(13) of Directive 93/42/EEC to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';	*Possibility to use the new 2017/745 mechanism also during the time when the directives are applied.* *This subpara is maintained. Only included here to show the entire para.*

The Member States shall lay down the rules on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive. The Member States shall notify the Commission of those rules and of those measures by 25 February 2020 and shall notify it, without delay, of any subsequent amendment affecting them.	(5) in Article 113, '25 February 2020' is replaced by '25 February 2021';	*Due to the current situation only 2 or 3 MS have sent in notifications.*
1. From 26 May 2020, any publication of a notification in respect of a notified body in accordance with Directives 90/385/EEC and 93/42/EEC shall become void.	(6) Article 120 is amended as follows: (a) in paragraph 1, '26 May 2020' is replaced by '26 May 2021',	*So NBs notified under the Directive can continue their work.*
3. By way of derogation from Article 5 of this Regulation, a device which is a class I device pursuant to Directive 93/42/EEC, for which the declaration of conformity was drawn up prior to 26 May 2020 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, or which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2020 it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.	***(aa) paragraph 3 is replaced by the following:*** ***3. By way of derogation from Article 5 of this Regulation, a device which is a class I device pursuant to Directive 93/42/EEC, 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, or which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2021 it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.***	*Really needed, Normally sufficient to change the dates as proposed in point (a), but good to have the entire text here as this text is the result of the corrigendum. Thus entire text will be explicitly approved in OLP.* *No change.* *See above.*

4. Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2020, and devices placed on the market from 26 May 2020 pursuant to paragraph 3 of this Article, may continue to be made available on the market or put into service until 26 May 2025.	(b) 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 paragraph 3 of this Article, may continue to be made available on the market or put into service until 26 May 2025.',	*Normally sufficient to change the dates as proposed in point (a), but good to have the entire text here as this text is the result of the corrigendum. Thus entire text will be explicitly approved in OLP.*
5. By way of derogation from Directives 90/385/EEC and 93/42/EEC, devices which comply with this Regulation may be placed on the market prior to 26 May 2020.	(c) in paragraph 5, '26 May 2020' is replaced by '26 May 2021',	*Desirable to have as many devices as possible compliant with the Regulation already before 26 May 2021. So this provision should apply one more year.*
6. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified prior to 26 May 2020. Notified bodies which are designated and notified in accordance with this Regulation may carry out the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation prior to 26 May 2020.	(d) paragraph 6 is amended as follows: (i) in the first sentence, '26 May 2020' is replaced by '26 May 2021', (ii) in the second sentence, '26 May 2020' is replaced by '26 May 2021',	*Necessary to designate NBs before 2017/745 applies. Better to change the whole paragraph, as the date was established through a corrigendum. Thus entire text will be explicitly approved in OLP.* ***6. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified prior to 26 May 2021. Notified bodies which are designated and notified in accordance with this Regulation may carry out the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation prior to 26 May 2021.*** *Replaced with above.*

	(e) in paragraph 10, '26 May 2020' is replaced by '26 May 2021',	*The date here was also established through the corrigendum, desirable to confirm in OLP by exchanging the entire para.*
10. Devices falling within the scope of this Regulation in accordance with point (g) of Article 1(6) which have been legally placed on the market or put into service in accordance with the rules in force in the Member States prior to 26 May 2020 may continue to be placed on the market and put into service in the Member States concerned.		***10. Devices falling within the scope of this Regulation in accordance with point (g) of Article 1(6) which have been legally placed on the market or put into service in accordance with the rules in force in the Member States prior to 26 May 2021 may continue to be placed on the market and put into service in the Member States concerned.***
	(f) paragraph 11 is amended as follows:	
11. Clinical investigations which have started to be conducted in accordance with Article 10 of Directive 90/385/EEC or Article 15 of Directive 93/42/EEC prior to 26 May 2020 may continue to be conducted. As of 26 May 2020, however, the reporting of serious adverse events and device deficiencies shall be carried out in accordance with this Regulation.	(i) in the first sentence, '26 May 2020' is replaced by '26 May 2021',	*Part of general delay of application.*
	(ii) in the second sentence, '26 May 2020' is replaced by '26 May 2021';	*Part of general delay of application.*
	(7) in Article 122, the first paragraph is amended as follows:	
Without prejudice to Articles 120(3) 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 2020, with the exception of:	(a) in the introductory sentence, '26 May 2020' is replaced by '26 May 2021';	*Part of general delay of application.*

-	(b) the following indent is added: "– Article 11(13) of Directive 93/42/EEC and Article 9(9) of Directive 90/385/EEC which are repealed with effect from [insert date – date of entry into force of this Regulation]";	*Consequence of (4) above!* *Article 11(13) of 93/42/EEC* 13. By derogation from paragraphs 1 to 6, the competent authorities may authorize, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the procedures referred to in paragraphs 1 to 6 have not been carried out and the use of which is in the interest of protection of health. *Article 9(9) of 90/385/EEC* 9. By derogation from paragraphs 1 and 2 the competent authorities may authorize, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the procedures referred to in paragraphs 1 and 2 have not been carried out and the use of which is in the interest of protection of health. *So national derogations replaced by 59(1) and 59(2) of Reg. (EU) 2017/745.*
2. It shall apply from 26 May 2020	(8) Article 123 is amended as follows: (a) in paragraph 2, '26 May 2020' is replaced by '26 May 2021',	*Part of general delay of application.*
(a) Articles 35 to 50 shall apply from 26 November 2017. However, from that date until 26 May 2020, the obligations on notified bodies pursuant to Articles 35 to 50 shall apply only to those bodies which submit an application for designation in accordance with Article 38;	(b) paragraph 3 is amended as follows: (i) in point (a), '26 May 2020' is replaced by '26 May 2021',	*Part of general delay of application.*
(d) without prejudice to the obligations on the Commission pursuant to Article 34, where, due to circumstances that could not reasonably have been foreseen when drafting the plan referred to in Article 34(1), Eudamed is not fully functional on 26 May 2020, the obligations and requirements that relate to Eudamed shall apply from the date corresponding to six months after the date of publication of the notice referred to in Article 34(3). The provisions referred to in the preceding sentence are	(ii) in the first sentence of point (d), '26 May 2020' is replaced by '26 May 2021',	*Compare point (3).*

(f) for implantable devices and for class III devices Article 27(4) shall apply from 26 May 2021. For class IIa and class IIb devices Article 27(4) shall apply from 26 May 2023. For class I devices Article 27(4) shall apply from 26 May 2025;	(iii) point (f) is replaced by the following: '(f) Article 27(4) shall apply to class IIa and class IIb devices from 26 May 2023 and to class I devices from 26 May 2025;',	*Classification Rule 8 makes all implantable devices intended to administer medicinal products class III. But the rewording would give two years transitional period for implantable class IIa and IIb, which is not intended. Therefore delete change!.* ~~'(f) Article 27(4) shall apply to class IIa and class IIb devices from 26 May 2023 and to class I devices from 26 May 2025;',~~
(g) for reusable devices that shall bear the UDI carrier on the device itself, Article 27(4) shall apply from two years after the date referred to in point (f) of this paragraph for the respective class of devices in that point;	(iv) point (g) is replaced by the following: '(g) with regard to reusable devices that are required to bear the UDI carrier on the device itself, Article 27(4) shall apply to: (i) implantable devices and class III devices from 26 May 2023; (ii) class IIa and class IIb devices from 26 May 2025; (iii) class I devices from 26 May 2027;',	*The new wording is clearer.* *No change of date by the amending Regulation.* (i) implantable devices and class III devices from 26 May 2023; (ii) class IIa and class IIb devices from 26 May 2025; *No change of date by the amending Regulation.*
-	(v) the following point (j) is added: "(j) Article 59 shall apply from [insert date – date of entry into force of this Regulation]';	*Consequence of (4) above!*
(h) The Commission, after consultation with the Member States and relevant scientific experts shall provide guidance for expert panels for consistent interpretation of the criteria in point (c) before 26 May 2020.	(9) in point (h) of point 5.1 of Annex IX,'26 May 2020' is replaced by '26 May 2021'.	*Part of general delay of application.*