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WORKING DOCUMENT

From:	Presidency
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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 simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I *- Exchange of views*

Delegations will find in Annex the first Presidency compromise text on Cluster 6 - Interplay with AI Act, Dedicated IVD-specific discussion and transitional provisions for orphan devices - to be discussed at the meetings of the Working Party on Pharmaceuticals and Medical Devices on 10-11 September 2026. Other final provisions will be discussed later as part of the second compromise text.

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

Interplay with the AI Act

(23) The use of artificial intelligence in medical devices and in vitro diagnostic medical devices can help foster innovation and improve diagnosis and treatment of patients. The parallel application of Regulations (EU) 2017/745 and (EU) 2017/746, as applicable, and Regulation (EU) 2024/1689[1] of the European Parliament and of the Council could lead to overlaps of requirements and stifle innovation. To prevent those overlaps and to simplify the regulatory framework for artificial intelligence-enabled devices, the application of Regulation (EU) 2024/1689 to those devices should be limited to those provisions referred to in Article 2(2) of that Regulation. The references to Regulations (EU) 2017/745 and (EU) 2017/746 in Annex I to Regulation (EU) 2024/1689 should therefore be moved from Section A to Section B. Where needed, the Commission may use its implementing and delegated powers to lay down specific requirements regarding artificial intelligence, taking into account the requirements set out in Chapter III, Section 2, of Regulation (EU) 2024/1689. **With a view to ensuring a level of protection consistent with Regulation (EU) 2024/1689, the Commission should in particular address in those implementing or delegated acts the following aspects: […].** Moreover, notified bodies that are designated to assess high-risk AI systems falling under Regulations (EU) 2017/745 or (EU) 2017/746, as applicable, should meet also the specific AI-related requirements set out in Article 31 of Regulation (EU) 2024/1689.

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1 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).

Amendments to Regulation (EU) 2024/1689

Annex I to Regulation (EU) 2024/1689 is amended as follows:

(1) in Section A, points 11 and 12 are deleted;

(2) in Section B, the following points are added:

‘21. 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);

22. 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).’

PUBLIC

Transitional provisions for orphan devices

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

(95) in Article 120, the following paragraphs 14 and 15 are added:

'14. By way of derogation from Article 5 and from paragraphs 3 to 3e of this Article, a device as referred to in paragraph 3a or 3b of this Article that meets the criteria for an orphan device as referred to in Article 52a(3) may be placed on the market or put into service after the dates referred to in paragraphs 3a and 3b of this Article if the following conditions are met:

(a) an expert panel referred to in Article 106 has issued an opinion confirming the fulfilment of the criteria for an orphan device as referred to in Article 52a(3);

(b) there are no significant changes in the design and intended purpose of the device;

(c) the device does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

~~The requirements of this Regulation, with the exception of Chapters IV, V and VI, shall apply to~~**Where** a device referred to in the first subparagraph **is placed on the market in accordance with this paragraph, the requirements of this Regulation shall apply with the exception of Chapter IV, Articles 52 to 59c, and Articles 61(4) and 62**.

By way of derogation from Article 86(1), manufacturers of class IIa devices, class IIb devices and class III devices placed on the market or put into service in accordance with this paragraph shall update the PSUR at least annually. On an annual basis, the manufacturer shall submit the PSUR and, where applicable, an update of the summary of safety and clinical performance to the competent authority of the Member State in which it is established.

PUBLIC

The competent authority of the Member State may require the manufacturer to conduct defined post-market surveillance or PMCF activities within a specified period of time to generate additional clinical data to confirm the safety and performance of the device and to evaluate any undesirable side-effects and the acceptability of the benefit-risk ratio.

~~Devices placed on the market or put into service in accordance with this paragraph, which do not have a valid certificate in accordance with paragraph 2, shall not bear the CE marking.~~ In its EU declaration of conformity, the manufacturer shall make reference to the fact that the device is an orphan device placed on the market or put into service in accordance with this ~~provision~~**paragraph**.

For a device placed on the market or put into service in accordance with this paragraph, the manufacturer shall ensure that its EU declaration of conformity and relevant certificate are uploaded to Eudamed. Where the certificate is no longer valid in accordance with paragraph 2, the manufacturer shall inform the competent authority of the Member State in which it is established, and shall update the information on Eudamed accordingly.

The manufacturer shall inform the intended users about the fact that the device is an orphan device placed on the market or put into service in accordance with this provision, where applicable, in the summary of safety and clinical performance and in the **labelling,** instructions for use ~~or~~**and, where appropriate,** any other accompanying documentation.

At least every ~~10~~**7** years, the manufacturer shall request an opinion from an expert panel referred to in Article 106 confirming the fulfilment of the criteria for an orphan device as referred to in Article 52a(3). **The expert panel opinion shall be provided to the manufacturer and the competent authority of the Member State in which the manufacturer is based.**

PUBLIC

Where the expert panel issues a negative opinion, the competent authority shall decide, with due consideration to this opinion, whether continued placing on the market or putting into service of the device in accordance with this paragraph is no longer appropriate. Where the competent authority decides this is no longer appropriate, the device may continue to be placed on the market or put into service in accordance with this paragraph for no longer than one year following the competent authority's decision, after which Article 5 shall apply.

15. [As regards devices for which a conformity assessment procedure is pending on …[OP please insert the date = six months after the date of entry into force of this Regulation], or for which a certificate is issued by a notified body before that date, the manufacturer and the notified body may agree to continue applying the provisions of this Regulation in the form applicable before …[OP please insert the date = six months after the date of entry into force of this Regulation] until the conformity assessment procedure is finalised or until the certificate is renewed.';]

PUBLIC

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

(78) in Article 110, the following paragraphs 12 and 13 are added:

‘12. By way of derogation from Article 5 and from paragraphs 3 to 3e of this Article, a device as referred to in paragraph 3a or paragraph 3b of this Article that meets the criteria for an orphan device set out in Article 48a(3) may be placed on the market or put into service beyond the dates referred to in paragraphs 3a and 3b if the following conditions are met:

(a) an expert panel referred to in Article 106 of Regulation (EU) 2017/745 has issued an opinion confirming the fulfilment of the criteria for an orphan device set out in Article 48a(3);

(b) there are no significant changes to the design and intended purpose of the device;

(c) the device does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

~~The requirements of this Regulation, with the exception of Chapters IV, V and VI, shall apply to the~~**Where a** device referred to in the first subparagraph **is placed on the market in accordance with this paragraph, the requirements of this Regulation shall apply, with the exception of Chapter IV, Articles 48 to 54c, and Article 58**. By way of derogation from Article 81(1), manufacturers of class C and class D devices placed on the market or put into service in accordance with this paragraph shall update the PSUR at least annually. On an annual basis, the manufacturer shall submit the PSUR and, where applicable, an update of the summary of safety and performance to the competent authority of the Member State in which it is established.

PUBLIC

The competent authority of the Member State may require the manufacturer to conduct defined post-market surveillance or PMPF activities within a specified period of time to generate additional data to confirm the safety and performance of the device and to evaluate the acceptability of the benefit-risk ratio.

~~Devices placed on the market or put into service in accordance with this paragraph, which do not have a valid certificate in accordance with paragraph 2, shall not bear the CE marking.~~ In its EU declaration of conformity, the manufacturer shall make reference to the fact that the device is an orphan device placed on the market or put into service in accordance with this paragraph.

For a device placed on the market or put into service in accordance with this paragraph, the manufacturer shall ensure that its EU declaration of conformity and relevant certificate are uploaded to Eudamed. Where the certificate is no longer valid in accordance with paragraph 2, the manufacturer shall inform the competent authority of the Member State in which it is established, and shall update the information on Eudamed accordingly.

The manufacturer shall inform the intended users that the device is an orphan device placed on the market or put into service in accordance with this paragraph, where applicable, in the summary of safety and performance and in the **labelling,** instructions for use ~~or~~ **and, where appropriate,** any other accompanying documentation.

At least every ~~10~~**7** years, the manufacturer shall request an opinion from an expert panel referred to in Article 106 of Regulation (EU) 2017/745 confirming the fulfilment of the criteria for an orphan device set out in Article 48a(3) of this Regulation. **The expert panel opinion shall be provided to the manufacturer and the competent authority in the Member State in which the manufacturer is based.**

PUBLIC

Where the expert panel issues a negative opinion, the competent authority shall decide, with due consideration to this opinion, whether continued placing on the market or putting into service of the device in accordance with this paragraph is no longer appropriate. Where the competent authority decides this is no longer appropriate, the device may continue to be placed on the market or put into service in accordance with this paragraph for no longer than one year following the competent authority's decision, after which Article 5 shall apply.

13. [As regards devices for which a conformity assessment procedure is pending on …[OP please insert the date = six months after the date of entry into force of this Regulation] or for which a certificate is issued by a notified body before that date, the manufacturer and the notified body may agree to continue applying the provisions of this Regulation in the form applicable before …[OP please insert the date = six months after the date of entry into force of this Regulation] until the conformity assessment procedure is finalised or until the certificate is renewed.';]

PUBLIC

Dedicated IVD-specific discussion

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

(2) Article 2 is amended as follows:

(b) in point (7), the introductory wording is replaced by the following:

‘‘companion diagnostic’ means a device which is essential for the safe and effective use of one or more corresponding medicinal product(s) to:’;

(16) The following Article 19a is inserted:

‘Article 19a

Kits

A kit shall contain at least one in vitro diagnostic medical device which may or may not individually bear the CE marking in conformity with this Regulation. A kit may **also** contain the following components:

(a) **accessories to an** in vitro diagnostic medical ~~devices or their accessories~~ **device** which may or may not individually bear the CE marking in conformity with this Regulation;

(b) medical devices or their accessories bearing the CE marking in conformity with Regulation (EU) 2017/745;

(c) other products which are used within the in vitro diagnostic examination or the presence of which in the kit is otherwise justified, and where those products are in conformity with the Union legislation that applies to them.’

PUBLIC

(22) Article 29 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. For ~~companion diagnostics,~~ class C ~~devices for self-testing~~ and class D devices, other than devices for performance studies, the manufacturer shall draw up a summary of safety and performance.

The summary of safety and performance shall be written in a way that is clear to the intended user **and shall be made available to the public via Eudamed**.

The draft of the summary of safety and performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 48. The manufacturer shall ensure that the summary of safety and performance is available to the public in Eudamed and ~~shall~~ mention on the label or instructions for use where the summary is available.’;

(b) paragraph 2 is amended as follows:

(i) point (a) is replaced by the following:

‘(a) the identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN, and a reference to the location of the instructions for use in Eudamed;’;

(ii) points ~~(b),~~ (f), (g) and (h) are deleted;

PUBLIC

(29) Article 48 is amended as follows:

(a) in paragraph 3, the second and third subparagraphs are deleted;

(b) in paragraph 4, the second subparagraph is deleted;

(c) paragraphs 5 and 6 are deleted;

(d) paragraph 7 is replaced by the following:

‘7. Manufacturers of class C devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I**,** II and III of Annex IX **including an assessment of the technical documentation as specified in Section 4 of that Annex shall be done for at least one representative device per generic device group.**

The selection of samples of technical documentation for assessment shall be proportionate to the risk and compliance history of the generic device group as applicable.’;

(e) in paragraph 8, the second subparagraph is deleted;

(f) paragraph 9 is replaced by the following:

‘9. Manufacturers of class B devices, other than devices for performance study, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX **including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device per category of device.**

The selection of samples of technical documentation for assessment shall be proportionate to the risk and compliance history of the category of devices as applicable.’;

PUBLIC

(g) the following paragraph 9a is inserted:

‘9a. Manufacturers of class B devices, other than devices for performance study, may, instead of the conformity assessment procedure referred to in paragraph 9, choose to apply a conformity assessment as specified in Annex X coupled with a conformity assessment as specified in Annex XI with the exception of its Section 5.’;

(h) ~~in paragraph 10, the second subparagraph is deleted;~~

(i) the following paragraphs 10a and 10b are inserted:

‘10a. In the case of devices for self-testing **or near-patient testing**, in addition to the procedures applicable pursuant to paragraph 3, 7 or 9, the procedure specified in Section 5.1 of Annex IX shall also apply.

10b. In the case of companion diagnostics, in addition to the procedures applicable pursuant to paragraph 3, 4, 7 or 8, the procedure specified in Section 5.2 of Annex IX or in Section 3, point (k), of Annex X, as applicable, shall also apply.’;

(j) paragraphs 12 and 13 are replaced by the following:

‘12. The documents relating to the procedures referred to in paragraphs 1 to 4 and 7 to 10b shall be available in any official language of the Union acceptable to the **authority responsible for** notified ~~body~~**bodies**.

13. The Commission may, by means of implementing acts, specify the detailed arrangements and procedural aspects of the conformity assessment procedures with regard to any of the following aspects:

(a) in respect of class B and class C devices, the basis for the selection of ~~the~~ representative device**(s)** for the assessment of the technical documentation as referred to in Section 2.3 of Annex IX;

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(b) the modalities of unannounced on-site audits and sample tests to be conducted by notified bodies in accordance with Section 3.4 of Annex IX, taking into account the risk-class and the type of device;

(c) the frequency of samples of the manufactured devices or batches of class D devices to be sent to an EU reference laboratory designated pursuant to Article 100, in accordance with Section 4.12 of Annex IX and Section 5.1 of Annex XI;

(d) the physical, laboratory or other tests to be carried out by notified bodies in the context of sample tests, assessment of technical documentation and type;

(e) the modalities of the conformity assessment procedures regarding breakthrough devices and orphan devices set out in Article 48a.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 107(3).';

(k) the following paragraph 14 is added:

'14. The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend Annexes IX, X and XI in order to adapt those Annexes to technical or scientific progress or to developments regarding conformity assessment of devices at international level ~~and to take into account the needs of~~**, in** particular ~~devices in view of their special characteristics.;~~**with regard to:**

(a) the application and documentation to be submitted by the manufacturer to the notified body;

(b) the audits and assessments to be conducted by the notified body for initial certification and for surveillance assessments, including the assessment of the technical documentation of representative devices;

PUBLIC

(c) the specific additional procedures laid down in Annex IX, Section 5;

(d) the administrative provisions regarding the keeping of documentation.

When adopting delegated acts pursuant to this paragraph, the Commission shall, where relevant, take into account the needs of particular devices in view of their special characteristics.';

(30) the following Articles 48a and 48b are inserted:

'Article 48a

Conformity assessment of breakthrough devices and of orphan devices

1. For the conformity assessment of breakthrough devices and orphan devices, ~~for which~~**where the conformity assessment procedure requires the involvement of** a notified body**,** is involved in the conformity assessment, the procedures laid down in Article 48 shall apply subject to the specific arrangements set out in this Article.

2. A device shall be considered a breakthrough device if it meets **all the**~~the~~ following criteria:

(a) ~~the device~~**it** is expected to introduce in the Union a high degree of novelty with respect to the device technology or the related clinical procedure or the application of the device in clinical practice;

(b) ~~the device~~**it** is expected to provide a significant positive clinical impact on patient or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following:

(i) offering a significant positive clinical or health impact compared to available alternatives and the state of the art;

(ii) fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.

3. A device shall be considered an orphan device if it meets **all** the following criteria:

(a) the device is intended to provide information on a disease or condition that presents in not more than 12 000 individuals in the Union per year;

(b) at least one of the following criteria is met:

(i) there are insufficient available alternatives;

(ii) the device is expected to provide a clinical benefit compared to available alternatives or the state of the art.

4. Upon a duly substantiated request by a manufacturer or a notified body, an expert panel as referred to in Article 106 of Regulation (EU) 2017/745 shall provide an opinion **with respect to confirming** ~~as to~~ whether the criteria set out in paragraph 2 or 3 of this Article, as applicable, are fulfilled. **In addition, upon a duly substantiated request by a notified body, an expert panel shall provide an** ~~That~~ opinion **with respect to confirming whether the criteria set out in paragraph 7 of this Article are fulfilled. Those opinions** shall be published on a dedicated website without disclosing any confidential information as referred to in Article 102 and shall be duly taken into consideration by the manufacturer and the notified body.

5. Where the opinion of the expert panel ~~confirms~~**has confirmed** the fulfilment of the criteria set out in paragraph 2 or 3 of this Article, the manufacturer of a breakthrough device or of an orphan device, as applicable, may request advice from the expert panels referred to in Article 106 of Regulation (EU) 2017/745 regarding its performance evaluation strategy and appropriate analytical or clinical performance data for the performance evaluation of the device.

PUBLIC

6. For a ~~confirmed~~ breakthrough device or an orphan device, **confirmed by the relevant expert panel,** as applicable, the notified body involved in the conformity assessment procedure set out in Article 48 shall ~~prioritise~~ **offer priority access to supports to the manufacturer throughout** the conformity assessment ~~and apply~~**procedure.**

These supports may include, where appropriate~~, a rolling review with a view to reduce assessment timelines.~~**:**

(a) Reduced assessment timelines;

(b) Rolling reviews of technical documentation;

(c) Priority access, free of charge, to the dialogues outlined in Annex VII section 1.2.9;

(d) Proportionate reductions in related fees; and

(e) Deferral of payments of fees until the relevant conformity assessment activity is finalised.

The notified body shall give due consideration to an opinion or advice provided by the expert panel in accordance with paragraph 4 or 5 and, where it does not follow such opinion or advice, it shall provide duly justified reasons. The notified body may ask the expert panel to clarify the opinion it has provided.

7. The notified body shall issue a certificate pursuant to Article 51 where**, based on their assessment of the performance evaluation report,** the pre-market clinical evidence, even if based on limited clinical performance data~~, is deemed adequate,~~ provided that ~~either~~ **each** of the following ~~conditions is~~ **criteria is** fulfilled:

(a) the benefit of the immediate availability on the market of the device outweighs the risk associated with the fact that additional clinical performance data are still required;

(b) the benefit-risk ratio of the device is favourable and the manufacturer commits to providing additional data from post-market performance follow-up activities.

Where appropriate, the notified body shall limit the validity of the certificate and specify any conditions for or limitations to the certificate's validity in accordance with Article 51, such as specific post-market performance follow-up activities to be conducted within a specified period of time.

8. The Commission is empowered to adopt delegated acts in accordance with Article 108 in order to amend this Article to adapt to technical and scientific progress and to take into account developments regarding conformity assessment of breakthrough devices or orphan devices at international level.

9. The Commission may, by means of implementing acts, lay down further details of the procedure for the conformity assessment of breakthrough devices or orphan devices set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

Article 48b

Digitalisation of technical documentation, conformity assessment and reports

1. The manufacturer may draw up and make available the technical documentation and any reports or other documents required pursuant to this Regulation in digital format, in particular structured machine-readable format, provided that it is possible to transform it into human-readable format, and that there is version-control to enable the conduct of retrospective conformity checks. Where the technical documentation, reports or other documents are to be submitted to and assessed by a notified body **or made available to competent authorities for the purposes of market surveillance**, the manufacturer shall **ensure that the digital format is suitable for and agreed** ~~agree~~ with the notified body ~~on the digital format~~ **or competent authority or national authorities responsible for notified bodies as applicable**.

PUBLIC

2. Where necessary to ensure that the digital format of the technical documentation, reports or other documents is reliable, interoperable and standardised, the Commission may, by means of CS as referred to in Article 9, lay down minimum requirements or functional specifications for the digital format.';

(31) in Article 49, paragraph 5 of is replaced by the following:

'5. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities in the public interest and with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.';

(32) Article 50 is replaced by the following:

'Article 50

Mechanism for scrutiny of conformity assessments

1. The MDCG**, a competent authority** or the Commission may, based on reasonable concerns, request advice from an expert panel in relation to the safety and performance of any device. For that purpose, the MDCG**, a competent authority** or the Commission may request the notified body that issued the certificate for the device in question to submit to the expert panel its performance evaluation assessment report and any subsequent surveillance assessment reports regarding that device. The expert panel may request the notified body or the manufacturer to submit any additional information needed for its assessment. **The expert panel may request an assessment from the respective authority responsible for notified bodies.**

PUBLIC

2. The MDCG**, a competent authority** or the Commission may, based on reasonable concerns, request advice from one or more EU reference laboratories, **based on their expertise related to** ~~on the basis of~~ laboratory testing, in relation to the safety and performance of any device, provided that the device **or the field of laboratory testing** falls within the scope of designation of those EU reference laboratories. For that purpose, the MDCG**, a competent authority** or the Commission may request the notified body that issued the certificate for the device in question to submit to the EU- reference laboratories its performance evaluation assessment report**, other relevant parts of the technical documentation** and any subsequent surveillance assessment reports regarding that device. The EU reference laboratories may request the notified body or the manufacturer to submit samples of the device or any additional information needed for their assessment.

3. The notified body shall give utmost consideration to the advice of the expert panel or the EU reference laboratory, as applicable, and, where needed, take any appropriate measures, including those referred to in Article 51(3) and (4).';

(33) Article 51 is amended as follows:

(a) paragraphs 1 and 2 are replaced by the following:

'1. The notified bodies shall issue certificates in accordance with Annexes IX, X and XI in an official language of the Union and ~~immediately~~ upload them in Eudamed **in a timely manner**. The minimum content of the certificates shall be as set out in Annex XII.

2. The ~~validity of~~**EU technical documentation assessment** certificates **related to Class D devices, companion diagnostics, and Class C devices for self-testing and near patient testing, shall be valid for the period they indicate, which shall not exceed five years.**

On application by the manufacturer, the initial validity of the certificates for Class D devices, companion diagnostics, and Class C devices for self-testing and near patient testing, may be extended for a further period not limited in time, based on a re-assessment after the initial five years and periodic reviews thereafter, in accordance with the applicable conformity assessment procedures and with Annex VII, Section 4.11.

The certificates related to all other devices shall not be limited in time~~, unless in exceptional cases where~~**.**

Notwithstanding subparagraphs 1 and 2, the notified body ~~considers it necessary to~~**may** limit the period of validity **of certificates it issues** based on duly justified grounds.

In those cases, the notified body shall indicate the period of validity on the certificate. If the period of validity of the certificate is limited, on application by the manufacturer, the notified body may, following an assessment performed in accordance with Annex VII, Section 4.11, extend the validity of the certificate. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.';

(b) the following paragraph 2a is inserted:

'2a. During the validity of the certificate, **where applicable** the notified body shall carry out appropriate surveillance activities, including periodic reviews taking into consideration developments of the state of the art**, in accordance with Section 4.11 of Annex VII**. Those reviews shall be proportionate to the risk class of the device.';

(c) paragraph 3 is replaced by the following:

'3. Notified bodies may impose conditions on the **validity of the** certificate~~'s validity, such as limiting the intended purpose of a device or requiring the manufacturer to undertake specific PMPF studies pursuant to Part B~~**, in accordance with Section 4.8** of Annex ~~XIII~~**VII**.';

(d) in paragraph 4, the first sentence is replaced by the following:

'Where a notified body finds that the requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any conditions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body.';

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

'The notified body shall enter in the electronic system referred to in Article 52 any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and conditions imposed on certificates.';

(34) in Article 52, ~~points (f) and (i) are~~**point(i) is** deleted;

(35) Article 54 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. By way of derogation from Article 48, on a duly justified request, any competent authority may authorise for a limited period of time **or for a defined number of devices,** 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 conformity assessment procedures have not been carried out, provided the use of that device is in the interest of public health, patient safety or patient health.';

(b) the following ~~paragraph 1a is~~**paragraphs 1a, 1b and 1c are** inserted:

'1a. By way of derogation from Article 6(2) ~~and~~**,** on a duly justified request, any competent authority may authorise for a limited period of time **or for a defined number of devices, the use of a device that is not placed on the market but in the context of a commercial activity for** the provision of a diagnostic or therapeutic service referred to in that Article to a natural or legal person**(s)** established within the territory of the Member State concerned, using a device for which the applicable conformity assessment procedures set out in this Regulation have not been carried out, provided the provision of such service is in the interest of public health, patient safety or patient health.~~;~~

1b. Where appropriate, the competent authority shall impose and specify conditions or limitations to the exemption as applicable, such as conditions on labelling, incident reporting, and traceability, and limitations on time and number of devices.

1c. Where appropriate, and in order to support the decision-making process referred to in the first paragraph, the competent authority may request an opinion from the relevant expert panel established under Regulation (EU) 2017/745.';

(c) paragraph 2 is replaced by the following:

'2. The Member State shall inform the Commission~~,~~ **and** the other Member States ~~and the relevant expert panels referred to in Article 106 of Regulation (EU) 2017/745~~ of any decision to authorise **or refuse** the placing on the market or putting into service of a device **in accordance with paragraph 1, or the use of a device for**~~, or~~ the provision of a service, in accordance with ~~paragraph 1 or~~ paragraph 1a ~~of this Article~~, where such authorisation is granted for use other than for a single patient.

The Commission shall share this information with the relevant expert panels referred to in Article 106 of Regulation (EU) 2017/745.

PUBLIC

The Member State shall make information about such authorisations publicly available.';

(d) in paragraph 3, the first subparagraph is replaced by the following:

'Where a request pursuant to paragraph 1 or paragraph 1a has been submitted to competent authorities in more than one Member State and based on an opinion**, requested by the Commission or a Member State,** of an expert panel referred to in Article 106 of Regulation (EU) 2017/745, the Commission, in exceptional cases relating to public health, patient safety or patient health, may, by means of implementing acts, extend for a limited period of time **or number of devices** the validity of an authorisation granted by a Member State in accordance with paragraph 1 or paragraph 1a of this Article to the territory of the Union, or provide an authorisation referred to in paragraph 1 or paragraph 1a of this Article for the territory of the Union. The Commission may set the conditions under which the device may be placed on the market or put into service, or under which the diagnostic or therapeutic service may be provided. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

The Commission shall make information about extensions and authorisations publicly available.';

(e) the following paragraphs 4 and 5 are added:

'4. In the event of a public health emergency at Union level recognised in accordance with Article 23 of Regulation (EU) 2022/2371 of the European Parliament and of the Council*****, the Commission may, by means of implementing acts, on its own initiative after consulting the MDCG**, and if appropriate, the relevant expert panel**, authorise the placing on the market or putting into service of a device in accordance with paragraph 3. The authorisation shall cease to apply at the latest when the recognition of the public health emergency is terminated pursuant to Article 23(2) of Regulation (EU) 2022/2371. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(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 107(4).

5. The Commission may, by means of implementing acts, lay down rules further specifying the procedure set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

***** Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).';

(36) the following Articles 54a, 54b and 54c are inserted:

'Article 54a

Derogations from certain requirements in the event of a serious cross-border threat to health, disaster or crisis

1. Upon a duly justified request ~~by a manufacturer~~, a competent authority may authorise for a limited period of time **or a limited number of devices**, by way of derogation from the relevant provisions in Annexes II, III, IX, X and XI, an exemption from the requirements related to changes to the manufacturing~~,~~ **or** design ~~or intended purpose~~ of a CE marked device, where it is in the interest of public health, patient safety or patient health in either of the following circumstances:

(a) a serious cross-border threat to health as defined in Article 3, point (1) of Regulation (EU) 2022/2371;

(b) a disaster or a crisis within the meaning of Regulation (EU) ../…. of the European Parliament and of the Council******+.

2. The manufacturer shall ensure that the manufactured devices remain in conformity with the relevant general safety and performance requirements set out in Annex I.

The manufacturer shall ensure that any changes to the manufacturing or design of the device exempted in accordance with paragraph 1 do not adversely affect the benefit-risk ratio of the device.

3. The competent authority may request the notified body that issued a certificate for the device in question to assist it in the assessment of the request referred to in paragraph 1.

3a. Where appropriate, the competent authority shall impose and specify conditions or limitations, as applicable, to the authorisation of exemption in accordance with paragraph 1. These may include, but are not limited to, conditions on labelling, incident reporting, and traceability, and limitations on time and number of devices.

4. Where applicable, the manufacturer shall keep the notified body that issued a certificate for the device in question informed about **the authorisation and** any changes made regarding the manufacturing, design or intended purpose of a CE marked device in accordance with the authorisation referred to in paragraph 1.

5. Where a request pursuant to paragraph 1 has been submitted to competent authorities in more than one Member State, the Commission, in exceptional cases relating to public health, patient safety or patient health, may, by means of implementing acts, extend for a limited period of time **or a limited number of devices,** the validity of an exemption granted by a Member State in accordance with paragraph 1 to the territory of the Union, or provide an exemption referred to in paragraph 1 for the territory of the Union. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

PUBLIC

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 107(4).

_____

****** Regulation (EU) .../... of the European Parliament and of the Council of ... on ... (OJ ..., ELI). [+] OJ: Please insert in the text the number of the Regulation contained in 2025/0223(COD) (Proposal for a Regulation on the Union Civil Protection Mechanism and Union support for health emergency preparedness and response, and repealing Decision No 1313/2013/EU) and insert the number, date, title and OJ reference of that Regulation in the footnote.

Article 54b

Regulatory sandboxes at national level

1. Member States, on their own initiative or upon a substantiated request by manufacturer ~~or a prospective manufacturer,~~ may establish one or more regulatory sandboxes to which the application of certain requirements of Chapters V or VI or of Annexes I, VIII, IX, X, XI, XIII or XIV would not be appropriate **from a technical or scientific viewpoint, and that, with regard to those requirements, every precaution has been taken to protect the health and safety of patients, users, and other persons**. The Member States shall designate the competent authority that is responsible for the supervision of the regulatory sandbox.

   Member States may also establish regulatory sandboxes jointly with other Member States.

1a. Regulatory sandboxes shall not involve devices for performance studies or the placing on the market, or putting into service of, devices which do not comply with the requirements of this Regulation other than those that are not applicable pursuant to paragraph 1.

2. The activities within a regulatory sandbox shall take place pursuant to a specific sandbox plan that ~~clearly identify the requirements of this Regulation referred to in paragraph 1, which are temporarily adapted or waived in the~~**shall set out clinical, scientific and regulatory justification for the necessity to establish a** regulatory sandbox **including at least**~~, a justification that the application of those requirements is not considered to be appropriate and an explanation as to how potential risks related to the adaptation or waiver are to be controlled and mitigated. The plan shall also identify the reasonable duration of the regulatory sandbox necessary to achieve its objectives and the participants in the regulatory sandbox and their respective roles.~~**:**

(a) identification of the requirements of this Regulation referred to in paragraph 1, which, by way of derogation from this Regulation, are temporarily adapted in the regulatory sandbox;

(b) justification that the application of those requirements is considered not appropriate and an explanation as to how potential risks related to the adaptation are controlled and mitigated;

(c) recommendations for alternative or mitigation measures, where appropriate; and

(d) identification of the reasonable duration of the regulatory sandbox necessary to achieve its objectives and the participants in the regulatory sandbox and their respective roles.

3. A regulatory sandbox shall be set up only if the following conditions are met:

(a) the device is expected to address unmet medical needs or to provide a significant clinical benefit to patients or to the health system compared with similar existing alternatives**, if any,** or the state of the art;

PUBLIC

(b) the application of the requirements of this Regulation referred to in paragraph 1 would **not be appropriate due to scientific or regulatory challenges arising from characteristics or methods related to** ~~impede or significantly delay the development of~~ the device ~~and access by healthcare professionals or lay users to such device~~.

4. The Member State may request an expert panel referred to in Article 106 of Regulation (EU) 2017/745 to provide scientific, technical or regulatory advice on the design of the draft sandbox plan.

5. Any participant in the regulatory sandbox shall, without undue delay, inform the competent authority that is responsible for the supervision of the regulatory sandbox **and the competent authority according to Article 84(2)** about any ~~harm~~ **serious incidents** occurred in relation to the implementation of the regulatory sandbox. **Any risks identified during the implementation of the regulatory sandbox shall be appropriately managed in accordance with the risk management system as described in Section 3 of Annex I.** The competent authority shall **have the power to** take immediate and adequate corrective measures, including ~~to~~ **temporarily or permanently suspend participation in the sandbox, or** suspend, revoke or restrict the scope of the regulatory sandbox**, including amending the sandbox plan**.

6. ~~Manufacturers and prospective~~ Manufacturers participating in a regulatory sandbox shall remain liable under applicable Union and national law for any damage inflicted on third parties as a result of their activities taking place in the regulatory sandbox.

7. The Member State shall inform the Commission and the MDCG about the establishment of a regulatory sandbox and keep them informed about its implementation and outcome.

7a. Where a Member State has taken a measure referred to in paragraph 5 of this Article, that Member State shall communicate the corresponding decision and the grounds therefor to the Commission and the MDCG.

PUBLIC

Article 54c

Union regulatory sandboxes

1. The Commission, on its own initiative or upon a substantiated request by a Member State, may establish by means of implementing acts for a limited time and pursuant to a specific plan, Union regulatory sandboxes, which shall inform whether the existing requirements appropriately regulate a specific type of device with particular characteristics or emerging technologies, and there is a risk that the existing requirements:

   (a) would ~~impede or significantly delay the development of such devices and access by healthcare professionals or patients to those devices; or~~**not be appropriate due to scientific or regulatory challenges arising from characteristics or methods related to the device;**

   (b) would not adequately protect the health and safety of patients, users or other persons or other aspects of public health.

   Union regulatory sandboxes shall not involve **devices for performance studies or** the placing on the market or putting into service of devices which do not comply with this Regulation.

2. The Commission shall**, following consultation with MDCG,** request an expert panel referred to in Article 106 of Regulation (EU) 2017/745 to provide scientific, technical or regulatory advice on the design of a Union regulatory sandbox.

3. The Commission shall **consult with** ~~inform~~ the MDCG about the establishment of a regulatory sandbox and keep it informed about its outcome.

4. The Commission ~~may~~**shall**, by means of implementing acts, specify common principles or the detailed arrangements for the establishment, operation and supervision of regulatory sandboxes pursuant to Article 54b or of Union regulatory sandboxes pursuant to this Article. ~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).~~

Those implementing acts shall include common principles on at least the following:

(a) eligibility and selection criteria for participation in a regulatory sandbox;

(b) procedures for the application, participation, monitoring, exiting from and termination of a regulatory sandbox, including the sandbox plan and outcome;

(c) the terms and conditions, and rights and obligations applicable to the participants.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

5. The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend this Article or Article 54b in order to adapt to scientific, technical or regulatory progress and to take into account developments regarding regulatory sandboxes, including in areas other than in vitro diagnostic medical devices.';

(37) ~~in Article 55, the following paragraph 1a is inserted:~~

'1a. ~~The competent authority of the Member State which issued the certificate of free sale in accordance with paragraph 1 shall make that certificate publicly available in Eudamed.';~~

PUBLIC

(38) Article 56 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Manufacturers shall plan, conduct and document a performance evaluation in accordance with this Article and with Part A of Annex XIII to confirm the safety and performance of the device, in particular those concerning the performance characteristics referred to in Chapter I and Section 9 of Annex I, under normal conditions of use according to the intended purpose of the device, and shall evaluate the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I.

The performance evaluation shall follow a defined and methodologically sound procedure for the demonstration of the following, in accordance with this Article and with Part A of Annex XIII:

(a) scientific validity;

(b) analytical performance;

(c) clinical performance.

The data and conclusions drawn from the assessment of those elements shall constitute sufficient clinical evidence for the device.

The manufacturer shall **conduct the performance evaluation with the aim to establish the clinical evidence and** specify and justify the level of the clinical evidence necessary to confirm the safety and performance of the device **and the scientific and methodological approach used to generate this clinical evidence**. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

The performance evaluation, its results and the clinical evidence derived from it shall be documented in a performance evaluation report as referred to in Section 1.3 of Annex XIII, which shall be part of the technical documentation referred to in Annex II relating to the device concerned.’;

PUBLIC

(b) paragraphs 2 to 5 are deleted.

(c) paragraph 6 is replaced by the following:

‘6. The performance evaluation, its documentation and, where applicable and needed, the summary of safety and performance referred to in Article 29 shall be updated throughout the life cycle of the device concerned with data and findings obtained from implementation of the manufacturer’s PMPF plan in accordance with Part B of Annex XIII and the post-market surveillance plan referred to in Article 79, whenever those data and findings provide information relevant for the confirmation of safety and performance of the device.’;

(d) the following paragraph 8 is added:

‘8. The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend Annex XIII in the light of technical and scientific progress and developments at international level having due regard to the protection of the health and safety of patients, users or other persons and other aspects of public health.’;

PUBLIC

(39) the following Article 56a is inserted:

'Article 56a

Advice from expert panels

For class C and class D devices, a manufacturer may, prior to its **clinical** performance study or ~~clinical~~ performance evaluation, consult an expert panel as referred to in Article 106 of Regulation (EU) 2017/745, with the aim of reviewing the manufacturer's intended strategy for demonstrating ~~clinical~~ performance **evaluation** or proposals for any clinical performance study**. Where the sponsor of the performance study is not the manufacturer of the device, the manufacturer shall make the advice of the expert panel available to the sponsor within 30 days**. The manufacturer and the notified body involved in any future conformity assessment procedure shall, in the performance evaluation report and the performance evaluation assessment report, give due consideration to the advice of the expert panel, and where they do not follow that advice, they shall provide duly justified reasons.';

(40) Article 58 is amended as follows:

(a) in paragraph 1, point (a) is deleted;

(b) in paragraph 1, point (c) is replaced by the following:

'(c) where the conduct of the study involves additional invasive procedures**, with the exception of routine blood sampling or taking a swab from the nasopharynx**, including high-risk procedures for collection of specimens, or other risks for the subjects of the studies,';

(c) ~~paragraph 2 is deleted;~~

(d) in paragraph 5, point (a) is replaced by the following:

'(a) the performance study is the subject of an authorisation by the Member State(s) in which the ~~specimens~~ **subjects** for the performance study are to be ~~collected~~ **enrolled**, in accordance with this Regulation, unless otherwise stated;';

(41) ~~in Article 64(1), point (b) is replaced by the following:~~

‘(b) ~~there are scientific grounds to expect that participation of the subject in the performance study will have the potential to produce:~~

(i) ~~a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering or improving the health of the subject, or in the diagnosis of his or her condition; or~~

(ii) ~~a benefit for the population represented by the subject, provided that the performance study poses only minimal risk to, and imposes minimal burden on, the subject in comparison with the standard treatment of the subject’s condition;’;~~

(42) Article 66 is amended as follows:

(a) in paragraph 1, the first subparagraph is replaced by the following:

‘The sponsor of a performance study referred to in Article 58(1) and (2) shall enter and submit an application to the Member State(s) in which the ~~specimens~~ **patients** for the performance study are to be ~~collected~~ **enrolled** (referred to for the purposes of this Article and Article 71 as ‘Member State concerned’) accompanied by the documentation referred to in Sections 2 and 3 of Annex XIII and in Annex XIV.’;

(b) paragraph 7 is replaced by the following:

‘7. The sponsor may start the performance study as soon as the Member State concerned has notified the sponsor of its authorisation and provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the performance study. The Member State shall notify the sponsor of the authorisation within 45 days of the validation date of the application referred to in paragraph 5. The Member State may extend this period by a further 20 days for the purpose of consulting with experts.’;

(43) in Article 67, paragraph 2 is replaced by the following:

‘2. Member States shall ensure that the assessment is done jointly by an appropriate number of persons who collectively have the necessary qualifications and experience.’;

(44) in Article 68, the following paragraph 7 is added:

‘7. The processing of personal data in the context of a performance study, including the secondary use of personal data initially collected for other studies, shall be deemed to be carried out for scientific research purposes as referred to in Article 9(2), point (j), of Regulation (EU) 2016/679 ~~of the European Parliament and of the Council~~ *******, **without prejudice to the obligations and requirements set out in that Regulation**.**;**

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*******Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/679/oj).’;

(44a) in Article 69, paragraph 3, point (a) is replaced by the following:

‘*(a) protection of personal data in accordance with Regulation ~~(EC) No 45/2001~~ **(EU) 2018/1725**;’;*

(45) in Article 70(1), the second and third sentences are replaced by the following:

‘The sponsor shall include the documentation referred to in Part A, Section 2, of Annex XIII and in Chapter I, Sections 1, 3 and 4, of Annex XIV. Article 58(5), points (b) to (l) and (p), Article 71(1), Articles 72 and 73, and Article 76(5) and (6), and the relevant provisions of Annexes XIII and XIV shall apply to PMPF studies involving additional invasive or burdensome procedures.’;

(46) in Article 71, paragraphs 1 and 2, and paragraph 3, introductory wording and point (a), are replaced by the following:

‘1. If a sponsor intends to introduce modifications to a performance study that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the data generated by the study, it shall notify, by means of the electronic system referred to in Article 69, the Member State(s) concerned of the reasons for and the nature of those modifications. The sponsor shall include an updated version of the relevant documentation referred to in Annex XIV as part of the notification. Changes to the relevant documentation shall be clearly identifiable.

2. Where the performance study has been the subject of an authorisation in accordance with Article 58(5), point (a), the Member State shall assess any substantial modification to the performance study in accordance with the procedure laid down in Article 67.

The Member State shall notify the sponsor of the outcome of its assessment within 38 days of receipt of the sponsor's notification under paragraph 1. During its assessment, the Member State may request additional information from the sponsor. The period of 38 days shall be suspended from the date of the first request until such time as the additional information has been received.

3. The sponsor may implement the modifications referred to in paragraph 1 ~~if~~ **as soon as** the Member State concerned has notified the sponsor of its authorisation, or ~~without such authorisation at the earliest 38 days after the notification referred to~~ **following expiry of the period defined** in paragraph ~~1~~**2, whichever is sooner**, unless:

(a) the Member State concerned has notified the sponsor of its refusal based on the grounds referred to in Article 67(4) or on considerations of public health, of subject and user safety or health, or of public policy; or’;

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(47) in Article 73(1), the first sentence is replaced by the following:

'If the sponsor has temporarily halted a performance study or has terminated a performance study early, it shall, within 15 days of the temporary halt or early termination, inform the Member State in which that performance study has been temporarily halted or terminated early, by means of the electronic system referred to in Article 69, providing a justification.';

(48) Article 74 is amended as follows:

(a) in paragraph 4, the second subparagraph is replaced by the following

'The final assessment report shall be taken into account by all Member States concerned when deciding on the sponsor's application in accordance with paragraph 11.';

(b) in paragraph 5, the first and second sentence are replaced by the following:

'Each Member State concerned may request, on a single occasion, additional information from the sponsor. The sponsor shall submit the requested additional information within 12 days of receipt of the request.';

(c) in paragraph 6, the words '50 days' are replaced by the words '~~20~~**30** days';

(d) the following paragraph 15 is added:

'15. The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend this Article in light of experience gained from the practical application of the coordinated assessment procedure, in particular as regards timelines and the authorisation of performance studies subject to a coordinated assessment.';

(49) Article 75 is deleted;

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(50) the following Article 75a is inserted:

'Article 75a

Performance studies in combined studies

Performance studies that are part of combined studies, and which are subject to authorisation in accordance with Article 58, ~~may~~**shall** be carried out in accordance with Article 14c of Regulation (EU) No 536/2014.

~~If the sponsor chooses to apply~~**Where** Article 14c of Regulation (EU) No 536/2014 **applies**, the requirements laid down therein and in any implementing and delegated acts adopted in accordance with that Article shall apply in place of the corresponding requirements laid down in this Regulation.

Member States shall ensure that the assessment of the clinical investigation part of the combined study is done in accordance with the requirements specified in article 67.';

(70) Article 100 is amended as follows:

(a) paragraph 2 is amended as follows:

(i) point (a) is replaced by the following:

'(a) to verify the performance claimed by the manufacturer and the compliance of class D devices with the applicable CS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as provided for in Section 4.9 of Annex IX and in Section 3, point (j), of Annex X;';

PUBLIC

(ii) point (d) is replaced by the following:

‘(d) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices, where requested ~~on the basis~~**by the Commission, the MDCG, competent authorities, or notified bodies with due consideration** of comparative test results or other studies;’;

(iii) ~~points (e) and (j) are~~**point (j) is** deleted;

(iv) the following subparagraph is added:

‘The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend the first subparagraph by adding, adapting or removing tasks from the list of tasks of the EU reference laboratories.’;

(b) paragraph 3 is deleted;

(c) in paragraph 4, point (b) is replaced by the following:

‘(b) have at their disposal the necessary equipment and reference material to carry out the tasks assigned to them;’;

(d) in paragraph 5, point (j) is deleted;

(e) paragraph 7 is replaced by the following:

‘7. Where notified bodies ~~or Member States~~ request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they may be required to pay fees to wholly or partially cover the costs incurred by that laboratory in carrying out its tasks according to predetermined and transparent terms and conditions.

EU reference laboratories shall establish lists of their standard fees and shall make those lists publicly available. They shall notify the lists to the Commission, which shall make references to them available to the public on a dedicated website.’;

PUBLIC

(2) Annex II is amended as follows:

(a) Section 1.1. is amended as follows:

(i) point (c) is replaced by the following:

‘(c) the intended purpose of the device as referred to in Section 20.4.1, point (c), of Annex I;’;

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

‘(g) the description of the components and where appropriate, the description of the critical ingredients of relevant components such as antibodies, antigens, enzymes and nucleic acid primers;’;

(b) in Section 3.1., point (a) is replaced by the following:

‘(a) where applicable, a description of the critical reagents such as antibodies, antigens, enzymes and nucleic acid primers not provided but recommended for use with the device;’;

(c) Section 6.1.2.6., point (c) is replaced by the following:

‘(c) statistical methods such as Receiver Operating Characteristic (ROC) to generate results and if applicable, define grey-zone/equivocal zone.’;

(d) Section 6.1.3. is deleted;

(e) in Section 6.2., the heading and the first paragraph are replaced by the following:

‘6.2. Information on overall performance evaluation and clinical studies

The documentation shall contain the performance evaluation plan referred to in Section 1.1 of Annex XIII and the performance evaluation report referred to in Section 1.3.2 of Annex XIII.’;

PUBLIC

(f) in Section 6.5., the following point (e) is added:

'(e) Where the device incorporates as an integral part a medical device that has an action ancillary to that of the device, as referred to in Article 1(4) of this Regulation, the documentation shall include the results of the assessment of the conformity of the medical device part with the relevant general safety and performance requirements set out in Annex I to Regulation (EU) 2017/745 contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device. Where those results of the conformity assessment are not available and where for the conformity assessment of medical device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, an opinion on the conformity of the medical device part with the relevant general safety and performance requirements set out in Annex I to Regulation 2017/745 issued by a notified body designated in accordance with that Regulation for the type of device in question shall be included in the documentation.';

(5) Annex VII is amended as follows:

(k) Section 3.2.3. is amended as follows:

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

'The personnel responsible for establishing qualification criteria and for authorising other personnel to perform specific conformity assessment activities shall not be external experts or be subcontracted.';

(ii) in the second sentence, the sixth indent is replaced by the following:

'- adequate experience in conformity assessments under this Regulation, Regulation (EU) 2017/745 or previously applicable law within a notified body.';

PUBLIC

(l) in Section 3.2.4., the first sentence is replaced by the following:

'The notified body shall have permanent availability of personnel with relevant clinical expertise.';

(m) in Section 3.2.7., the first sentence is replaced by the following:

'The personnel with overall responsibility for final reviews and decision-making on certification shall not be external experts or be subcontracted.';

(n) in Section 3.4.1., first paragraph, the following sentence is added:

'They shall inform the manufacturer accordingly.';

(o) in Section 4.1., the second paragraph is replaced by the following:

'The requirements laid down in Sections 4.3., 4.4., 4.7. and 4.8. shall not be subcontracted and shall not be fulfilled by external experts.';

(p) in Section 4.2., point (a), the second sentence is replaced by the following:

'That description shall include which languages are acceptable for submission of documentation and for any related correspondence and the modalities for carrying out the dialogue referred to in Section 1.2.9 of this Annex before an application is lodged.';

(q) in Section 4.3., second paragraph, the third sentence is replaced by the following:

'This contract shall have clear terms and conditions and contain obligations that enable the notified body to act as required under this Regulation, including an obligation on the manufacturer to inform the notified body of vigilance reports, the right of the notified body to suspend, limit or withdraw certificates issued and the duty of the notified body to fulfil its information obligations.';

PUBLIC

(r) in Section 4.5.1., the second paragraph is amended as follows:

(i) the eighth indent is replaced by the following:

‘- in the case of class B or class C devices**, as referred to in Article 48**, to assess the technical documentation of the representative device(s),’;

(ii) the tenth indent is deleted:

(iii) the following indents are added:

‘- where appropriate, to perform a rolling review of the manufacturer’s data or documentation as they become available,

– to leverage evidence from previously performed assessments~~.~~**,**

– **in case of class A devices that are placed on the market in sterile condition, assess the quality management system only in relation to the relevant special aspects of these devices.**’;

(s) Section 4.5.2. is amended as follows:

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

(1) the introductory wording is replaced by the following:

‘As part of the assessment of the quality management system, a notified body shall prior to or in relation with an audit and in accordance with its documented procedures:’;

(2) the fourth indent is replaced by the following:

‘- clearly identify, for ~~class B and class C~~**the** devices **referred to in Section 4.5.1, eighth indent**, the representative devices selected for the assessment of technical documentation as referred to in Annexes II and II, and;’

PUBLIC

(2a) the following indent is inserted between the fourth and fifth indent:

'- draw up and keep up to date, for in the case of the devices referred to in Section 4.5.1, ninth indent, a sampling plan justifying the device(s) selected for the assessment of technical documentation as referred to in Annexes II and III, taking into account the risk-based approach as referred to in Article 48 and considering the range of devices covered by the manufacturer's application.';

(ii) in point (b), the fourth indent is replaced by the following:

'- the documentation shall be sampled in such as a manner as to reflect the risks associated with the intended use of the device, the complexity of the manufacturing technologies, the range and classes of devices produced or under certification and any available post-market surveillance information,';

(t) in Section 4.5.3., the third paragraph which is headed 'Verification by examination and testing of every product batch' is replaced by the following:

'Verification by examination and testing of products or product batches

The notified body shall:

(a) have documented procedures, sufficient expertise and access to facilities for the verification by examination and testing of products or product batches;

(b) establish a test plan identifying all relevant and critical parameters which need to be tested under the notified body's responsibility and document its selection for the selection of the parameters;

(c) have documented procedures to carry out the appropriate assessments and tests in order to verify the conformity of the device with the requirements of this Regulation including, where applicable, procedures in relation to testing by EU reference laboratories in accordance with Annexes IX, X and XI;

(d) have documented procedures providing for the reaching of an agreement with the applicant concerning when and where necessary tests that are not to be carried out by the notified body itself are to be performed;

(e) assume full responsibility for test results in accordance with documented procedures, except where testing was carried out by EU reference laboratories in accordance with Annexes IX, X or XI of this Regulation; test reports submitted by the manufacturer shall only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.';

(u) in Section 4.6., the introductory sentence in the second paragraph is replaced by the following:

'The report(s) of the notified body shall:';

(v) Section 4.8. is amended as follows:

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

'The notified body shall have documented procedures for decision-making including as regards the allocation of responsibilities for the issuance, suspension, limitation and withdrawal of certificates.';

(ii) the third sentence is amended as follows:

(1) the fourth indent is replaced by the following:

'- decide whether conditions or limitations need to be defined for the certification,';

PUBLIC

(2) the fifth indent is replaced by the following:

'- where appropriate, decide, based on the novelty, risk classification, performance evaluation and conclusions from the risk analysis of the device, on a period of certification, **not exceeding five years for initial certification of class D devices, companion diagnostics, and class C devices for self-testing and near patient testing,';

(3) the eighth indent is replaced by the following:

'- issue a certificate or certificates in accordance with the minimum requirements laid down in Annex XII and shall indicate whether there are conditions or limitations associated with the certification,';

(w) Section 4.9. is amended as follows:

(i) in the first paragraph, the fourth indent is replaced by the following:

'- the intended purpose of or claims made for the device.'

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

'The procedures and contractual arrangements referred to in the first paragraph shall clearly distinguish between changes that do not need to be reported, that need to be reported without requiring prior approval and that require prior approval.';

(iii) the third paragraph is amended as follows:

(1) the introductory sentence is replaced by the following:

'In accordance with its documented procedures, the notified body in question shall, where changes require prior approval:';

PUBLIC

(2) the following fourth paragraph is added:

'Where appropriate, the notified body and the manufacturer shall agree on a predetermined change control plan enabling the manufacturer to implement changes in accordance with such a plan without prior information.';

(x) Section 4.10. is amended as follows:

(i) the first paragraph is amended as follows:

(1) the second indent is replaced by the following:

'- for screening relevant sources of scientific and clinical data and post-market information relating to the scope of their designation. That screening shall be conducted in the framework of the coordination group established in Article 49 to avoid unnecessary duplication and to enhance efficiency and work-sharing. The findings from the screening shall be taken into account in the planning and conduct of surveillance activities,';

(2) the first sentence of the third indent is replaced by the following:

'- to assess whether any reported serious incident related to a serious public health threat or any field safety corrective action taken or envisaged by the manufacturer or required of it by a competent authority has an impact on the validity of existing certificates. The results of the evaluation and any decisions taken shall be thoroughly documented.';

PUBLIC

(ii) the second paragraph is amended as follows:

(1) the opening sentence is replaced by the following:

'The notified body in question shall, with regard to signals arising from vigilance data to which they have access under Article 87(2), decide on which of the following options to apply, where appropriate:';

(2) the first indent is deleted;

(iii) the third paragraph is amended as follows:

(1) the first indent is replaced by the following:

'- conduct surveillance audits of the manufacturer which shall be planned and conducted in line with the relevant requirements in Section 4.5.';

(2) the eight indent is replaced by the following:

'- where necessary, impose conditions or limitations on the relevant certificate, or suspend or withdraw it.';

(y) Section 4.11. is replaced by the following:

'Periodic reviews and extension of a certificate's period of validity

The notified body shall have documented procedures in place **relating to the re-assessment of EU technical documentation assessment certificates and** relating to the periodic reviews of the approved quality management systems or EU technical documentation assessment certificates or EU type-examination certificates.

PUBLIC

Those procedures shall require the manufacturer in question to submit at predefined intervals a summary of changes ~~and of relevant data gathered by the manufacturer's post-market surveillance system. The notified body shall assess such information and shall pay particular attention to clinical evidence gained from post-market surveillance and PMPF activities undertaken since the previous certification or periodic review~~ **and scientific findings for the device**, including ~~appropriate updates to manufacturers' performance evaluation reports, without repeating assessments already conducted.~~**:**

(a) all changes to the originally approved device, including changes not yet notified,

(b) relevant data gathered by the manufacturer's post-market surveillance system,

(c) changes to the regulatory requirements, such as changes to the legal requirements, revised or new harmonised standards, CS or equivalent documents, and

(d) changes in medical, scientific and technical state of the art.

The notified body shall assess such information and shall pay particular attention to clinical evidence gained from post-market surveillance and PMPF activities undertaken since the previous certification or periodic review, including appropriate updates to manufacturers' performance evaluation reports, without repeating assessments already conducted.

In the case of EU technical documentation assessment certificates where a maximum period of validity is indicated in accordance with Article 51(2), the notified body shall conduct a reassessment of the relevant technical documentation prior to extending the period of validity.

PUBLIC

The notified body shall have documented procedures in place relating to the extension of the period of validity of a certificate in cases where it has exceptionally limited the period of validity **or for EU technical documentation assessment certificates where a maximum period of validity is indicated in accordance with Article 51(2)**. Those procedures shall require the manufacturer to submit prior to the expiry of the certificate the data or documentation specified by the notified body to enable it to decide about the extension of the period of validity of the certificate.';

– (6) Annex IX is amended as follows:

(a) in Section 2.3., the third and fourth paragraphs are replaced by the following:

'Moreover, in the case of class B and class C devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation, as referred to in Annexes II and III, as specified in Sections 4.3. to 4.8.~~, for a representative device selected as follows:~~ **and Articles 48(7) and 48(9).**

- ~~for class B devices, one device;~~

- ~~for class C devices, one device per generic device group.~~

In choosing the representative device**(s)**, the notified body shall apply a risk-based approach, taking into account the principle of proportionality and in particular, the novelty of the technology, the novelty of the analyte and/or marker being detected, the potential impact on the patient and standard medical practice, similarities in design, technology, manufacturing and, where applicable, sterilisation methods, the intended purpose, the application by the manufacturer of harmonised standards or CS for the device and the results of any previous relevant assessments that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the representative device taken.

The notified body may include a 'for-cause' assessment of the technical documentation of additional representative devices on duly justified grounds identified during the quality management system assessment.

PUBLIC

If the quality management system and the technical documentation of the assessed representative device conform~~s~~ to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The notified body shall notify the manufacturer of its decision to issue the certificate. The decision shall contain the conclusions of the audit and ~~a reasoned~~ be **included in the** report **of the notified body in accordance with Section 4.6 of Annex VII**.';

(b) in Section 3.2., the second indent is replaced by the following:

'- the documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the PMPF plan, for the representative devices, and of the provisions on vigilance set out in Articles 82 to 87,';

(c) Section 3.3. is replaced by the following:

'3.3. Notified bodies shall periodically carry out appropriate audits and assessments to make sure that the manufacturer in question applies the approved quality management system and the post-market surveillance plan**, taking into account the state of the art**. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers ~~and/~~or subcontractors. On justified grounds, ~~the~~**a surveillance** audit may be conducted remotely instead of on-site**. The notified body shall inform the authority responsible for notified bodies on the justified grounds and the conducted remote audits**. The notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report.

PUBLIC

The notified body shall carry out the surveillance audits and assessments once every 12 months. However, where justified in light of the results of previous surveillance audits and assessments, and in the absence of any concerns resulting from data from post-market surveillance or vigilance, the notified body ~~shall~~**may** carry out the surveillance audits and assessments only once every 24 months.';

(d) Section 3.4. is amended as follows:

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

'3.4. The notified body shall perform audits, at short notice or unannounced, on the site of the manufacturer and, where appropriate, the site of the manufacturer's suppliers ~~and/~~or subcontractors, when justified based on concerns related to post-market surveillance or vigilance data or at the request of a competent authority **or, in the absence thereof, randomly but at least once per five years**. The short-notice or unannounced audit may be combined with the periodic surveillance assessment referred to in Section 3.3. or be performed in addition to that surveillance assessment.';

(ii) in the second paragraph, the first sentence is replaced by the following:

'Within the context of such unannounced on-site audits, the notified body may test an adequate sample of the devices produced or an adequate sample from the manufacturing process to verify that the manufactured device is in conformity with the technical documentation.';

(iii) in the third paragraph, the first sentence is replaced by the following:

'Instead of, or in addition to, the sampling referred to in the second paragraph, the notified body may take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation.';

PUBLIC

(e) Section 3.5. is replaced by the following:

'3.5. In the case of class B and class C devices, during the surveillance assessment the notified body may include ~~a 'for-cause'~~ **an** assessment of the technical documentation ~~of representative~~**as specified in Section 4 for the device or** devices ~~where the notified body has identified potential concerns~~**concerned** on the basis of ~~post-market surveillance data or other duly justified grounds~~**further samples chosen in accordance with the rationale documented by the notified body in accordance with the third paragraph of Section 2.3**.';

(f) Section 3.7. is replaced by the following:

'3.7. If the notified body finds a divergence between the sample taken from the devices produced or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose conditions or limitations on it.';

(g) the heading of Section 4 is replaced by the following:

'4. Assessment of the technical documentation;'

(h) in Section 4.2., the second sentence is replaced by the following:

'It shall include the technical documentation as referred to in Annexes II and III or a plan for submission of such technical documentation **to be agreed with the notified body**.';

(i) in Section 4.4., the second sentence is replaced by the following:

'The notified body shall use ~~device~~**product** reviewers with sufficient clinical expertise and including external clinical experts with direct and current experience relating to the clinical application of the device in question for the purposes of that review.';

PUBLIC

(j) Section 4.8. is replaced by the following:

'4.8. The notified body shall provide the manufacturer with a report on the technical documentation assessment, including a performance evaluation assessment report.';

(k) Section 4.9. is amended as follows:

(i) the second paragraph is deleted;

(ii) the fourth paragraph is replaced by the following:

'The scientific opinion of the EU reference laboratory and any possible updates shall be included in the documentation of the notified body concerning the device. The notified body shall, when making its decision, give due consideration to the views expressed in the scientific opinion of the EU reference laboratory. The notified body shall not deliver the certificate if the scientific opinion of the EU reference laboratory is unfavourable.';

(l) in Section 4.10., the first ~~and third sentences are~~**sentence is** deleted;

(la) in Section 4.10., the third sentence is replaced with the following:

'The certificate shall contain a description of the intended purpose of the device.';

(m) Section 4.12. is amended as follows:

(i) the third sentence is replaced by the following:

'Furthermore, the manufacturer shall make the samples of manufactured batches of devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that the manufacturer shall send samples of the manufactured batches of devices to the EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate tests.';

PUBLIC

(ii) the following sentence is added:

'Where no EU reference laboratory has been designated in accordance with Article 100, those arrangements may include that the notified body conducts verification of samples or batches by alternative means.';

(n) ~~Section 5.1. is amended as follows:~~

(i) ~~the heading is replaced by the following:~~

~~'Assessment of the technical documentation of class B, C and D devices for self-testing;'~~

(ii) ~~point (a) is replaced by the following:~~

~~'(a) The manufacturer of class B, C and D devices for self-testing shall lodge with the notified body an application for the assessment of the technical documentation.';~~

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

~~'(iii) data showing the suitability of the device in view of its intended purpose for self-testing;';~~

PUBLIC

(o) Section 5.2. is amended as follows:

(i) point (c) is replaced by the following:

‘(c) The notified body shall, before issuing an EU technical documentation assessment certificate for the companion diagnostic and on the basis of the draft summary of safety and performance and the draft instructions for use, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, either of which to be referred to in this Section as ‘the medicinal products authority consulted’ depending on which has been consulted under this point, regarding the suitability of the clinical performance of the device in relation to the medicinal product concerned. The assessment of the medicinal products authority consulted shall not repeat the assessment to be performed by the notified body in accordance with this Regulation. Where the medicinal product falls exclusively within the scope of the Annex I to Regulation (EC) No 726/2004 of the European Parliament and of the Council*, the notified body shall seek the opinion of the EMA. If the medicinal product concerned is already authorised, or if an application for its authorisation has been submitted, the notified body shall consult the medicinal products authority, or the EMA, that is responsible for the authorisation.

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* Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/726/oj).’;

PUBLIC

(ii) in point (d), after the second sentence the following sentences are inserted:

'When preparing its opinion, the medicinal products authority consulted may request the notified body, or the manufacturer, to provide within a specific time period additional information necessary for its assessment referred to in point (c). In case of such a request, the time-limit set out in this paragraph shall be suspended until the additional information requested is provided.';

(iii) in point (f), the first sentence is replaced by the following:

'Before changes affecting the performance and/or the intended purpose and/or the suitability of the clinical performance of the device in relation to the medicinal product concerned are made, the manufacturer shall inform the notified body of the changes.';

(iv) the following point (g) is added:

'(g) points (c) to ~~(f)~~**(e)** shall not apply where the following conditions are met:

(i) the companion diagnostic has the same intended purpose as another already CE-marked companion diagnostic for which a medicinal products authority issued a favourable opinion in accordance with point (d) or Section 3 of Annex X, point (k)

(ii) the manufacturer shows equivalent performance to that already CE-marked companion diagnostic.';

PUBLIC

– (7) Annex X is amended as follows:

(a) ~~Section 2 is amended as follows:~~

(i) ~~the third indent is replaced by the following:~~

‘- ~~in the case of devices for self-testing, test reports, including results of studies carried out with intended users, and data showing the handling suitability of the device in relation to its intended purpose for self-testing;’~~

(ii) ~~the fifth indent is replaced by the following:~~

‘- ~~data showing the suitability of the device in relation to its intended purpose for self-testing,’;~~

(b) Section 3 is amended as follows:

(i) point (c) is replaced by the following

‘(c) review the clinical evidence presented by the manufacturer in the performance evaluation report in accordance with Section 1.3.2 of Annex XIII. The notified body shall use device reviewers with sufficient clinical expertise and, if necessary, use external clinical experts with direct and current experience relating to the clinical application of the device in question for the purposes of that review;’;

(ii) point (i) is replaced by the following:

‘(i) draw up an EU type-examination report on the results of the assessments and tests carried out under points (a) to (g), including the performance evaluation assessment report referred to in point (e);’;

PUBLIC

(iii) point (j) is amended as follows:

(1) the second paragraph is deleted;

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

'The scientific opinion of the EU reference laboratory and any possible updates shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion of the EU reference laboratory, when making its decision. The notified body shall not deliver the certificate if the scientific opinion of the EU reference laboratory is unfavourable;';

PUBLIC

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

‘(k) for companion diagnostics, seek the opinion, on the basis of the draft summary of safety and performance and the draft instructions for use, of one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMA (either of which to be hereinafter referred to as ‘the medicinal products authority consulted’ depending on which has been consulted under this point) on the suitability of the clinical performance of the device in relation to the medicinal product concerned. The assessment of the medicinal products authority consulted shall not repeat the assessment to be performed by the notified body in accordance with this Regulation. Where the medicinal product falls exclusively within the scope of the Annex I of Regulation (EC) No 726/2004, the notified body shall consult the EMA. If the medicinal product concerned is already authorised, or if an application for its authorisation has been submitted, the notified body shall consult the medicinal products competent authority, or the EMA, that is responsible for the authorisation. The medicinal products authority consulted shall deliver its opinion within 60 days of receipt of all the necessary documentation. This 60-day period may be extended once for a further 60 days on justified grounds. When preparing its opinion, the medicinal products authority consulted may request the notified body, or the manufacturer, to provide within a specific time period additional information necessary for its assessment. In case of such a request, the time-limit set out in this paragraph shall be suspended until the additional information requested is provided. The opinion of the medicinal products authority consulted and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the opinion expressed by the medicinal products authority consulted when making its decision. It shall convey its final decision to the medicinal products authority consulted.

PUBLIC

This point shall not apply where the following conditions are met:

(i) the companion diagnostic has the same intended purpose as another already CE-marked companion diagnostic for which a medicinal products authority issued a favourable opinion in accordance with the previous paragraph or Section 5.2. of Annex IX, point (d);

(ii) the manufacturer shows equivalent performance to that already CE-marked companion diagnostic; and'

(v) point (l) is replaced by the following:

'(l) draw up the EU type-examination report referred to in point (i) taking into account the scientific opinions provided under points (j) and (k),'

(c) in Section 4, the second sentence is deleted;

(d) in Section 5.5., the first sentence is replaced by the following:

'Where the changes affect the performance or the intended purpose of a companion diagnostic approved through the EU type-examination certificate or the suitability of its clinical performance in relation to a medicinal product, the notified body shall consult the medicinal products competent authority that was involved in the initial consultation or the EMA.';

– (8) Annex XI is amended as follows:

(a) in Section 2, the second sentence is replaced by the following:

'By issuing an EU declaration of conformity, the manufacturer shall be deemed to ensure, and to declare, that the device concerned meets the requirements of this Regulation which apply to the device, and in the case of devices that undergo a type examination, conforms to the type described in the EU type-examination certificate.';

(b) Section 5.1. is amended as follows:

(i) the third sentence is replaced by the following:

‘Furthermore, the manufacturer shall make samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that the manufacturer shall send samples of the manufactured devices or batches of devices to an EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate laboratory tests.’;

(ii) the following sentence is added:

‘Where no EU reference laboratory has been designated in accordance with Article 100, those arrangements may include that the notified body conducts verification of samples or batches by alternative means.’;

– (9) Annex XII is amended as follows:

(a) Chapter I is amended as follows:

(i) in Section 4, point (b) is replaced by the following:

‘(b) EU quality management system certificates and EU production quality assurance certificates shall include the identification of the devices or groups of devices, the risk classification, **the intended purpose** and the manufacturing site(s) covered.’;

(ii) ~~Section 7 is deleted;~~

(b) Chapter II is amended as follows:

(i) Section 6 is replaced by the following:

‘6. where applicable, date of expiry;’;

PUBLIC

(ii) Section 7 is replaced by the following

'7. data needed for the unambiguous identification of the device or devices where applicable as specified in Section 4 of Chapter I;';

(iii) Section 10 is replaced by the following:

'10. reference to relevant CS and, harmonised standards;';

(10) Annex XIII is amended as follows:

(a) Section 1.1. is amended as follows:

(i) the first and second indents are replaced by the following:

'- a specification of the intended purpose of the device as referred to in Section 20.4.1, point (c), of Annex I, including a specification of the analyte or marker to be determined by the device;

– 'a specification of the characteristics of the device as described in Section 9 of Annex I;';

(ii) the third indent is deleted;

(b) in Section 1.2., the third indent is replaced by the following:

'- generate any new or additional data necessary to address outstanding issues; where appropriate this may be supported by computational modelling and in silico testing.';

(c) in Section 1.2.1., the second paragraph is replaced by the following:

'The scientific validity of the analyte or marker shall be demonstrated and documented in a dedicated section of the performance evaluation report.';

PUBLIC

(d) in Section 1.2.2., the fourth paragraph is replaced by the following:

'Analytical performance shall be demonstrated and documented in a dedicated section of the performance evaluation report.';

(e) Section 1.2.3. is replaced by the following:

'1.2.3. Demonstration of the clinical performance

The manufacturer shall demonstrate the clinical performance of the device in relation to all the parameters described in point (b) of Section 9.1. of Annex I, unless any omission can be justified as not applicable.

Demonstration of the clinical performance of a device shall be based on one or a combination of the following sources:

- clinical performance studies of the device concerned or of a device for which equivalence to the device concerned can be demonstrated;
- other studies published in **peer-reviewed** scientific literature on the device concerned or of a device for which equivalence to the device concerned can be demonstrated;
- other clinical experience published in peer-reviewed scientific literature with the device concerned or a device for which equivalence to the device concerned can be demonstrated;
- clinically relevant information coming from post-market surveillance, in particular the PMPF;
- published experience gained by routine diagnostic testing.

Clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data.

Clinical performance shall be demonstrated and documented in a dedicated section of the performance evaluation report.';

PUBLIC

(f) in Section 1.3.1., the first sentence is replaced by the following:

'The manufacturer shall assess all relevant scientific validity, analytical and clinical performance data.';

(g) in Section 1.3.2., first paragraph, the second sentence is replaced by the following:

'This report shall include an assessment of scientific validity, analytical performance and clinical performance allowing demonstration of sufficient clinical evidence.';

(ga) in Section 1.3.2, the following paragraph is added after the last indent of the second paragraph:

'Both favourable and unfavourable data considered in the performance evaluation shall be included in the technical documentation.';

(h) Section 1.3.3. is deleted;

(i) Section 2.3.2., second paragraph, is amended as follows:

(i) in point (k), the reference to 'Section 9.1 of Chapter I of Annex I' is replaced by the reference to 'Section 9.1 of Annex I';

(ii) in point (l), the following sentence is added:

'for combined studies, endpoints reporting on the device and medicinal product together may be used;';

(iii) point (n) is replaced by the following:

'information on use of data from left-over specimen banks, genetic or tissue banks, patient or disease registries etc. with description of reliability and representativity and statistical analysis approach; assurance of relevant method for determining the true clinical status of patient specimens;';

PUBLIC

(j) Section 3, is replaced by the following:

'3. OTHER PERFORMANCE STUDIES

By analogy, the performance study plan referred to in Section 2.3.2, and the performance study report, referred to in Section 2.3.3, shall be documented for performance studies other than clinical performance studies.';

(k) in Section 4, first paragraph, the following sentence is added:

'Where ~~PMCF~~**PMPF** is deemed not applicable, the manufacturer shall provide a justification in the post-market surveillance plan as referred to in Section 1 of Annex III.';

(l) Section 6 is replaced by the following:

'6. The manufacturer shall analyse the findings of the PMPF and document the results in the performance evaluation report and the technical documentation.';

(m) Section 8 is deleted;

– (11) Annex XIV is amended as follows:

(a) Chapter I is amended as follows:

(i) Section 1.2. is replaced by the following:

'1.2. if different from those in Section 1.1, name, address and contact details of the manufacturer of the device intended for the performance study and, if applicable, of its authorised representative;';

(ii) Section 1.5. is replaced by the following

'1.5. status of the performance study, such as the first submission, resubmission, substantial modification;';

PUBLIC

(iii) Section 1.7. is replaced by the following:

‘1.7. if the application is a resubmission with regard to a device for which an application has been already submitted, the date or dates and reference number or numbers of the earlier application or in the case of substantial modification, reference to the original application.’

PUBLIC