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WORKING DOCUMENT

From:	Presidency
To:	Delegations
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Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards 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 Second Presidency compromise text, part 2, to be discussed at the meetings of the Working Party on Pharmaceuticals and Medical Devices on 24-25 September 2026. This compromise covers all aspects not already covered in ST 12287/26 and recitals.

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

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Recitals

(1) [Regulations (EU) 2017/745[1] and (EU) 2017/746[2] of the European Parliament and of the Council establish regulatory frameworks to ensure the smooth functioning of the internal market as regards medical devices and *in vitro* diagnostic medical devices, respectively, taking as a base a high level of protection of health for patients and users. At the same time, Regulations (EU) 2017/745 and (EU) 2017/746 set high standards of quality and safety for medical devices and *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such devices. Furthermore, both Regulations significantly reinforce key elements of the previous regulatory framework set out in Council Directives 90/385/EEC[3] and 93/42/EEC[4] and in Directive 98/79/EC of the European Parliament and of the Council[5], such as the supervision of notified bodies, risk classification, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, and require the setting up of the European database on medical devices (Eudamed) to enable transparency and traceability in respect of medical devices and *in vitro* diagnostic medical devices.

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

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

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

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

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

(2) The extension of the transitional periods provided for in Article 120 of Regulation (EU) 2017/745 and Article 110 of Regulation (EU) 2017/746 mitigated the risk of shortages of medical devices and *in vitro* diagnostic medical devices in the Union, but did not address underlying structural problems related to the implementation of both Regulations.

(3) In its targeted evaluation[6] of Regulations (EU) 2017/745 and (EU) 2017/746, the Commission confirmed that the Regulations have strengthened the regulatory framework through stricter requirements on the designation and oversight of notified bodies, the conduct of conformity assessments, and the generation of clinical evidence. However, the evaluation also highlighted several shortcomings and inefficiencies in the regulatory framework, resulting in unnecessary burdens for manufacturers. Overly complex and often disproportionate requirements, costly, lenghthy and unpredictable conformity assessment procedures affect the availability of devices, the competitiveness of manufacturers in the Union, in particular of small and medium-sized enterprises, and innovation in medical technology. This has a negative impact on the level of healthcare and patient safety in the Union.

(4) To address the shortcomings identified, the existing rules should be simplified, and administrative burden should be reduced without jeopardising the high level of public health and patient safety. Moreover, the predictability and cost-efficiency of the application of both Regulations should be enhanced to achieve their initial objectives.

(5) Regulation (EU) 2017/745 includes in its scope certain groups of devices which are similar to medical devices but for which the manufacturer claims only an aesthetic or another non-medical purpose. To enhance legal certainty and to ensure consistency, it should be clarified that accessories for such products without a medical purpose are also included within the scope of Regulation (EU) 2017/745.

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[6] SWD(2025)1051.

(6) The provisions in Regulation (EU) 2017/745 should be adapted to Regulation (EU) 2024/1938 of the European Parliament and of the Council[7], the new Union legislation in the area of substances of human origin (SoHO).

(7) To avoid a double layer of regulatory requirements, products that combine a medical device and an *in vitro* diagnostic medical device should be subject either to Regulation (EU) 2017/745 or to Regulation (EU) 2017/746, depending on the product's principal mode of action, whilst the general safety and performance requirements of the other Regulation should apply to the part of the device that has an ancillary function.]

(7a) For integral products combining a medical device and an in vitro diagnostic medical device, the determination of whether the action of one component is principal or ancillary should be based on objective criteria, including the primary intended purpose of the product, the relevance of the component for clinical decision-making, the risks related to the interaction with the body and its functional contribution to the overall safety and performance of the integral product.

(8) [The definition of nanomaterial in Regulation (EU) 2017/745 should be updated to bring it in line with Commission Recommendation of 10 June 2022 on the definition of nanomaterial[8].

(9) Clinical data are an important source of information for demonstrating the safety and performance of a device. However, the process of generating clinical data is often lengthy and costly. The definition of clinical data should be broadened to enable the use of data generated through studies on the device concerned that are published in scientific literature, but not necessarily peer-reviewed.

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7 Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety of substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L 2024/1938, 17.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj).

8 Commission Recommendation of 10 June 2022 on the definition of nanomaterial, C/2022/3689 (OJ C 229, 14.6.2022, p. 1).

(10) Devices that are well-established technologies have a lower risk profile than other devices of the same risk class. They are therefore subject to certain exemptions or more proportionate requirements in Regulation (EU) 2017/745. To make the application of those provisions more flexible and future-proof, a definition of term well-established technology devices should be included in that Regulation, based on guidance developed by the Medical Device Coordination Group[9], and the existing lists of devices in Articles 18, 52 and 61 of Regulation (EU) 2017/745 should be replaced by a reference to the newly defined term.

(11) To ensure legal certainty and to safeguard the principle of free movement of goods, the coordination mechanism between national competent authorities for decisions on the regulatory status of a product and on the classification of a device, should be streamlined and, where appropriate, involve external expertise from an expert panel, supported by the European Medicines Agency (EMA). The decision on the regulatory status, however, should remain with the national authorities or, where appropriate, with the Commission acting through implementing acts.

PUBLIC

[9] MDCG 2020-6 *Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC; A guide for manufacturers and notified bodies* (April 2020).

(12) The manufacture and use of devices within health institutions ('in-house devices') under certain conditions is essential for the provision of health care in cases where the needs of the target patient group cannot be met by devices available on the market. While the strict conditions for the exemption of such in-house devices from most of the requirements set out in Regulation (EU) 2017/745 or Regulation (EU) 2017/746 should in principle remain in place, some flexibility should be introduced in order to remove unnecessary administrative burden on health institutions, to promote clinical research on in-house devices and to enable the access of patients to in-house devices where no alternatives exist. For example, some documentation obligations should be removed, especially under Regulation (EU) 2017/746 for health institutions accredited to EN ISO 15189. The transfer of an in-house device to another health institution should be possible where justified in the interest of public health, patient health or patient safety. Also, to provide legal certainty for health institutions, when a device becomes available on the market that serves the target patient group's needs in an equivalent manner to the in-house device, the health institution should have a lengthy transition period until the exemption for in-house manufacturing ceases to apply. Due to their importance for preparedness and response to public health emergencies, the condition that no device is available on the market serving the target patient group's needs in an equivalent manner, should be removed for in-house *in vitro* diagnostic medical devices.

(13) Laboratories that conduct clinical research in the context of clinical trials of medicinal products subject to Regulation (EU) No 536/2014 often develop tests in-house to meet patient needs in clinical trials. Where those tests are not manufactured on an industrial scale and are not commercialised, the situation of such laboratory-developed tests is similar to in-house devices manufactured and used within a health institution. The exemption from certain requirements of Regulation (EU) 2017/746, as provided for in Article 5(5) of that Regulation, should therefore also apply to laboratory-developed tests used exclusively for clinical trials.

(14) To ensure a level playing field between devices sold online and those sold via traditional distribution channels, certain information requirements applicable to distance sales should be strengthened. In particular, it should be clarified that Member States may also order, on grounds of public health, the cessation of activity of providers of diagnostic or therapeutic services by way of information society services, as defined in Directive (EU) 2015/1535 of the European Parliament and of the Council[10], without prejudice to national law regulating the medical profession.

(15) While it should remain the responsibility of each Member State to determine the language in which information should be supplied to the users within their territory, Member States should consider accepting such information in other languages of the Union that are commonly understood in the medical field, especially regarding devices intended for professional users, in order to reduce costs for translations.

(16) To reduce complexity and enhance consistency, redundant provisions that simply state that requirements in other provisions within Regulation (EU) 2017/745 or Regulation (EU) 2017/746, or in other legislation, apply, should be removed.

(17) Some manufacturers have their devices designed and manufactured by another legal or natural person. Whilst Regulations (EU) 2017/745 and (EU) 2017/746 have increased transparency regarding the person that designs and manufactures the device, the responsibilities of the manufacturer regarding its access to the parts of the technical documentation that may be drawn up by the original equipment supplier should be clarified, also for the purpose of supervision by competent authorities.]

[10] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1, ELI: http://data.europa.eu/eli/dir/2015/1535/oj).

(17a) Where manufacturers have their devices designed or manufactured by another legal or natural person, the manufacturer is expected to hold the full technical documentation in order to demonstrate that the medical device placed on the market, under their own name, meets the requirements of this Regulation. Where the manufacturer does not hold the rights related to product design or manufacturing, a technical file with redacted proprietary information could be accepted as long as the redacted information is not essential for conformity assessment and these redactions are as limited as possible. In these cases, the manufacturer should have contractual arrangements in place that ensures full disclosure of all applicable information by the legal or natural person that designed or manufactures the device to the notified body or any national competent authority.

(18) [To facilitate and streamline the application of the information obligation in cases of the interruption or discontinuation of supply of certain devices as laid down in Regulations (EU) 2017/745 and (EU) 2017/746, and to enhance legal certainty regarding the devices that are subject to that information obligation, a central IT tool for the notification and information sharing should be made available. Moreover, the EMA should be empowered to draw up and publish a list of devices covered by the information obligation. The support provided by the EMA in situations of interruption or discontinuation of supply should also take into account the contribution provided by the Executive Steering Group on Shortages of Medical Devices (MDSSG) established by Regulation (EU) 2022/123 of the European Parliament and of the Council[11]. To ensure a high level of public health protection, continuous access and availability of medical devices and *in vitro* diagnostic medical devices, and to strengthen health emergency preparedness and response, Member States and the Commission should have the possibility to request manufacturers of devices, which are included in the list of devices covered by the information obligation, to provide information regarding risks and weaknesses within the supply chain that may affect the supply of such devices. That information can be used for assessing possible vulnerabilities in the supply chain of critical devices, for example within the framework of the MDSSG.

[11] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/123/oj).

(19) Having regard to advances in digital communication and digital compliance tools and in order to reduce administrative burden, it should be specified that communication between the relevant actors and compliance with legal obligations, including the drawing up of documentation, reports and other documents as well as conformity assessment procedures should in principle be possible in digital form. Moreover, where no specific format is required, digital formats, such as electronic signatures, should be accepted by default.

(20) To simplify rules and reduce compliance costs, some overly prescriptive requirements, such as the qualification requirements for the person responsible for regulatory compliance or the permanent and continuous availability of that person when not part of the manufacturer's organisation, should be removed. Also, unnecessary reporting and certification requirements regarding the repackaging or relabelling of devices that are already placed and further distributed within the internal market, for example outside the manufacturer's official distribution schemes, should be removed.

(21) The Commission Report[12] on the operation of Article 17 of Regulation (EU) 2017/745 highlighted that the application of the rules on single-use devices is fragmented across the Union and the relevant requirements are complex to implement, resulting in a very limited and unattractive market for the reprocessing of single-use devices. To simplify the rules regarding single-use devices and to increase the re-use of devices for economic and environmental reasons, it should be the responsibility of the manufacturer to determine whether and how a device can be reprocessed, based on the device's characteristics and properties. Unless the indication of single-use is duly justified by the manufacturer, devices should be subject to reprocessing, whilst single-use devices or devices which cannot be further reprocessed should be subject to full refurbishing.

[12] Report from the Commission to the European Parliament and the Council of 29 November 2024 on the operation of Article 17 of Regulation (EU) 2017/745 of the European Parliament and the Council on single-use devices and their reprocessing (COM(2024)560 final).

(22) The unique device identification (UDI) system and the registration of devices in the European database for medical devices (Eudamed) are fundamental tools for ensuring the traceability and transparency of devices made available on the Union market. To enhance clarity and legal certainty, the respective provisions related to those tools laid down in Regulations (EU) 2017/745 and (EU) 2017/746 should be clarified and streamlined.]

(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[13] of the European Parliament and of the Council could lead to overlaps of requirements**, excessive administrative burden for economic operators** 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~~**The** Commission **should be empowered to adopt** ~~may use its~~ implementing and delegated **acts**~~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: […]~~**general requirements regarding data and data governance; record-keeping; transparency and information to deployers; and human oversight should be added in the general safety and performance requirements laid down in Annex I of Regulations (EU) 2017/745 and (EU) 2017/746**. 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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13 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).

(24) [The summary of safety and clinical performance under Regulation (EU) 2017/745 and the summary of safety and performance under Regulation (EU) 2017/746 ensure transparency regarding the clinical evidence on which the safety and performance assessment of the device is based. As the drawing up and updating of such a summary is costly, the range of devices subject to that requirement should be clearly limited to those devices for which a systematic assessment of the device's technical documentation is required pursuant to Regulations (EU) 2017/745 and (EU) 2017/746. Moreover, the summary should be drawn up in a way that is clear for the intended user of the device. To reduce burden and enhance cost-efficiency, additional versions for other persons, such as patients, should not be required. Moreover, as the draft summary is in any case part of the documentation to be submitted to the notified body, a separate validation of the summary by the notified body should not be required. In addition, duplication of information to be provided in the summary and in the instructions for use should be avoided.

(25) In accordance with Regulations (EU) 2017/745 and (EU) 2017/746, notified bodies exercise a key function in the medical device regulatory system as the issuance of a certificate by a notified body is a prerequisite for market access of most devices. In order to ensure that devices benefit from uniform and predictable conditions for market access, the accountability of notified bodies and the degree of harmonisation of their conformity assessment activities should therefore be enhanced. For that purpose, the process for the assessment of applicant notified bodies and their designation should be streamlined. Moreover, the oversight of notified bodies should be tightened through the involvement of joint assessment teams also in the monitoring of notified bodies. In light of such changes, the full reassessment of notified bodies every five years is no longer required and should therefore be removed.

(26) To streamline the assessment and monitoring of notified bodies, the joint assessment teams should include the national authority responsible for the notified body as well as experts from other Member States and experts nominated by the Commission. Moreover, the national authority responsible for the notified body should be tasked with deciding on disputes between manufacturers and notified bodies that arise in the context of conformity assessment procedures.

(27) Even though most notified bodies are private for-profit entities, they exercise their function in the public interest. With regard to manufacturers that are micro or small enterprises within the meaning of Commission Recommendation 2003/361/EC[14] and with regard to orphan devices, notified bodies should therefore be required to reduce their fees for conformity assessment activities in accordance with Regulations (EU) 2017/745 and (EU) 2017/746.]

(27a) The mechanism provided for in Article 50(6) should remain an exceptional measure. It should therefore be applied only where other measures available under this Regulation cannot be applied effectively. Such measures including derogations under Article 59 and, where applicable, measures available to competent authorities pursuant to Articles 94 to 97. It should be used only where those measures are not suitable or sufficient to safeguard public health or patient health or safety.

~~(28) To enhance predictability regarding the fees charged by notified bodies for conformity assessment activities of devices in accordance with Regulations (EU) 2017/745 and (EU) 2017/746 and to prevent excessively high fees, the Commission should be empowered to adopt implementing acts to set the level and structure of fees by the notified bodies, without prejudice to the potential application of Articles 101 and/or 102 of the Treaty on the Functioning of the European Union to the way notified bodies set their prices or carry out their economic activities.~~

(29) [Devices are classified in different classes depending on their level of risk. Some of the classification rules should be adapted to reflect the inherent risk of devices, resulting in a lower risk classification, such as for reusable surgical instruments or accessories for active implantable devices.

[14] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).

(30) For lower and medium-risk devices, the involvement of notified bodies in the conformity assessment process should be reduced so that it is proportionate to the risk class of the device. For example, for class IIa and non-implantable class IIb devices, or most class C devices, where the notified body is to assess the technical documentation on a sampling basis, it should be clarified that the technical documentation assessment is only needed for one representative device of a category of devices or a generic device group, or in the case of class B devices only for one device from the manufacturer's product portfolio. Additional technical documentation assessment during surveillance activities should only be carried out when potential concerns exist based on data available from the post-market surveillance system. As class A sterile devices are of low risk, notified body involvement for those devices should be removed.

(31) To support innovation and the development and availability of breakthrough technology and of devices intended for small groups of patients, the conformity assessment procedures should be adapted to address the specific situation of those devices. For that purpose, criteria for breakthrough devices and orphan devices should be included in Regulations (EU) 2017/745 and (EU) 2017/746, based on guidance developed by the Medical Device Coordination Group. If the status as a breakthrough device or orphan device is confirmed by an expert panel, the review of the device by the notified body should be prioritised, if necessary with additional advice from the expert panels.

(32) The clinical evaluation consultation procedure provided for in Regulation (EU) 2017/745 is a tool to scrutinise the assessment of notified bodies regarding certain high-risk devices. The procedure should be focused on devices where that exceptional scrutiny gives an additional assurance for patient safety. The scope of the clinical evaluation consultation procedure should therefore be limited to class III implantable devices, removing from its scope class IIb active devices intended to administer and/or remove a medicinal product. However, there should be the possibility to add specific types of high-risk devices to the scope of the clinical evaluation consultation procedure by way of delegated act, where justified on grounds of patient safety.]

PUBLIC

(32a) To ensure that clinical investigations accurately represent the target population in all its diversity, and to enhance the medical devices available for vulnerable populations, medical devices which are likely to offer significant clinical benefit should be fully and appropriately studied in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups. The protection of vulnerable populations, in this context, such as incapacitated subjects, minors and pregnant or breastfeeding women, requires a proper consideration of the risks of exclusion against risks of inclusion in clinical investigations. This is in accordance with the 2024 version of the World Medical Association's Declaration of Helsinki.

(33) [The performance evaluation assessment procedure provided for in Regulation (EU) 2017/746 is not effective for certain class D devices as it mixes up the responsibilities of expert panels and notified bodies. It should therefore be removed and replaced with an early scientific advice process for high-risk *in vitro* diagnostic medical devices that provides for the possibility of manufacturers to seek advice from expert panels on their performance evaluation strategy.

(34) When the validity of a certificate for medical devices or for *in vitro* diagnostic medical devices issued by a notified body expires, notified bodies are to assess whether the certificate can be renewed. This creates administrative burden, uncertainty and unnecessary costs. The maximum validity period of certificates issued by notified bodies should therefore be removed, unless the notified body considers it necessary to limit the validity on justified grounds, such as in the case of a certificate issued with conditions where the manufacturer has to collect additional clinical data after certification in the post-market phase, as may be the case for breakthrough technology devices.

PUBLIC

(35) In order to respond to a public health emergency at Union level recognised in accordance with Regulation (EU) 2022/2371 of the European Parliament and of the Council[15], or to ensure the supply of medical devices and *in vitro* diagnostic medical devices falling under the definition of medical countermeasures within the framework of Council Regulation (EU) 2022/2372[16], the Commission should be able to authorise, by means of implementing acts, the placing on the market or putting into service of devices for which a conformity assessment in accordance with Regulations (EU) 2017/745 and (EU) 2017/746 has not been carried out. Moreover, where specific CE marked devices are needed, for example in greater numbers or with an adapted intended purpose, to respond to a public health emergency or a disaster or crisis, Member States, or the Commission, should be able to exempt manufacturers from certain requirements related to the manufacturing, design or intended purpose of the device.]

(36) To ensure that the legal framework governing the highly innovative sectors of medical devices and in vitro medical devices is future-proof and able to support innovation, Member States and the Commission should be able to establish regulatory sandboxes in the field of medical devices or in vitro diagnostic medical devices to facilitate the development and testing of innovative devices or regulatory approaches under strict oversight. **Those regulatory sandboxes should be available to manufacturers, including early-stage start-ups and device developers.**

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15 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).

16 Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (OJ L 314, 6.12.2024, p. 64, ELI: http://data.europa.eu/eli/reg/2022/2372/oj).

(37) [Article 4 of Directive 2010/63/EU of the European Parliament and the Council[17] prescribes that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of an animal-based procedure. Non-animal tests such as New Approach Methodologies (NAMs), which include innovative *in-vitro* (cell or tissue-based), *in-chemico* (chemical-based), *in-silico* (computer-based) approaches, or combinations of these, can increasingly replace or complement animal-based tests for safety and performance studies. The use of non-animal methods, including NAMs, to provide scientific evidence in clinical and non-clinical studies should therefore be promoted.

(38) As the safety and performance of many devices other than high-risk devices can be sufficiently demonstrated using non-clinical data, including NAMs, the possibility to use non-clinical data to confirm the safety and performance of a device in the conformity assessment should therefore be made more prominent in Regulation (EU) 2017/745.

(39) Clinical data are often available for devices that are equivalent to the device under conformity assessment. In order to make the conditions under which manufacturers can claim equivalence more flexible, the requirement in Regulation (EU) 2017/745 for a contract with the manufacturer of the equivalent device granting access to its technical documentation should therefore be removed and the equivalence criteria be adapted.

(40) Post-market clinical follow-up (PMCF) is an important requirement in Regulation (EU) 2017/745 to identify any safety issues that might appear during real world use of the device. To reduce the number of reports that manufacturers are required to draw up, manufacturers should be able to include the findings of the PMCF directly in the updated clinical evaluation report, without the need to draw up a separate PMCF evaluation report.

[17] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276 20.10.2010, p. 33, ELI: http://data.europa.eu/eli/dir/2010/63/2019-06-26).

(41) The obligation to prepare a periodic safety update report (PSUR) is an important tool provided for in Regulations (EU) 2017/745 and (EU) 2017/746 that requires manufacturers to verify the safety and performance of a device during its lifetime. In order to avoid unnecessary costs and administrative burden for manufacturers and to make the obligation more proportionate, the frequency for updating the PSUR should be reduced depending on the risk class of the device.

(42) Unnecessary overlaps and duplication of assessments between different actors in the regulatory system negatively impact the efficiency and consistency of that regulatory system. Therefore, the roles and responsibilities of competent authorities and notified bodies, in particular regarding the assessment of vigilance cases, should be clarified and any unnecessary elements removed.

(43) There is a growing number of clinical studies involving, simultaneously, a clinical trial of a medicinal product subject to Regulation (EU) No 536/2014 of the European Parliament and of the Council[18], a performance study of an *in vitro* diagnostic medical device subject to Regulation (EU) 2017/746 or a clinical investigation of a medical device subject to Regulation (EU) 2017/745 ('combined studies'). To address concerns raised regarding the complexity of applying multiple Regulations to those combined studies, sponsors should be enabled to submit a single application for a combined study leading to its coordinated assessment under Regulation (EU) No 536/2014. Regulations (EU) 2017/746 and Regulation (EU) 2017/745 should not be applicable where a single application has been submitted.

[18] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p.1, ELI; http://data.europa.eu/eli/reg/2014/536/oj).

(44) Regulation (EU) 2024/2847 of the European Parliament and of the Council[19] requires manufacturers to notify actively exploited vulnerabilities and severe incidents having an impact on the security of products with digital elements in order to ensure that the relevant national computer security incident response teams (CSIRTs) designated as coordinators, and the European Union Agency for Cybersecurity (ENISA), have an adequate overview of vulnerabilities and incidents impacting the internal market. Medical devices and *in vitro* diagnostic medical devices, however, are exempted from Regulation (EU) 2024/2847. While cybersecurity related incidents need to be reported in accordance with existing vigilance rules in Regulations (EU) 2017/745 and (EU) 2017/746 when they qualify as serious incidents, cybersecurity related incidents that do not concern public health or patient safety, are not reported. This is an important cybersecurity gap. Manufacturers of connected devices should therefore be obliged to report also those incidents to the CSIRTs and ENISA through Eudamed.

(45) The key actors under Regulations (EU) 2017/745 and (EU) 2017/746, namely manufacturers, competent authorities, notified bodies and the Commission, should have access to experts with relevant scientific, clinical, technical and regulatory expertise. Enhanced coordination and access to expertise result in a predictable and reliable regulatory framework. The type of expertise available in the expert panels range of areas in which expert panels provide advice and their involvement in the regulatory system set out in Regulations (EU) 2017/745 and (EU) 2017/746 should therefore be expanded. The mandate of the EMA to support the expert panels in accordance with Regulation (EU) 2022/123 should be amended accordingly.

[19] Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) (OJ L 2024/2847, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2847/oj).

(46) Regulations (EU) 2017/745 and (EU) 2017/746 provide for a decentralised regulatory system. Effective coordination between national authorities is essential to ensure the smooth functioning of the internal market and a coherent application of the requirements laid down in the Regulations to ensure a uniform high level of protection of patient safety and public health. For an effective and efficient coordination, national authorities need scientific, technical and administrative support, which can be provided in the most adequate way by the EMA, as it already manages the medical device expert panels. The EMA should therefore be mandated to provide, on behalf of the Commission, the necessary support for the coordination between national competent authorities to facilitate uniform application of Regulations (EU) 2017/745 and (EU) 2017/746.

(47) The Union participates in the International Medical Device Regulators Forum (IMDRF)[20], which is a voluntary group of regulators from around the world that aims to accelerate international regulatory harmonisation and convergence in the field of medical devices and *in vitro* diagnostic medical devices. To a large extent, the Union regulatory system for medical devices reflects guidelines developed in the framework of the IMDRF. To increase efficiency, reduce duplication of regulatory efforts and promote global convergence, the Commission and Member States should actively participate in, and make use of, international regulatory cooperation and reliance mechanisms or reliance programmes.

(48) To avoid the risk of misunderstanding regarding kits that are *in vitro* diagnostic medical devices and that integrate products which are subject to other Union legislation, such as medicinal products, it should be clarified that products which are included in kits should be in conformity with the legislation applicable to those products.

[20] International Medical Device Regulators Forum (IMDRF) | International Medical Device Regulators Forum

(49) Regulation (EU) 2017/746 introduced specific provisions for companion diagnostics. In light of the experience gained from the application of those provisions, it is necessary to clarify in the definition of companion diagnostics that a companion diagnostic may be linked to more than one medicinal product. Moreover, to avoid any unnecessary duplication in the assessment of companion diagnostics, it should be clarified that the consultation of a medicinal products authority should only be necessary regarding novel companion diagnostics and that a consulted medicinal products authority should not repeat the assessment carried out by a notified body.

(50) Performance studies are an important source of clinical evidence for *in vitro* diagnostic medical devices. The rules applicable to the conduct of performance studies should be simplified in cases where they do not present any additional risks to the subjects of the study, such as in cases where the study involves routine blood draws from non-vulnerable individuals or where studies on companion diagnostics are conducted using left-over samples.

(51) The transition from the previous regulatory framework to that under Regulations (EU) 2017/745 and (EU) 2017/746 has led to the discontinuation of certain devices intended for small groups of patients, as the costs for the transition made it economically difficult for manufacturers to undertake conformity assessment in accordance with those Regulations. The discontinuation of those orphan devices jeopardises the level of care and patient protection, where no alternative diagnosis or treatment methods are available. Manufacturers should therefore be allowed, subject to certain conditions, to continue marketing orphan devices that were lawfully marketed in accordance with the Directives 90/385/EEC, 93/42/EEC and 98/79/EC without the need to conduct a conformity assessment procedure pursuant to Regulations (EU) 2017/745 and (EU) 2017/746.

(52) Certain Annexes to Regulations (EU) 2017/745 and (EU) 2017/746, which further specify the obligations and requirements applicable to notified bodies, economic operators and devices, should be aligned with the changes made in the corresponding provisions of those Regulations and to reflect the same objectives, namely simplification, burden reduction, enhanced cost-efficiency of the certification process and further digitalisation.

PUBLIC

(53) To reduce costs and length of conformity assessment procedures for medical devices that integrate a medicinal substance or a SoHO, the consultation of the medicinal products authorities or the SoHO authorities should be streamlined and shortened. Substance-based medical devices that are systematically absorbed by the human body are medical devices. They do not incorporate any substance that, if used separately, would fall under Union legislation on medicinal products. The consultation of a medicinal products authority in the framework of the conformity assessment of such substance-based medical devices is not appropriate and should therefore be removed.

(54) Regulations (EU) 2017/745 and (EU) 2017/746 delegated to the Commission the power to adopt delegated acts in accordance with Article 290 TFEU in order to amend certain non-essential provisions in Regulations (EU) 2017/745 and (EU) 2017/746. Having regard to the experience with the application of those Regulations and the necessity to maintain a level of flexibility regarding the often very technical and procedural requirements in the Regulations, the power to adopt delegated acts should be provided also for other non-essential provisions in Regulations (EU) 2017/745 and (EU) 2017/746, to adapt them to experience gained from their application, scientific or technical progress or developments at international level.

(55) Regulations (EU) 2017/745 and (EU) 2017/746 conferred on the Commission the power to adopt implementing acts. In order to ensure uniform conditions of implementation of those Regulations additional implementing powers should be conferred on the Commission.]

(56) Since the objectives of this Regulation, namely simplification and burden reduction of the rules on medical devices and on *in vitro* diagnostic medical devices, while preserving the objectives of Regulations (EU) 2017/745 and (EU) 2017/746 as such, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

PUBLIC

(57) Regulations (EU) 2017/745 and (EU) 2017/746 should therefore be amended accordingly.

(58) In order to allow all affected parties sufficient time to take the necessary measures to comply with this Regulation, the application of certain provisions should be deferred. However, provisions that do not require time for preparation should be applicable from the date of the entry into force of this Regulation.

(59) This Regulation introduces binding requirements for cross-border digital public services within the meaning of Regulation (EU) 2024/903 of the European Parliament and of the Council[21]. An interoperability assessment has therefore been completed. The Digital Dimensions chapter of the Legislative Financial and Digital Statement constitutes the resulting report,

PUBLIC

[21] Regulation (EU) 2024/903 of the European Parliament and of the Council of 13 March 2024 laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act) (OJ L 2024/903, 22.3.2024, ELI: http://data.europa.eu/eli/reg/2024/903/oj).

Amendments to Regulation (EU) 2017/745

PUBLIC

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

(3) Articles 3 and 4 are replaced by the following:

(…)

'Article 4

Regulatory status of products

1. **Upon a duly substantiated request by a manufacturer or an authorised representative established within a Member State, or on its own initiative, the competent authority of that Member State (the 'responsible competent authority') shall, after obtaining information from the manufacturer or authorised representative and, where applicable, the notified body that issued the certificate for that product, determine whether the specific product of the requesting manufacturer or authorised representative falls within the definition of a medical device as set out in Article 2(1) or the definition of 'accessory for a medical device' set out in Article 2(2), or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex ('the regulatory status of a product'), taking into account this Regulation and any harmonised criteria established at Union level.**

~~The competent authorities of the Member States shall, when necessary, exchange experience, cooperate and coordinate their activities, with the support of the Agency as referred to in Article 106b (1) point (a), when determining whether a specific product, or category, or group of products, falls within the definition of 'medical device' set out in Article 2, point (1), or the definition of 'accessory for a medical device' set out in Article 2, point (2), or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex.~~

2. **Where the competent authority has justified doubts during the determination referred to in paragraph 1, it may consult the competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a).**

~~The Member States shall, when necessary, ensure an appropriate level of consultation of the relevant competent authorities of the Member States in the fields of in vitro diagnostic medical devices, medicinal products, substances of human origin (SoHO), biocides, food products, cosmetics or other products subject to Union legislation, where the determination of whether a product has the regulatory status of a device involves aspects concerning the borderline with any of those types of products. As part of providing its support as referred to in Article 106b (1) point (a), the Agency shall, where necessary, ensure an appropriate level of consultation of the relevant advisory or regulatory bodies established in the relevant Union legislation, such as the SoHO Coordination Board, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA).~~

3. **Where a competent authority (the 'initiating competent authority'), on the basis of information obtained through vigilance activities, market surveillance activities or any other relevant information, has justified doubts as to the regulatory status of a product for which neither the manufacturer nor the authorised representative is established within its Member State, the competent authority shall refer the matter to the responsible competent authority.**

~~Where a competent authority of a Member State, as part of its market surveillance activities, considers that a product that is CE marked in accordance with Article 20, does not fall within the scope of this Regulation, it shall consult the competent authorities of the other Member States regarding its envisaged decision determining the regulatory status of the product in question.~~

PUBLIC

4. **Following consultation with the initiating competent authority and after having obtained information from the manufacturer or authorised representative, and, where applicable, the notified body, the responsible competent authority shall determine the regulatory status of the concerned product within 6 months. Where the initiating and the responsible competent authorities agree on the regulatory status of the product, the responsible competent authority shall issue the determination and communicate it to the initiating competent authority and the competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a).**
~~Where a competent authority of a Member State raises a substantiated disagreement regarding the envisaged decision on the status of the product referred to in paragraph 3, the initiating authority shall refer the matter to the MDCG for an opinion.~~

~~When necessary, the MDCG may seek the advice of an expert panel as referred to in Article 106. The expert panel shall provide the requested advice to the MDCG within 30 days. The MDCG shall provide its opinion within 30 days of receiving the advice from the expert panel.~~

~~The initiating competent authority shall give utmost consideration to the opinion of the MDCG and shall, where applicable, conduct an evaluation in accordance with Article 94.~~

5. **Where a competent authority does not agree with the determination of the regulatory status by the responsible competent authority, the responsible competent authority shall consult the national competent authorities in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) who shall issue an opinion on the regulatory status of the product.**
~~The outcomes of the coordination activities of the competent authorities in accordance with this Article, the opinions of the MDCG, and the advice of the expert panel delivered in accordance with paragraph 4 of this Article and Article 4a(2) shall be made publicly available, without disclosing any confidential information as referred to in Article 109.';~~

6. Where a majority of the Member States' competent authorities referred to in point 2 or point 5 consider it justified, they may refer the case for the consideration of the MDCG. The MDCG shall provide its opinion on the regulatory status and may request the Commission to decide on the regulatory status of the specific product, by means of implementing acts.

7. During the consideration of the regulatory status referred to in paragraph 6, the MDCG, or the Commission in agreement with the MDCG, may consult the relevant expert panel. The manufacturer or authorised representative, as well as the notified body that issued the certificate, if applicable, will be provided with the opportunity to present their positions on the regulatory status of the product to the competent authorities, MDCG or the relevant expert panel, as applicable.

8. Where appropriate, the competent authorities, the Agency in fulfilling its tasks described in Article 106b or the MDCG as applicable, shall ensure an appropriate level of consultation with the competent authorities of the Member States responsible for medicinal products, substances of human origin (SoHO), biocidal products, food, cosmetics or any other products regulated under Union legislation where the determination of the regulatory status of a product involves questions concerning the borderline between such products and medical devices. In such cases, the Agency in fulfilling its tasks described in Article 106b shall also ensure an appropriate level of consultation with the relevant Union bodies established under the applicable legislation, including, where relevant, the SoHO Coordination Board, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA).

9. Within 60 days of the request referred to in paragraph 7, the relevant expert panel shall provide advice to the MDCG or the Commission.

PUBLIC

10. Within 90 days of the request referred to in paragraph 6, the MDCG shall issue its opinion on the regulatory status of the product. Where an expert panel is consulted in accordance with paragraph 7, the clock shall stop until the advice from the expert panel is received.

11. Within 180 days of the request from the MDCG referred to in paragraph 6, the Commission shall propose to the Committee referred to in Article 114(1) a decision on the regulatory status of the product. That decision shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 114(3). In adopting its decision, the Commission shall take the utmost account of the advice and opinions issued by the expert panel and the MDCG.

12. The outcomes of the coordination activities of the competent authorities in accordance with this Article, the opinions of the MDCG, and the advice of the expert panel delivered in accordance with this Article shall be made publicly available, without disclosing any confidential information as referred to in Article 109.

13. This Article shall not apply where within the framework of another Union legislation the regulatory status of the product, or category or group of products concerned has been determined as falling within the scope of that other Union legislation, or where a procedure for the determination of the regulatory status is ongoing within the framework of another Union legislation.

PUBLIC

~~(4) the following Article 4a is inserted:~~

~~*'Article 4a*~~

~~Opinion on and determination of the regulatory status of a product~~

~~1. A competent authority, a notified body, a manufacturer, an authorised representative, a developer of a product or the Commission may submit a substantiated request for an opinion from the competent authorities, in accordance with the coordination activities of the competent authorities referred to in Article 4(1), on the question whether a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory for a medical device', or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex. Where, in such a request, the requester considers that the product in question is a device, the request shall also specify the proposed classification of the device in accordance with Article 51 and Annex VIII.~~

~~Requests by a notified body may only be submitted with regards to the product of an applicant.~~

~~1a. A manufacturer, an authorised representative or a developer of a product may submit a substantiated request as referred to in paragraph 1 only if they have requested from the competent authority of the Member State, in which they are established, advice on the same matter and have not received any advice within a period of three months.~~

~~2. Where necessary, the competent authorities may request the advice of an expert panel referred to in Article 106. The expert panel shall provide its advice to the competent authorities within 30 days. The competent authorities shall provide their opinion within 30 days of receiving the advice from the expert panel. The time limits provided for in this subparagraph shall be suspended for the duration of any consultation of relevant Union bodies.~~

~~The requester shall give utmost consideration to the opinion of the competent authorities.~~

PUBLIC

3. Having regard to the opinion referred to in paragraph 2 or in Article 4(4), a Member State may submit a substantiated request to the Commission to determine whether a specific product, or category or group of products, falls within the definitions of 'medical device' or 'accessory for a medical device', or whether a product falls within the scope of Annex XVI or is an accessory for a product listed in that Annex.

The Commission shall decide on the substantiated request of the Member State or on its own initiative, by means of implementing acts, within 180 days, which shall be adopted in accordance with the examination procedure referred to in Article 114(3).

The Commission may ask the expert panel or the competent authorities for clarifications or refer the opinion back for further consideration, including in cases where a Member State's substantiated request raises new questions of a scientific or technical nature.

4. This Article shall not apply where within the framework of another Union legislation the regulatory status of the product, or category or group of products concerned has been determined as falling within the scope of that other Union legislation, or where a procedure for the determination of the regulatory status is ongoing within the framework of another Union legislation.

4a. The Commission may, after consulting the MDCG, by means of implementing acts, lay down the procedure, for the application of paragraphs 1 to 5 of Article 4 and of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';

PUBLIC

(5) Article 5 is amended as follows:

(a) paragraph 5 is amended as follows:

(i) the first subparagraph is amended as follows:

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

‘(a) the devices are not transferred to another legal entity~~,~~**. A device may be transferred** ~~except~~ to another health institution in **exceptional circumstances where** the**re is a** duly justified interest of public health, patient safety or patient health, or to prepare or respond to a public health emergency**.**

Where such transfers occur, the transferring and receiving health institutions shall notify the competent authority of the Member State in which they are based and provide the justification.’;

(1a) point (aa) is added:

‘(aa) the devices are not manufactured on an industrial scale.’;

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

‘(d) upon request by a competent authority, the health institution provides information on the use of such devices and the justification referred to in point(c);’;

(3) point (f) is replaced by the following:

‘(f) the health institution draws up documentation that is sufficiently detailed to enable the competent authority to ascertain that the relevant general safety and performance requirements set out in Annex I are met;’;

(4) point (g) is deleted;

PUBLIC

(ii) the second sentence of the second subparagraph is replaced by the following: 'Member States shall retain the right to restrict the manufacture, the use, or the transfer of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.';

(iia) the third subparagraph is deleted.

(iii) The following three subparagraphs are added:

'For the purposes of the first subparagraph, point (a), in the case of a transfer of the device to another health institution, the transferring and receiving health institutions shall ensure traceability of the device. This information shall be made available to a competent authority upon request.

For the purposes of the first subparagraph, point (c), from the date that the health institution becomes aware that the target patient group's specific needs can be met by an equivalent device available on the market and registered on Eudamed, it may continue to manufacture and use its device for a maximum period of 5 years.

For the purposes of the first subparagraph, point (h), where the device is transferred in accordance with point (a), both the transferring and the receiving health institution shall report to each other any incident related to the device.';

(b) the following paragraphs 7 and 8 are added:

'7. The Commission**, in consultation with the MDCG,** is empowered to adopt delegated acts in accordance with Article 115 to amend ~~Annex I in order to adapt~~ the ~~general safety and performance~~ requirements **regarding the design and manufacture, or the information to be supplied with the device** set out ~~there~~in **Chapters II and III of Annex I to take account of** ~~to align them, where necessary, to~~ scientific or technical progress**, users' needs** or ~~to~~ international developments**, including to address risks from** ~~or to add requirements in relation to~~ emerging ~~risks or~~ technologies.

PUBLIC

8. When adopting implementing acts pursuant to paragraph 6 of this Article, delegated acts pursuant to paragraph 7 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council***, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation.

_____

*** 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).';

(6) Article 6 is amended as follows:

(a) the following paragraph 2a is inserted:

'2a. Any natural or legal person offering a device in accordance with paragraph 1 or a service in accordance with paragraph 2 shall provide in the offer at least the information referred to in Annex I, Section 23.2, points (a) to (d) and (m), and access to the instructions for use.';

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

'3. Upon request by a competent authority, any natural or legal person offering a device in accordance with paragraph 1 or a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity drawn up in accordance with Article 19 or the statement drawn up in accordance with Article 21(2) for the device concerned and cooperate with the competent authorities of the Member State where the device or the service is offered.

4. A Member State may, on grounds of protection of public health, require a provider of a service as defined in Article 1(1), point (b), of Directive (EU) 2015/1535, or a provider of a service in accordance with paragraph 2, to cease its activity.';

(7) in Article 7, the following subparagraph is added:
'Without prejudice to national law regarding the exercise of the medical profession, the first subparagraph shall also apply to devices used for the provision of a service referred to in Article 6(2).';

(8) in Article 9(1), the first sentence is replaced by the following:
'Where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns, the Commission, after having consulted the MDCG, may, by means of implementing acts, adopt common specifications (CS) in respect of the requirements set out in this Regulation, in particular the reports and plans to be drawn up by manufacturers, the general safety and performance requirements set out in Annex I, the technical documentation set out in Annexes II and III, the conformity assessment procedures set out in Annexes IX to XI and the procedure for custom-made devices set out in Annex XIII, the clinical evaluation and post-market clinical follow-up set out in Annex XIV or the requirements regarding clinical investigation set out in Annex XV.';

(9) Article 10 is amended as follows:

(-a) paragraph 7 is replaced by the following:

'7. Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27.';

(-aa) The following paragraph 7a is added:

'7a. Manufacturers shall comply with the obligations referred to in Articles 29 and 31.';

PUBLIC

(b) paragraph 9 is replaced by the following:

‘9. Manufacturers shall put in place an appropriate quality management system to ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in device design or characteristics and changes in the harmonised standards or CS by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner. Manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device.

The quality management system shall cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation.;

The quality management system shall address at least the following aspects:

(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;

(b) identification of applicable general safety and performance requirements and exploration of options to address those requirements;

(c) responsibility of the management;

(d) resource management, including **human resources, and the** selection and control of suppliers and subcontractors;

(e) **control of changes to the device and quality management system, and** risk management as set out in in Section 3 of Annex I;

(f) clinical evaluation in accordance with Article 61 and Annex XIV, including PMCF;

(g) product realisation, including planning, design, development, production and service provision;

(h) verification of the UDI assignments made in accordance with Article 27(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29;

(i) setting-up, implementation and maintenance of a post-market surveillance system, in accordance with Article 83;

(j) handling communication with competent authorities, notified bodies, other economic operators, customers or other stakeholders**, including the handling of complaints**;

(k) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;

(l) management of corrective and preventive actions and verification of their effectiveness;

(m) processes for monitoring and measurement of output, data analysis and product improvement**, including audits**.';

(d) in paragraph 11, the following subparagraph is added:

'When determining the official language of the Union in which the information set out in Section 23 of Annex I or other information to be provided by the manufacturer shall be made available, Member States shall consider accepting another official language of the Union in which the information is made available, taking into consideration the technical knowledge, experience, education or training of the average intended user(s).';

PUBLIC

(g) paragraph 15 is replaced by the following:[22]

'15. Where manufacturers have their devices designed or manufactured by another legal or natural person, the information on the identity of that person shall be part of the information to be submitted in accordance with Article 29(1).';

(h) in paragraph 16, '85/374/EEC' is replaced by '(EU) 2024/2853';

(10) Article 10a is amended as follows:[23]

(a) paragraph 1 is replaced by the following:

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

PUBLIC

22 See new recital (17a) in support of Article 10(15).

23 ~~The Presidency suggests reordering the paragraphs as follows: paragraph 5 proposed by the Commission would become paragraph 2, the new paragraph 5a would become paragraph 3, paragraph 6 proposed by the Commission would become paragraph 4, the current (unchanged) paragraphs 2 and 3 would become paragraphs 5 and 6 and the paragraph 4 proposed by the Commission would become paragraph 7.~~

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

(b) the following paragraphs 4, 5, 5a and 6 are added:

'4. The Commission, ~~where needed~~ in cooperation with the Agency, **and in consultation with the MDCG,** shall set up, maintain, and manage an IT system to facilitate the reporting and information exchange regarding cases of interruption or discontinuation of the supply of devices in accordance with ~~[~~paragraphs 1, 2, 4, 5, 5a, 6~~]~~. That IT system shall be integrated in or interoperable with the European database on medical devices referred to in Article 33~~.~~ **and shall be accessible to manufacturers, competent authorities, health institutions, healthcare professionals.** It shall also enable health institutions and healthcare professionals to inform competent authorities about the unavailability or the immediate risk of unavailability of devices needed for the exercise of their professional activity. ~~This IT system shall be accessible to manufacturers, competent authorities, health institutions and healthcare professionals.~~ Information ~~relating~~**referred** to **in paragraph 6** ~~manufacturing sites, production volumes, and related operational data~~ shall be accessible exclusively to the Commission, the Agency and the competent authorities.

5. The Agency, in ~~collaboration with~~ **particular through** the Executive Steering Group on Shortages of Medical Devices (MDSSG) established by Article 21 of Regulation (EU) 2022/123, **and in collaboration with the MDCG,** shall develop a methodology to identify the devices, or categories of devices, for which it is reasonably foreseeable that an interruption or discontinuation of supply could result in serious harm or a risk of serious harm to patients or public health as referred to in paragraph 1. Based on that methodology, the Agency, in **particular through** ~~collaboration with~~ the MDSSG **and in collaboration with the MDCG** and in agreement with the Commission, shall **propose** ~~draw up, publish and keep up to date~~ a list of devices, or categories of devices, **that are deemed to meet that criteria. The Commission shall, by means of implementing acts and taking into account the list proposed by the Agency, adopt, publish and keep up to date a list of devices, or categories of devices, for which an interruption or discontinuation of supply could result in serious harm or risk of serious harm to patients or public health in one or more Member States,** to which ~~[~~paragraphs 1, 2, 3, 4, 5a and 6~~]~~ shall apply. The methodology shall be **drawn up and published** ~~developed~~ within one year from the date of application of this Regulation. The list of devices, or categories of devices, shall be developed within one year from the date of the development of the methodology. The list shall be reviewed and updated regularly, to ensure its continued relevance and accuracy. For the purpose of this paragraph, the MDCG, representatives of manufacturers, other relevant actors in the supply chain for the medical device sector and representatives of healthcare professionals, of patients and of consumers may be consulted as necessary.

For the purposes of ~~[~~paragraphs 1, 2, 3, 4, 5a and 6~~]~~, the obligations shall only apply to devices included in the list drawn up in accordance with this paragraph, when available.

5a. Economic operators shall establish, maintain and keep up to date a shortage prevention plan for the devices included in the list drawn up in accordance with ~~[~~paragraph 5~~]~~. Shortage prevention plans shall be made available to the competent authority upon request. They shall be developed on the basis of a risk-based approach and shall identify specific measures and actions to be taken in the event of an actual supply interruption.

6. The competent authorities of the Member States or the Commission may request the manufacturers of devices included in the list drawn up in accordance with ~~[~~paragraph 5~~]~~ to provide all necessary information regarding risks and weaknesses within the supply chain which may affect the supply of such devices, including manufacturing sites, their addresses and manufacturing stage they cover, the existence of any backup sites, production capacity and volume of sales. Manufacturers of those devices shall register on the IT system referred to in ~~[~~paragraph 4~~]~~ and be identifiable as such to the Commission and the competent authorities.';

(11) in Article 11, paragraph 4 is replaced by the following:
'The mandate referred to in paragraph 3 of this Article shall not delegate the manufacturer's obligations laid down in Article 10(1), (2), (3), (4), (5), (6), **(7),** (9), (10), (11) and (12).';

(12) in Article 14, paragraph 2 is amended as follows:

~~(a) in the first subparagraph, point (d) is replaced by the following:~~

~~'(d) that, where applicable, a UDI has been assigned by the manufacturer in accordance with Article 27(3).';~~

(b) the second subparagraph is replaced by the following:
'In order to meet the requirements referred to in the first subparagraph, the distributor may apply a sampling method that is representative of the devices supplied by that distributor.';

(13) Article 15 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices.

The person responsible for regulatory compliance shall be able to demonstrate that they have acquired and keep up to date the knowledge necessary to perform the tasks referred to in this Article.

The requisite expertise shall be demonstrated by either of the following:

(a) successful completion of a university degree in law, medicine, pharmacy, engineering or another relevant discipline, or an equivalent qualification in relevant studies, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) two years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing.';

(b) paragraph 2 is replaced by the following:

'2. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC**** shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person at their disposal.

****Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).';

PUBLIC

(c) in paragraph 3, point (c) is replaced by the following:

'(c) the post-market surveillance obligations are complied with in accordance with Article 83;';

(d) paragraph 6 is replaced by the following:

'6. Authorised representatives shall have at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements or medical devices in the Union. **The availability of the person responsible for regulatory compliance shall be proportionate to the number of manufacturers represented by the authorised representative as well as to the risk class of the devices manufactured by them.**

The person responsible for regulatory compliance shall be able to demonstrate that they have acquired and keep up to date the knowledge necessary to perform the tasks referred to in this Article.

The requisite expertise shall be demonstrated by either of the following:

(a) successful completion of a university degree in law, medicine, pharmacy, engineering or another relevant discipline, or an equivalent qualification in relevant studies, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) two years of professional experience in regulatory affairs or in quality management systems relating to medical devices.';

(14) Article 16 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, the introductory wording is replaced by the following: 'A distributor, an importer or another natural or legal person who makes a ~~product~~ **device** available on the market, or places a ~~product~~ **device** on the market or puts it into service shall assume the obligations incumbent on manufacturers if it does any of the following:';

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

'The first subparagraph shall not apply to any healthcare professional or any other person who, while not considered a manufacturer, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.';

(b) paragraph 4 is replaced by the following:

'4. At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities referred to in points (a) and (b) of paragraph 2 shall submit to the competent authority a certificate~~,~~ **or a declaration** ~~issued by an independent conformity assessment body,~~ attesting that the quality management system of the distributer or importer complies with the requirements laid down in paragraph 3.';

(15) ~~in~~ Article 17 **is replaced by the following:**~~, paragraph 10 is deleted;~~

'1. ~~Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this Article~~. **The manufacturer shall determine whether a device is intended for single use, based on the design, construction, material and chemical, physical and biological properties of the device.**

2. Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation, which include obligations relating to the traceability of the reprocessed device in accordance with Chapter III of this Regulation. The reprocessor of the device shall be considered to be a ~~producer~~ **manufacturer for the purpose of Article** ~~43~~**(10) of Directive (EU) 2024/2853**~~85/374/EEC~~**.**

PUBLIC

3. **By way of derogation from paragraph 2, the rules relating to manufacturers' obligations laid down in this Regulation shall not apply** ~~as regards~~ **to single-use devices that are reprocessed and used within a health institution,** ~~Member States may decide not to apply all of the rules relating to manufacturers' obligations laid down in this Regulation~~ **provided that** ~~they ensure that~~**:**

(a) the safety and performance of the reprocessed device is equivalent to that of the original device ~~and the requirements in points (a), (b), (d), (e), (f), (g) and (h) of Article 5(5) are complied with~~**;**

(b) the reprocessing is performed in accordance with CS detailing the requirements concerning:

- **risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original device as well as of its planned application after reprocessing,**
- **the validation of procedures for the entire process, including cleaning steps,**
- **the product release and performance testing,**
- **the quality management system,**
- **the reporting of incidents involving devices that have been reprocessed, and**
- **the traceability of reprocessed devices.**

Member States shall encourage, and may require, health institutions to provide information to patients on the use of reprocessed devices within the health institution and, where appropriate, any other relevant information on the reprocessed devices that patients are treated with.

~~Member States shall notify the Commission and the other Member States of the national provisions introduced pursuant to this paragraph and the grounds for introducing them. The Commission shall keep the information publicly available.~~

PUBLIC

4. ~~Member States may choose to apply the~~**The provisions referred to in paragraph 3 shall also apply as regards single-use devices that are reprocessed by an external reprocessor at the request of a health institution, provided that the reprocessed device in its entirety is returned to that health institution and the external reprocessor complies with the requirements referred to in points (a) and (b) of paragraph 3.**

5. **The Commission shall adopt, in accordance with Article 9(1), the necessary CS referred to in point (b) of paragraph 3** ~~by 26 May 2021~~**. Those CS shall be consistent with the latest scientific evidence and shall address the application of the general requirements on safety and performance laid down in in this Regulation.** ~~In the event that those CS are not adopted by 26 May 2021 , reprocessing shall be performed in accordance with any relevant harmonised standards and national provisions that cover the aspects outlined in point (b) of paragraph 3.~~ **Compliance with CS or, in the absence of CS, with any relevant harmonised standards and national provisions, shall be certified by a notified body.**

6. **Only single-use devices that have been placed on the market in accordance with this Regulation, or prior to 26 May 2021 in accordance with Directive 93/42/EEC, may be reprocessed.**

7. **Only reprocessing of single-use devices that is considered safe according to the latest scientific evidence may be carried out.**

8. **The name and address of the legal or natural person referred to in paragraph 2 and the other relevant information referred to in Section 23 of Annex I shall be indicated on the label and, where applicable, in the instructions for use of the reprocessed device.**

   The name and address of the manufacturer of the original single-use device shall no longer appear on the label, but shall be mentioned in the instructions for use of the reprocessed device.

9. **A Member State** ~~that permits reprocessing of single-use devices~~ may ~~maintain or~~ **introduce national provisions that are stricter than those laid down in this Regulation and which restrict or prohibit, within its territory, the following:**

(a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;

(b) the making available or further use of reprocessed single-use devices.

Member States shall notify the Commission and the other Member States of those national provisions. The Commission shall make such information publicly available.

~~10. The Commission shall by 27 May 2024 draw up a report on the operation of this Article and submit it to the European Parliament and to the Council. On the basis of that report, the Commission shall, if appropriate, make proposals for amendments to this Regulation.~~

(16) Article 18 is amended as follows:

(a) in paragraph 1, second subparagraph, the first sentence is replaced by the following: 'The information referred to in the first subparagraph shall be provided, for the purpose of making it available to the patient who has been implanted with the device, by any means **accessible by the intended patient**, including in **printed,** electronic or digital format ~~where appropriate~~, that allow rapid access to that information**.** ~~and~~ **This** shall be stated in the language(s) determined by the concerned Member State.';

~~(b) paragraph 3 is replaced by the following:~~

~~'3. The following implants shall be exempted from the obligations laid down in this Article: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, where those implants are well-established technology devices. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this list by adding other types of implants to it or by removing implants therefrom;';~~

(17) in Article 19, the following paragraph 2a is inserted:

'2a. Declarations of conformity in accordance with paragraphs 1 and 2 may be provided in electronic form.';

(18) in Article 22, paragraph 2 is replaced by the following:

'2. The statement made pursuant to paragraph 1 shall contain at least the following information:

(a) an identification of the devices and, where applicable, other products included in the system or procedure pack, including where applicable their Basic UDI-DI;

(b) where applicable, an identification of the notified body involved in the sterilisation activities referred to in paragraph 3;

(c) a declaration by the natural or legal person that:

(i) they have verified the mutual compatibility of the devices and, if applicable, other products in accordance with the manufacturers' instructions and have carried out their activities in accordance with those instructions;

(ii) they have packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;

(iii) the activity of combining devices and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.';

(…)

(41) Article 51 is **replaced by the following** ~~amended as follows~~:

1. Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII.

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2. Upon a duly substantiated request by a manufacturer or an authorised representative established within a Member State, or on its own initiative, the competent authority of that Member State (the 'responsible competent authority') shall, after obtaining information from the manufacturer and, where applicable, the notified body that issued the certificate for that device, determine the class of the device of the requesting manufacturer, taking into account this Regulation, in particular Annex VIII and any harmonised criteria established at Union level.

3. Where the competent authority has justified doubts during the determination referred to in paragraph 1, it may consult the competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a).

4. A manufacturer or a notified body may refer any dispute between them arising from the application of Annex VIII to the responsible competent authority. Where the notified body concerned is established in a Member State other than that of the manufacturer or the authorised representative, the responsible competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.

5. Where a competent authority (the 'initiating competent authority'), on the basis of information obtained through vigilance activities, market surveillance activities or any other relevant information, has justified doubts as to the classification of a device for which neither the manufacturer nor the authorised representative is established within its Member State, it shall refer the matter to the responsible competent authority.

PUBLIC

6. Following consultation with the initiating competent authority and after having obtained information from the manufacturer or authorised representative and where applicable, the notified body that issued the certificate for that device, the responsible competent authority shall determine the classification within 6 months. Where the initiating and the responsible competent authorities agree on the classification of the device, the responsible competent authority shall issue the determination and communicate it to the initiating competent authority and the competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a).

7. Where a competent authority does not agree with the determination taken by the responsible competent authority and continues to have justified doubts regarding the classification of the device, the responsible competent authority shall consult the national competent authorities in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) who shall issue an opinion on the classification of the device.

8. Where a majority of the Member States' competent authorities referred to in point 7 consider it justified, they may refer the case for the consideration of the MDCG. The MDCG shall provide its opinion on the classification and may request the Commission to decide on the classification of the specific product, by means of implementing acts.

9. During the consideration referred to in paragraph 8, the MDCG, or the Commission in agreement with the MDCG, may consult the relevant expert panel. The manufacturer or authorised representative, as well as the notified body that issued the certificate, if applicable, will be provided with the opportunity to present their positions on the classification of the product to the competent authorities, MDCG or the relevant expert panel, as applicable.

10. Within 60 days of the request referred to in paragraph 9, the relevant expert panel shall provide advice to the MDCG or the Commission.

11. Within 90 days of the request referred to in paragraph 8, the MDCG shall issue an opinion on the classification of the product. Where an expert panel is consulted in accordance with paragraph 9, the clock shall stop until the advice from the expert panel is received.

12. Within 180 days of the request from the MDCG referred to in paragraph 8, the Commission shall propose to the Committee referred to in Article 114(1) a decision on the classification of the product. That decision shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 114(3). In adopting its decision, the Commission shall take the utmost account of the advice and opinions issued by the expert panel and the MDCG.

13. At the substantiated request of the MDCG, the Commission shall, decide by means of implementing acts, that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII, taking into consideration the principle of proportionality and classification of devices at international level.

14. In order to ensure the uniform application of the rules set out in Annex VIII, and taking account of the relevant opinion of the MDCG and the scientific opinion of the relevant expert panel, the Commission is empowered to adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.

15. The implementing acts referred to in paragraphs 13 and 14 of this Article shall be adopted in accordance with the examination procedure referred to in Article 114(3).

PUBLIC

16. The outcomes of the coordination activities of the competent authorities in accordance with this Article, the opinions of the MDCG, and the advice of the expert panel delivered in accordance with this Article shall be made publicly available, without disclosing any confidential information as referred to in Article 109.

~~(a) paragraph 2 is replaced by the following:~~

~~'2. The competent authorities of the Member States shall, when necessary, exchange experience, cooperate and coordinate their activities with the support of the Agency as referred to in Article 106b(1) point (a), when determining the classification of a device, or a category or group of devices. The results of the coordination activities of the competent authorities, including the results of any decision or measure adopted by a competent authority in accordance with Articles 51a or 51b and any opinion issued by an expert panel in relation to classification, shall be made publicly available, without disclosing any confidential information as referred to in Article 109.';~~

~~(b) in paragraph 3, point (b) is replaced by the following:~~

~~'(b) that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII, taking into consideration the principle of proportionality and classification of devices at international level.';~~

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

~~'In order to ensure the uniform application of the rules set out in Annex VIII, and taking account of the relevant scientific opinions of the relevant scientific committees or expert panels, the Commission is empowered to adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.';~~

~~(d) the following paragraph 7 is added:~~

~~'7. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend Annex VIII in order to adapt it to technical or scientific progress or to take into account developments regarding classification of devices at international level.';~~

PUBLIC

(42) the following Articles 51a and 51b are inserted:

'Article 51a

Classification in the event of a dispute between manufacturer and notified body

1. A manufacturer or a notified body may refer any dispute between them arising from the application of Annex VIII to the competent authority of the Member State in which the manufacturer has its registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State in which the authorised representative referred to in Section 2.2, second paragraph, point (b), last indent, of Annex IX has its registered place of business.

2. Within 60 days of receipt of the referral referred to in paragraph 1, the competent authority shall consult the other competent authorities in accordance with the coordination activities referred to in Article 51(2) regarding its draft classification decision.

The authority may within these 60 days ask for clarification or additional information about the referral, and the 60-day clock will stop until all relevant information has been received.

At the time of consultation of the competent authorities, the initiating competent authority may request the opinion of an expert panel with the support of the Agency.

If the requisite information is not provided within 60 days of it being requested by the authority, the referral may be considered as lapsed.

3. Where, within 30 days of sending the consultation referred to in the paragraph 2, no substantiated disagreement has been raised, the competent authority shall adopt its decision within 30 days of the expiry of the deadline of the consultation referred to in paragraph 2.

PUBLIC

4. Where, within 30 days of sending of the consultation referred to in paragraph 2, a substantiated disagreement has been raised regarding the draft classification decision, the matter shall be referred to the relevant expert panel as referred to in Article 106. That expert panel shall deliver a technical or scientific opinion on the matter within 30 days to be used by the competent authority to resolve the dispute between the notified body and the manufacturer. The competent authority may ask the expert panel for clarifications on its opinion.

5. Within 30 days of receipt of the expert panel opinion, or any requested clarification, referred to in paragraph 4, the competent authority shall adopt its decision, giving utmost consideration to the expert panel opinion. It shall notify the other Member States and the Commission of its decision without undue delay.

Article 51b

Challenges to the classification of CE marked devices

1. Where a competent authority, as part of its market surveillance activities considers that a device that is CE marked in accordance with Article 20, is not classified in accordance with Annex VIII, it shall consult the other competent authorities in accordance with the coordination activities referred to in Article 51(2) regarding its envisaged decision on the classification of the device.

2. Where, within 30 days of sending the consultation referred to in paragraph 1, no substantiated disagreement is raised, the competent authority may decide on the classification of the device in question and shall notify the other Member States and the Commission of its decision giving the reasons for the decision.

3. Where, within 30 days of sending of the consultation referred to in paragraph 1, a substantiated disagreement is raised regarding the envisaged measure on the classification, the matter shall be referred to an expert panel referred to in Article 106, which shall deliver an opinion on the classification of the device within 30 days. The competent authority may ask the expert panel for clarifications on its opinion.

PUBLIC

~~4. The competent authority shall give utmost consideration to the expert panel opinion. The competent authority shall, where necessary, conduct an evaluation in accordance with Article 94. Where the competent authority adopts a measure on the classification, it shall notify the other Member States and the Commission of its measure without undue delay.~~

~~4a. The Commission may, after consulting the MDCG, by means of implementing acts, lay down further details of the procedure for the application of Article 51a and of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';~~

(…)

(69a) the following Article 87b is inserted:

'Article 87b

Reporting of serious incidents under Regulation (EU) 2024/1698

For devices that incorporate AI systems according to Regulation (EU) 2024/1689 or are medical device AI systems in themselves, serious incidents in accordance with Article 3(49), point (c), of Regulation (EU) 2024/1689, related to the infringement of obligations under Union law intended to protect fundamental rights, shall be reported to the national competent authority chosen for that purpose under that Regulation by the Member States where the incident occurred.';

(…)

(74) Article 93 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices and on the compliance of economic operators with the obligations set out in this Regulation including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.’;

(b) the following paragraph 1a is inserted:

‘1a. Member States shall ensure that their national competent authorities are provided with adequate and sufficient technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation.’;

(c) paragraph 2 is replaced by the following:

‘2. The competent authorities shall draw up annual surveillance activity plans, taking into account the European market surveillance programme, which shall be developed and maintained by the MDCG, and local circumstances.’;

(d) the following paragraph 12 is added:

‘12. The competent authorities may exchange information in relation to their market surveillance activities and, where relevant, engage with the authorities responsible for notified bodies and the authorities responsible for vigilance.

Where appropriate, the competent authorities may also cooperate and exchange relevant information with other authorities, including in the fields of cybersecurity, artificial intelligence, and other areas where regulatory interplay exists, whose responsibilities are relevant to the performance of their market surveillance activities.

In respect of devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689, the competent authorities shall cooperate with market surveillance authorities of their Member State designated in accordance with Article 70 of Regulation (EU) 2024/1689.’;

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(75) Article 94 is replaced by the following:

'Article 94

Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

The competent authorities of a Member State shall, alone or in cooperation with the competent authorities of other Member States, carry out an evaluation of a device covering all the relevant requirements laid down in this Regulation relating to the risk presented by the device, or to any other non-compliance of the device, where they, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe either of the following:

(a) the device may 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;

(b) the device concerned otherwise does not comply with the requirements laid down in this Regulation.

The relevant economic operators and, where applicable and requested, the notified body that issued a certificate for the device in question shall cooperate with the competent authorities.

The competent authorities of the Member States may request any economic operator or notified body to submit documentation available to them, where access to such documentation is needed in the interest of public health or patient safety or health.';

(76) Article 95 is amended as follows:

(a) paragraph 3 is replaced by the following:

'3. The economic operators as referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken, within the period referred to in paragraph 1, throughout the Union in respect of all the devices concerned that they have made available on the market.';

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(b) paragraph 7 is amended as follows:

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

'Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of the notified measures taken by a Member State, those measures shall be deemed to be justified.';

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

'In that case, all Member States shall ensure that corresponding appropriate restrictive or prohibitive measures, including withdrawing, recalling or limiting the availability of the device on their national market, are taken without delay in respect of the device concerned.

Corresponding measures adopted by the other Member States pursuant to this paragraph shall be based on the notification referred to in paragraph 4. Those measures shall not be subject to the procedure referred to in paragraph 4.';

(77) Article 96 is amended as follows:

(b) in paragraph 2, the second sentence of the first subparagraph is replaced by the following:

'If the Commission considers that the national measure is unjustified, the Member State concerned, as well as any Member State that has taken corresponding restrictive or prohibitive measures, shall withdraw the measure.';

(78) Article 97 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Where, having performed an evaluation pursuant to Article 94, the competent authorities of a Member State find that a device ~~or an economic operator~~ does not comply with the requirements laid down in this Regulation but 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, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.';

(b) in paragraph 2, the first sentence is replaced by the following:

'Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1, the Member State concerned shall, without delay, take all appropriate measures to restrict or prohibit the product being made available on the national market or to ensure that it is recalled or withdrawn from the national market.';

(c) the following paragraph 2a is inserted:

'2a. The economic operator shall take any appropriate corrective action pursuant to paragraph 1 throughout the Union in respect of all the devices concerned that they have made available on the market, unless a competent authority takes other appropriate measures.';

(…)

(80) the title of Chapter VIII is replaced by the following:

'COOPERATION BETWEEN MEMBER STATES, THE MDCG, EXPERT LABORATORIES, EXPERT PANELS AND DEVICE REGISTERS, CONFLICTS OF INTEREST AND INTERNATIONAL COOPERATION';

(81) after the title of Chapter VIII, the following title is inserted:

'SECTION 1

Cooperation between Member States, the MDCG, expert panels, expert laboratories and device registers and conflict of interests';

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(82) Article 101 is replaced by the following:

'Article 101

Competent authorities

The Member States shall designate the competent authority or authorities responsible for the implementation and practical application of this Regulation. They shall ensure that those authorities are entrusted with sufficient powers, resources, equipment and knowledge necessary to effectively and efficiently perform their tasks pursuant to this Regulation, in practice. The Member States shall communicate the names and contact details of the competent authorities to the Commission which shall publish a list of competent authorities.';

(82a) In Article 102, paragraph 1 is replaced by the following:

'1. The competent authorities of the Member States shall cooperate with each other **and the authorities responsible for notified bodies shall cooperate with each other.** ~~,~~ **Both shall also cooperate with each other and** with the Commission and with the Agency. The Commission shall provide for the organisation of exchanges of information necessary to enable this Regulation to be applied uniformly.';

(83) in Article 102, paragraph 2 is deleted;

(84) Article 103 is amended as follows:

(a) in paragraph 2, second subparagraph, the second sentence is replaced by the following: 'They shall represent the competent authorities of the Member States and the authorities responsible for notified bodies of the Member States, as applicable.';

(b) paragraph 7 is replaced by the following:

'7. The MDCG shall establish standing or temporary sub-groups, including the subgroup defined in Article 105a.

Where appropriate, representatives of the coordination group referred to in Article 49 and organisations representing the interests of the medical device industry, including micro, small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC, healthcare professionals, laboratories, patients and consumers at Union level shall be invited to the MDCG and its sub-groups in the capacity of observers.';

(c) paragraph 9 is replaced by the following:

'9. The MDCG shall have the tasks laid down in Article 105 of this Regulation **and may delegate these or other tasks to the standing or temporary sub-groups referred to in paragraph 7**.';

(85) Article 104 is replaced by the following:

'The Commission shall support the functioning of the cooperation between national competent authorities**,** ~~and~~ between authorities responsible for notified bodies **and between national competent authorities and authorities responsible for notified bodies**.

~~It shall, in particular, provide for the organisation of exchanges of experience between competent authorities and between authorities responsible for notified bodies and provide support to the MDCG and its sub-groups.~~

It shall organise the meetings of the MDCG and its sub-groups, participate in those meetings**, provide support** and ensure the appropriate follow-up.';

(86) Article 105 is replaced by the following:

'Article 105

Tasks of the MDCG

Under this Regulation **and Regulation (EU) 2017/746**, the MDCG shall **monitor and contribute to the consistent, effective and harmonised application and implementation of these Regulations. It shall in particular** have the following tasks:

(a) to contribute**, when needed,** to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

(b) to advise the Commission, at its request, in matters concerning the coordination group of notified bodies as established pursuant to Article 49, including endorsement of the work programme and technical guidance developed by that group;

(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation~~, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of clinical evaluations and investigations by manufacturers, assessment by notified bodies and vigilance activities~~;

(d) to contribute to the continuous monitoring of technical progress and assessment of whether the general safety and performance requirements laid down in this Regulation and Regulation (EU) 2017/746 are adequate to ensure safety and performance of devices, and thereby contribute to identifying whether there is a need to amend Annex I to ~~this~~ **these** Regulation**s**;

(e) to contribute to the development of device standards, of CS and of scientific guidelines, including product specific guidelines~~, on clinical investigation of certain devices in particular implantable devices and class III devices~~;

~~(f) to assist the competent authorities of the Member States in their coordination activities in particular in the fields of classification and the determination of the regulatory status of devices, clinical investigations, vigilance and market surveillance including the development and maintenance of a framework for a European market surveillance programme with the objective of achieving efficiency and harmonisation of market surveillance in the Union, in accordance with Article 93;~~

(g) to provide advice, either on its own initiative or at request of the Commission, in the assessment of any issue related to the implementation of this Regulation;

(h) to contribute to harmonised administrative practice with regard to devices in the Member States;

(i) to advise the Commission**,** ~~and~~ competent authorities **and authorities responsible for notified bodies** regarding international regulatory cooperation in accordance with Articles 108a to 108c;

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(j) to conduct horizon scanning to identify technological, legal or external sectoral changes or developments which may impact the regulatory system and propose solutions;

(k) to support and oversee international initiatives aimed at improving harmonisation of regulatory operations and activities;

(l) ~~[to assist the competent authorities of the Member States in their coordination activities in particular in the fields of classification and the determination of the regulatory status of devices, clinical investigations, vigilance and market surveillance including the development and maintenance of a framework for a European market surveillance programme with the objective of achieving efficiency and harmonisation of market surveillance in the Union, in accordance with Article 93;]~~ **to provide an opinion with regards to the classification of devices and the determination of the regulatory status of products according to the provisions of Article 4 and Article 51;**

(m) to advise the Commission, at its request, and to assist the competent authorities of the Member States in matters concerning Union regulatory sandboxes and regulatory sandboxes at national level;

In addition to the tasks assigned to it in other provisions of this Regulation and Regulation (EU) 2017/746, the MDCG shall assist the Commission in the assessment of any issue related to the implementation of those Regulations.';

(86a) A new Article 105a is inserted as follows:

'Article 105a

Notified Body ~~Operations~~ Oversight subgroup

The Notified Body ~~Operations~~ **Oversight** subgroup (NBO) shall assist the MDCG on issues relating to notified bodies and conformity assessments, with the aim of consistent, effective and harmonised application and implementation of this Regulation with respect to notified bodies.

The NBO shall be composed of members representing the authorities responsible for notified bodies.

Under this Regulation and under the supervision of the MDCG, the NBO shall**, in particular,** have the following tasks:

(a) to develop draft best practice documents relating to the activities of the authorities responsible for notified bodies, for endorsement of the MDCG;

(b) to develop draft guidance documents for notified bodies in relation to the implementation of ~~this~~ **these** Regulation**s**, for endorsement of the MDCG;

(c) to initiate the draft work programme, the draft common templates and the draft technical guidance elaborated by the coordination group of notified bodies as established pursuant to Article 49;

(d) to contribute to develop training and qualification of the experts referred to in Article 40;

(e) **to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV, including being** ~~to be~~ consulted by the Commission on the composition of the joint assessment team referred to in Article 36;

(f) to monitor the conformity assessment activities of notified bodies;

(g) to monitor the designation and the surveillance activities of designating authorities;

(h) to provide the MDCG with proposals for improving harmonisation of practices amongst notified bodies and harmonisation of practices amongst designating authorities;

(i) to consider and draw from the exchange of experience referred to in Article 48 and to cooperate with the coordination group referred to in Article 49.

Where appropriate, representatives of the coordination group referred to in Article 49 shall be invited in the capacity of observers.';

PUBLIC

(86b) Article 106 is replaced by the following:

'Article 106

Expert panels

1. The Commission shall, by means of implementing acts and following consultation with the MDCG, make provision for expert panels to be designated to provide scientific, clinical **or**~~,~~ technical ~~or regulatory~~ opinions and advice in relation to the implementation of this Regulation and of Regulation (EU) 2017/746 to the Commission, the MDCG, Member States, notified bodies or manufacturers.

   Expert panels may be designated on a standing or temporary basis.

2. Expert panels shall consist of experts with proven up-to-date clinical, scientific, technical ~~or regulatory~~ expertise relevant to the field of medical devices or in vitro diagnostic medical devices reflecting the diversity of scientific and clinical approaches in the Union.

   Experts shall be appointed, in consultation with the MDCG, following publication of a call for expressions of interest. Depending on the type of task and the need for specific expertise, experts may be appointed to the panels for a maximum period of three years and their appointment may be renewed.

   When expert panels are requested to provide ~~clinical, scientific or technical~~ advice ~~[~~to the MDCG~~]~~ on the regulatory status of a product which involves aspects concerning the borderline with other types of products, experts with expertise in the field of the relevant other products shall be involved.

2a. The activities of the expert panels shall facilitate effective, harmonised and evidence-based application of this Regulation and Regulation (EU) 2017/746. Experts from national competent authorities shall be appropriately integrated within the expert panel structure **where necessary**~~either through involvement in specific panels, establishment of a standalone regulatory panel or both~~.

PUBLIC

3. The experts shall observe the principles of highest scientific competence and perform their tasks with impartiality, objectivity and transparency. They shall neither seek nor take instructions from notified bodies, manufacturers or other economic operators. Each expert shall draw up a declaration of interests, which shall be made publicly available.

3a. The Agency shall establish systems and procedures to actively manage and prevent potential conflicts of interest during the appointment of experts.

4. Expert panels shall take into account relevant information provided by stakeholders including patients' organisations and healthcare professionals' associations.

5. Experts may be included on a central list of available experts who, whilst not being formally appointed to a panel, are available to provide advice and to support the work of the expert panels as needed.

6. Experts from notified bodies shall not be involved in the clinical evaluation consultation procedure provided for in Article 54(1) **of this Regulation and Article 56a of Regulation (EU) 2017/746**.

An individual expert from a notified body shall not be involved in the provision of advice on a specific device for which the expert or their notified body have been involved in the conformity assessment. An expert from a notified body shall not be involved in the conformity assessment activities regarding a specific device for which the expert was involved in the provision of advice from an expert panel.

7. In addition to the tasks assigned to them in other provisions of this Regulation and of Regulation (EU) 2017/746, the expert panels shall support the MDCG and the Commission and have the following tasks:

(a) to provide scientific, clinical~~,~~ **and** technical ~~and regulatory~~ advice to the Commission, the MDCG, Member States or notified bodies in relation to the implementation of this Regulation or Regulation (EU) 2017/746;

PUBLIC

(b) to contribute to the development and maintenance of appropriate guidance and CS supporting the implementation of this Regulation or Regulation (EU) 2017/746;

(c) to support the MDCG and contribute to the development of standards at Union or international level, ensuring that such standards reflect the state of the art;

(d) to contribute to the identification of concerns and emerging issues concerning the safety and performance of medical devices, including in vitro diagnostic medical devices.

8. When adopting their opinions or advice, the members of the expert panels shall use their best endeavours to reach consensus. If consensus cannot be reached, the expert panels shall decide by a majority of their members, and the opinion or advice shall mention the divergent positions and the grounds on which they are based.

9. The Commission shall require manufacturers and notified bodies to pay fees for opinions and advice provided by expert panels. The structure and the level of the fees, as well as the scale and type of recoverable costs, shall be established by the Commission by means of implementing acts, taking into account the objectives of the adequate implementation of this Regulation, protection of health and safety, support of innovation and cost-effectiveness and the necessity to achieve active participation in the expert panels. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

The fees referred to in the first subparagraph shall be established in a transparent manner and on the basis of the costs for the services provided. The fees shall be reduced for manufacturers which are micro, small or medium-sized enterprises within the meaning of Recommendation 2003/361/EC, including in the case of a clinical evaluation consultation procedure initiated in accordance with Section 5.1, point (c), of Annex IX involving a manufacturer who is a micro, small or medium-sized enterprise within the meaning of Recommendation 2003/361/EC. The fees related to the opinions and advice provided by expert panels are payable to the Agency[24] pursuant to Article 30, point (f), of Regulation (EU) 2022/123.

[24] Lawyer-linguists will make the change throughout the Regulations.

10. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend paragraph 7 of this Article by adding, adapting or removing tasks from the list of tasks of the expert panels.';

(87) the following Articles 106a and 106b are inserted:

'Article 106a

Expert laboratories

1. The Commission may, by means of implementing acts and following consultation with the MDCG, designate expert laboratories, on the basis of their expertise in the field of testing of medical devices, such as physico-chemical characterisation, microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing and any other type of testing or assessment considered relevant for the evaluation of the safety, performance or regulatory compliance of specific devices, categories or groups of devices.

The Commission shall only designate expert laboratories for which a Member State or the Joint Research Centre has submitted an application for designation.

2. Expert laboratories shall satisfy the following criteria:
   (a) have adequate and appropriately qualified staff with adequate knowledge and experience related to the devices or in the type of laboratory testing for which they are designated;
   (b) have at their disposal the necessary equipment and reference materials to carry out the tasks assigned to them;
   (c) have the necessary knowledge of international standards and best practices;
   (d) have an appropriate administrative organisation and structure;
   (e) ensure that their staff observe the confidentiality of information and data obtained in carrying out their tasks;
   (f) act in the public interest and in an independent manner;

PUBLIC

(g) ensure that their staff do not have financial or other interests in the medical device industry which could affect their impartiality, declare any other direct and indirect interests they may have in the medical device industry and update this declaration whenever a relevant change occurs.

3. Expert laboratories may have the following tasks:

(a) to provide scientific and technical assistance to the Commission, the MDCG, the Agency, Member States and notified bodies in relation to the implementation of this Regulation, including at the request of the Commission or the MDCG and, the performance of appropriate tests, assessments or other evaluations necessary to support the assessment of the safety**,** ~~and~~ performance **or regulatory compliance** of any device;

(aa) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices in the field of laboratory testing for which they are designated, on the basis of comparative test results or other studies;

(b) to support the MDCG in the development and maintenance of appropriate guidance and CS supporting the implementation of this Regulation;

(c) to support the MDCG in the development of standards at Union or international level, ensuring that such standards reflect the state of the art;

(ca) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures and for market surveillance;

(d) to support the MDCG in the identification and investigation by laboratory testing of concerns and emerging issues on the safety**,** ~~and~~ performance **or regulatory compliance** of medical devices;

(e) to provide scientific and technical assistance, including independent investigations of devices, to Member States and the Commission in vigilance and market surveillance activities.

4. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend paragraph 3 of this Article by adding, adapting or removing tasks from the list of tasks of the expert laboratories.

PUBLIC

4a. The expert laboratories may establish a network in order to coordinate and harmonise their working methods with regards to testing and assessment.

5. The expert laboratories may charge fees in accordance with predetermined and transparent terms and conditions for scientific and technical assistance provided to the Agency or notified bodies for carrying out the requested task. For the provision of services within the public interest on request of the Commission or the MDCG, the expert laboratories may be granted a Union financial contribution. Member States may request, through the MDCG, testing from the expert laboratories.

5a. A financial allocation may also be made available from the general budget of the Union for the expert laboratories.

Article 106b

Support by the Agency

1. The Agency shall provide scientific, technical and administrative support to facilitate cooperation and coordination and exchange of experience between the national competent authorities designated under this Regulation and under Regulation (EU) 2017/746 ~~to facilitate the exchange of experience, cooperation and coordination~~ on operational regulatory activities among them and with the Commission~~,~~ with a view to ensuring a uniform practical application of such Regulations, in particular in the following areas:

(a) ~~[~~regulatory status of products and classification of devices in accordance with Articles 4~~, 4a,~~ **and** 51 **and Annex VIII** ~~, 51a and 51b~~ of this Regulation and Articles 3~~, 3a,~~ **and** 47 **and Annex VIII** ~~, 47a and 47b~~ of Regulation (EU) 2017/746;~~]~~

(b) derogations from the applicable conformity assessment procedures in accordance with Articles 59 and 59a of this Regulation and Articles 54 and 54a of Regulation (EU) 2017/746;

(c) clinical evaluation, clinical investigations, performance evaluation and performance studies in accordance with Chapter VI of this Regulation and Chapter VI of Regulation (EU) 2017/746, including support to the coordinating Member State for the coordinated assessment procedure for clinical investigations and performance studies referred to in Article 78 of this Regulation and Article 74 of Regulation (EU) 2017/746;

(d) vigilance and market surveillance in accordance with Chapter VII of this Regulation and Chapter VII of Regulation (EU) 2017/746, including, but not limited to, the support to the coordinating competent authority for the coordinated procedure referred to in Article 89(9) of this Regulation and Article 84(9) of Regulation (EU) 2017/746;

~~(e) assessment of whether criteria set out in paragraph 2 or paragraph 3 of Article 52a, as applicable, are fulfilled.~~

1a. The Agency shall report to the MDCG about the exchange of experience, cooperation and coordination between competent authorities in accordance with paragraph 1 and seek MDCG's guidance on strategic priorities and unresolved issues.

2. The Agency shall provide scientific, technical and administrative support to the Commission for the establishment of Union regulatory sandboxes in accordance with Article 59c of this Regulation and Article 54c of Regulation (EU) 2017/746.

2a. The Agency shall provide support to the national competent authorities and expert panels in coordinating their Union activities, and when requested by the MDCG, in order to promote consistent, predictable and harmonised application across Member States.

3. The Agency shall set up a support scheme for manufacturers of medical devices and in vitro diagnostic medical devices, which are micro, small and medium-sized within the meaning of Recommendation 2003/361/EC, regarding the requirements of this Regulation and of Regulation (EU) 2017/746.

4. The Agency shall have access to Eudamed and any electronic system referred to in Article 33(2) of Regulation (EU) 2017/745 or in Article 30(2) of Regulation (EU) 2017/746 that is not included in Eudamed.

5. The Agency shall have sufficient resources and knowledge in the area of medical devices and in-vitro diagnostics **medical devices** to effectively and efficiently perform its tasks pursuant to this Regulation.';

(88) in Article 107(1), the fourth and fifth sentences are replaced by the following:
'The declaration of interests shall be made publicly available on the Commission or the Agency website. This Article shall not apply to the representatives of stakeholder organisations participating in the MDCG or its sub-groups.';

(89) in Article 108, the first sentence is replaced by the following:
'The Commission, the Member States and the Agency shall take all appropriate measures to encourage the establishment of registers and databanks for specific types of devices, where appropriate including in vitro diagnostic medical devices, setting common principles to collect comparable information.';

(89a) Article 110 is replaced by the following:

'1. Member States shall apply Regulation (EU) 2016/679 to the processing of personal data carried out in the Member States pursuant to this Regulation.

2. Regulation (EU) 2018/1725 shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.';

(91) the following Article 110a is added:

'Article 110a

Submission of information or documents

The submission of information or documents in accordance with this Regulation shall **may** take place electronically.

PUBLIC

Member States may require that information or documents in accordance with this Regulation shall be submitted electronically to the relevant authority.';

(92) Article 111 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. This Regulation shall be without prejudice to the possibility for Member States and the Commission to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost-recovery principles.';

(b) in paragraph 2, second sentence, the words 'on request' are deleted;

(93) ~~[~~**in** Article 112 **the following final sentence** is **added**~~deleted;~~]
'This Article shall continue to apply until the date of application of Article 40a.';

~~(94) Article 116 is deleted;~~

(…)

(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.

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.

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.

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 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 label~~ling~~, instructions for use and, where appropriate, any other accompanying documentation.

At least every 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.

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.';

(96) Article 121 is replaced by the following:

'Article 121

Evaluation

No sooner than …[*Publications Office, please insert the date five years after the date of application of this Regulation*], the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council.

Member States and notified bodies shall provide the Commission with the information necessary for the preparation of that report.'

(97) in Article 123(3), point (d), the following third subparagraph is added:
'After the date of application of the provisions referred to in the first subparagraph of this point, where Member States maintain national databases, the relevant information available in Eudamed for those national databases shall be retrieved from Eudamed. This shall be without prejudice to the possibility for Member States to maintain or develop complementary national functionalities and data elements necessary for national market surveillance or other regulatory tasks, avoiding duplication of Union data, where possible.;'

(1) Annex I is amended as follows:

(a) Section 10.6 is replaced by the following:

'10.6. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials as defined in Commission Recommendation C/2022/3689*.

* Commission Recommendation of 10 June 2022 on the definition of nanomaterial (OJ C 229, 14.6.2022, pp. 1).';

(b) Section 13 is amended as follows:

(i) Section 13.1. is replaced by the following:

'13.1. For devices manufactured utilising derivatives of substances of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with Article 1(6), point (g), the following shall apply:

(a) donor registration, donor-review, testing of donors, collection, storage, release, import, export and distribution of substances of human origin shall be done in accordance with Regulation (EU) 2024/1938;

(b) processing, preservation and any other handling of those substances of human origin or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process;

(c) the traceability system for those devices shall be complementary to and compatible with the traceability and data protection requirements laid down in Regulation (EU) 2024/1938.';

(ii) in Section 13.2., point (c) is replaced by the following:

'(c) in the case of devices manufactured utilising tissues or cells of animal origin or their derivatives, as referred to in Regulation (EU) No 722/2012, the particular requirements laid down in that Regulation, or in any subsequent implementing rules adopted pursuant to this Regulation, shall apply.';

(c) Section 17.4. is replaced by the following:

'17.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics, IT security measures and cybersecurity, including **appropriate technical, operational and organisational measures to ensure an appropriate level of cybersecurity** ~~protection against unauthorised access,~~ necessary to run the software as intended **such as protection against unauthorised access and handling of vulnerabilities**.';

(ca) Section 17.5 is added as follows:

'17.5. Devices that incorporate AI systems according to Regulation (EU) 2024/1689 or are medical device AI systems in themselves shall be designed and developed taking into account the following principles:

- **human oversight;**
- **record keeping;**
- **representativeness of data and data governance, including with regard to training, validation and testing;**
- **transparency and provision of information to deployers and users;**
- **accuracy and robustness.**

(d) Section 23.1. is amended as follows:

(ii) in point (c), the following sentence is added:
'Labels may be provided in digital form to the extent, and only under the conditions, set out in any implementing rules adopted pursuant to this Regulation.';

(iii) in point (f), the reference to 'Regulation (EU) No 207/2012' is replaced by the reference to 'Commission Implementing Regulation (EU) 2021/2226**

** Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices (OJ L 448, 15.12.2021, p. 32, ELI: http://data.europa.eu/eli/reg_impl/2021/2226/oj)';

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

'(i) For a device that is exclusively in use with a medicinal product in accordance with Article 19 of [Proposal for a Directive on the Union code relating to medicinal products for human use, and repealing Directive 2011/83/EC and Directive 2009/35/EC] and packaged together with a medicinal product, the instructions for use may be included, where needed, as part of the co-packaging of the medicinal product with the device. Moreover, the information on the label of the device may be limited to the particulars referred to in Section 23.2, points (a) and (c), where, following agreement of the competent authority responsible for the authorisation of the medicinal product, the following conditions are met:

- the information necessary for safe use and correct functioning of the device is provided to the user with the summary of product characteristics and/or package leaflet of the medicinal product under the responsibility of the marketing authorisation holder set out in [Proposal for a Directive on the Union code relating to medicinal products for human use, and repealing Directive 2011/83/EC and Directive 2009/35/EC];
- the traceability and identification of the device is ensured by the marketing authorisation holder.';

PUBLIC

(e) Section 23.2. is amended as follows:

(i) in point (e), the second and third indents are replaced by the following:

‘- substances of human origin or their derivatives, or

- tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 or in any subsequent implementing rules adopted pursuant to this Regulation;’

~~(ii) point (o) is deleted;~~

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

‘an indication that the device is a medical device or an accessory for a medical device;’

(f) in Section 23.4., point (s), the fourth indent is replaced by the following:

‘- if the device is intended to administer medicinal products, substances of human origin or tissues or cells of animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered,’;

PUBLIC

Amendments to Regulation (EU) 2017/746

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:';

(3) Article 3 is replaced by the following:

'Article 3

Regulatory status of products

1. **Upon a duly substantiated request by a manufacturer or an authorised representative established within a Member State, or on its own initiative, the competent authority of that Member State (the 'responsible competent authority') shall, after obtaining information from the manufacturer or authorised representative and, where applicable, the notified body that issued the certificate for that product, determine whether the specific product of the requesting manufacturer or authorised representative falls within the definition of an in vitro diagnostic medical device as set out in Article 2(2) or the definition of 'accessory for an in vitro diagnostic medical device' set out in Article 2(4), taking into account this Regulation and any harmonised criteria established at Union level.**
~~The competent authorities of the Member States shall, when necessary, exchange experience, cooperate and coordinate their activities, with the support of the Agency as referred to in Article 106b(1) point (a) of Regulation (EU) 2017/745, when determining whether a specific product, or category, or group of products, falls within the definition of an 'in vitro diagnostic medical device' or of an 'accessory for an in vitro diagnostic medical device'.~~

PUBLIC

2. **Where the competent authority has justified doubts during the determination referred to in paragraph 1, it may consult the competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) of Regulation 2017/745.**

~~The Member States shall, when necessary, ensure an appropriate level of consultation of the relevant competent authorities of the Member States in the fields of medical devices, medicinal products, substances of human origin (SoHO), biocides, food, cosmetics or other products subject to Union legislation, where the determination of the regulatory status of a product involves aspects concerning the borderline with any of those types of products. As part of providing its support as referred to in Article 106b(1) point (a) of Regulation (EU) 2017/745, the Agency, where necessary, ensure an appropriate level of consultation of the relevant advisory or regulatory bodies established in the relevant Union legislation, such as the SoHO Coordination Board, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA).~~

3. **Where a competent authority (the 'initiating competent authority'), on the basis of information obtained through vigilance activities, market surveillance activities or any other relevant information, has justified doubts as to the regulatory status of a product for which neither the manufacturer nor the authorised representative is established within its Member State, the competent authority shall refer the matter to the responsible competent authority.**

~~Where a competent authority of a Member State, as part of its market surveillance activities, considers that a product that is CE marked in accordance with Article 18, does not fall within the scope of this Regulation, it shall consult the competent authorities of the other Member States regarding envisaged decision determining the regulatory status of the product in question.~~

PUBLIC

4. **Following consultation with the initiating competent authority and after having obtained information from the manufacturer or authorised representative, and, where applicable, the notified body, the responsible competent authority shall determine the regulatory status of the concerned product within 6 months. Where the initiating and the responsible competent authorities agree on the regulatory status of the product, the responsible competent authority shall issue the determination and communicate it to the initiating competent authority and the competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) of Regulation (EU) 2017/745.**

~~Where a competent authority of a Member State raises a substantiated disagreement regarding the envisaged decision on the status of the product referred to in paragraph 3, the initiating authority shall refer the matter to the MDCG for an opinion. When necessary, the MDCG may seek the advice of an expert panel as referred to in Article 106 of Regulation (EU) 2017/745.~~

~~The expert panel shall provide the requested advice to the MDCG within 30 days. The MDCG shall provide its opinion within 30 days of receiving the advice from the expert panel.~~

~~The initiating competent authority shall give utmost consideration to the opinion of the MDCG and shall, where necessary, conduct an evaluation in accordance with Article 94.~~

PUBLIC

5. **Where a competent authority does not agree with the determination of the regulatory status by the responsible competent authority, the responsible competent authority shall consult the national competent authorities in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) of Regulation (EU) 2017/745 who shall issue an opinion on the regulatory status of the product.**

~~The outcomes of the coordination activities of the competent authorities in accordance with this Article, the opinions of the MDCG, and the advice of the expert panel delivered in accordance with paragraph 4 of this Article and Article 3a(2) shall be made publicly available, without disclosing any confidential information as referred to in Article 102.';~~

6. Where a majority of the Member States' competent authorities referred to in point 2 or point 5 consider it justified, they may refer the case for the consideration of the MDCG. The MDCG shall provide its opinion on the regulatory status and may request the Commission to decide on the regulatory status of the specific product, by means of implementing acts.

7. During the consideration of the regulatory status referred to in paragraph 6, the MDCG, or the Commission in agreement with the MDCG, may consult the relevant expert panel. The manufacturer or authorised representative, as well as the notified body that issued the certificate, if applicable, will be provided with the opportunity to present their positions on the regulatory status of the product to the competent authorities, MDCG or the relevant expert panel, as applicable.

PUBLIC

8. Where appropriate, the competent authorities, the Agency in fulfilling its tasks described in Article 106b of Regulation (EU) 2017/745 or the MDCG as applicable, shall ensure an appropriate level of consultation with the competent authorities of the Member States responsible for medicinal products, substances of human origin (SoHO), biocidal products, food, cosmetics or any other products regulated under Union legislation where the determination of the regulatory status of a product involves questions concerning the borderline between such products and medical devices. In such cases, the Agency in fulfilling its tasks described in Article 106b of Regulation (EU) 2017/745 shall also ensure an appropriate level of consultation with the relevant Union bodies established under the applicable legislation, including, where relevant, the SoHO Coordination Board, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA).

9. Within 60 days of the request referred to in paragraph 7, the relevant expert panel shall provide advice to the MDCG or the Commission.

10. Within 90 days of the request referred to in paragraph 6, the MDCG shall issue its opinion on the regulatory status of the product. Where an expert panel is consulted in accordance with paragraph 7, the clock shall stop until the advice from the expert panel is received.

11. Within 180 days of the request from the MDCG referred to in paragraph 6, the Commission shall propose to the Committee referred to in Article 107(1) a decision on the regulatory status of the product. That decision shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 107(3). In adopting its decision, the Commission shall take the utmost account of the advice and opinions issued by the expert panel and the MDCG.

12. The outcomes of the coordination activities of the competent authorities in accordance with this Article, the opinions of the MDCG, and the advice of the expert panel delivered in accordance with this Article shall be made publicly available, without disclosing any confidential information as referred to in Article 102.

13. This Article shall not apply where within the framework of another Union legislation the regulatory status of the product, or category or group of products concerned has been determined as falling within the scope of that other Union legislation, or where a procedure for the determination of the regulatory status is ongoing within the framework of another Union legislation.

~~(4) the following Article 3a is inserted:~~

~~*'Article 3a*~~

~~**Opinion on and determination of the regulatory status of products at Union level**~~

~~1. A competent authority, a notified body, a manufacturer, an authorised representative, a developer of a product or the Commission may submit a substantiated request for an opinion from the competent authorities, in accordance with the coordination activities of the competent authorities referred to in Article 3(1) on the question whether a specific product, or category or group of products, falls within the definitions of 'in vitro diagnostic medical device' or 'accessory for an in vitro diagnostic medical device'. Where, in such a request, the requester considers that the product in question is an in vitro diagnostic medical device, the request shall also specify the proposed classification of the device in accordance with Article 47 and Annex VIII.~~

~~Requests by a notified body may only be submitted with regards to the product of an applicant.~~

~~1a. A manufacturer or an authorised representative may submit a substantiated request as referred to in paragraph 1 only if they have requested from the competent authority of the Member State, in which they are established, advice on the same matter and have not received any advice within a period of three months.~~

PUBLIC

~~2. Where necessary, the competent authorities may request the advice of an expert panel referred to in Article 106 of Regulation (EU) 2017/745. The expert panel shall provide its advice to the competent authorities within 30 days. The competent authorities shall provide their opinion within 30 days of receiving the advice from the expert panel. The time limits provided for in this subparagraph shall be suspended for the duration of any consultation of relevant Union bodies.~~

~~The requester shall give utmost consideration to the opinion of the competent authorities.~~

~~3. Having regard to the opinion referred to in paragraph 2 or in Article 3(4), a Member State may submit a substantiated request to the Commission to determine whether a specific product, or category or group of products, falls within the definition of 'in vitro diagnostic medical device' or of 'accessory for an in vitro diagnostic medical device'.~~

~~The Commission shall decide on the substantiated request of the Member State, or on its own initiative, by means of implementing acts, within 180 days, which shall be adopted in accordance with the examination procedure referred to in Article 107(3).~~

~~The Commission may ask the expert panel or the competent authorities for clarifications or refer the opinion back to the competent authorities for further consideration, including in cases where a Member State's substantiated request raises new questions of a scientific or technical nature.~~

~~4. This Article shall not apply where within the framework of another Union legislation the regulatory status of the product, or category or group of products concerned has been determined as falling within the scope of that other Union legislation, or where a procedure for the determination of the regulatory status is ongoing within the framework of another Union legislation.~~

PUBLIC

~~4a. The Commission shall, after consulting with MDCG, by means of implementing acts, lay down the procedure for the application of paragraphs 1 to 5 of Article 3 and of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).';~~

(…)

(5) Article 5 is amended as follows:

(a) paragraph 5 is amended as follows:

(i) the first subparagraph is amended as follows:

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

'(a) the devices are not transferred to another legal entity~~;~~**.** ~~except~~**A device may be transferred** to another health institution in **exceptional circumstances where** the**re is a** duly justified interest of public health, patient safety or patient health, or to prepare or respond to a public health emergency**.**

Where such transfers occur, the transferring and receiving health institutions shall notify the competent authority of the Member State in which they are based and provide the justification.';

(1a) point (aa) is added:

'(aa) The devices are not manufactured on an industrial scale.';

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

'(c) the laboratory of the health institution is ~~accredited to~~**compliant with** standard EN ISO 15189 or, where applicable, national provisions for quality and competence in medical laboratories, including national provisions regarding accreditation;';

(3) point (d) is deleted;

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

'(e) upon request by a competent authority, the health institution provides information on the use of such devices to its competent authority;';

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

'(iii) **For Class A and B devices in accordance with the rules set out in Annex VIII a declaration that the health institution is accredited to the standard referred to in point (c) or that the devices meet the relevant general safety and performance requirements set out in Annex I and, where applicable, information on which requirements are not fully met with a reasoned justification therefor;**

For Class C and D devices in accordance with the rules set out in Annex VIII a declaration that ~~the health institution is accredited to the standard referred to in point (c) and that~~ the devices meet the relevant general safety and performance requirements set out in Annex I and, where applicable, information on which requirements are not fully met with a reasoned justification therefor; **Where the health institution is accredited to the standard referred to in point (c), the declaration may be limited to the relevant general safety and performance requirements set out in Annex I which are not covered by that standard.**';

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

'(g) as regards class D devices in accordance with the rules set out in Annex VIII, the health institution draws up documentation sufficiently detailed to enable the competent authority to ascertain that the relevant general safety and performance requirements set out in Annex I are met**.** Member States may apply this provision also to class C devices in accordance with the rules set out in Annex VIII;';

(7) point (h) is deleted;

(ii) the second sentence in the second subparagraph is replaced by the following: 'Member States shall retain the right to restrict the manufacture, or the use, or the transfer of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.';

(iia) the third subparagraph is deleted.

(iii) the following subparagraphs are added:

'For the purposes of the first subparagraph, point (a), in the case of a transfer of the device to another health institution, the transferring and receiving health institutions shall ensure traceability of the device. This information shall be made available to a competent authority upon request.

For the purposes of the first subparagraph, point (i), where the device is transferred in accordance with point (a), both the transferring and the receiving health institution shall report to each other any incident related to the device.

This paragraph shall also apply to devices manufactured and used within a laboratory that is established in the Union and provides consistent, state of the art testing services for clinical research, provided those devices are intended exclusively for use in the framework of a clinical trial subject to Regulation (EU) No 536/2014 of the European Parliament and of the Council*. Where, in this paragraph, reference is made to a health institution, such reference shall also be understood as reference to a laboratory referred to in the first sentence of this subparagraph.

_____

*Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1, ELI: http://data.europa.eu/eli/reg/2014/536/oj).';

PUBLIC

(b) the following paragraph**s** 7 **and 8 are** ~~is~~ added:

'7. The Commission**, in consultation with the MDCG,** is empowered to adopt delegated acts in accordance with Article 108, to amend the ~~general safety and performance~~ requirements **regarding the design and manufacture, or the information to be supplied with the device** set out in **Chapters II and III of** Annex I **to take account of** ~~in order to adapt them to~~ scientific or technical progress**, users' needs** or ~~to~~ international developments, **including to address risks from** ~~or to add requirements in relation to~~ emerging ~~risks or~~ technologies.

8. When adopting implementing acts pursuant to paragraph 6 of this Article, delegated acts pursuant to paragraph 7 of this Article or Common Specifications pursuant to Article 9 of this Regulation concerning devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council**, or that use high-risk AI systems as safety components, the Commission shall take into account the requirements set out in Chapter III, Section 2, of that Regulation.

** 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).';

(6) Article 6 is amended as follows:

(a) the following paragraph 2a is inserted:

'2a. Any natural or legal person offering a device in accordance with paragraph 1 or a service in accordance with paragraph 2 shall provide in the offer at least the information referred to in Section 20.2., points (a) to (e) and (m), of Annex I and access to the instructions for use.';

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

‘3. Upon request by a competent authority, any natural or legal person offering a device in accordance with paragraph 1 or a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity drawn up in accordance with Article 17 for the device concerned and cooperate with the competent authorities of the Member State in which the device or the service is offered.

4. A Member State may, on grounds of protection of public health, require a provider of a service, as defined Article 1(1), point (b), of Directive (EU) 2015/1535, or the provider of the service referred to in paragraph 2, to cease its activity.’;

(7) in Article 7, the following subparagraph is added:
‘Without prejudice to national law regarding the exercise of the medical profession, the first subparagraph shall also apply to devices used for the provision of a service referred to in Article 6(2).’;

(8) in Article 9(1), the first sentence is replaced by the following:
‘Where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns, the Commission, after having consulted the MDCG, may, by means of implementing acts, adopt common specifications (CS) in respect of the requirements set out in this Regulation, in particular the reports and plans to be drawn up by manufacturers, the general safety and performance requirements set out in Annex I, the technical documentation set out in Annexes II and III, the conformity assessment procedures set out in Annexes IX, X and XI, the performance evaluation and PMPF set out in Annex XIII or the requirements regarding performance studies set out in Annexes XIII and XIV.’;

PUBLIC

(9) Article 10 is amended as follows:

(-a) Paragraph 6 is replaced by the following:

'Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 24.';

(-aa) The following paragraph 6a is inserted:

'Manufacturers shall comply with the obligations referred to in Articles 26 and 28.';

(b) paragraph 8 is amended as follows:

(i) in the first subparagraph, the first sentence is replaced by the following:
'Manufacturers shall put in place an appropriate quality management system to ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation.';

(iia) in the third subparagraph, points (d), (e), (j) and (m) are replaced by the following:

'(d) resource management, including human resources and the selection and control of suppliers and subcontractors;

(e) control of changes to the device and quality management system, and risk management as set out in Section 3 of Annex I;

(j) handling communication with competent authorities, notified bodies, other economic operators, customers or other stakeholders including the handling of complaints;

(m) processes for monitoring and measurement of output, data analysis and product improvement including audits.';

(d) paragraph 10 is amended as follows:

(i) in the first subparagraph, the following sentence is added:
'When determining the official language of the Union in which the information set out in Section 20 of Annex I or other information to be provided by the manufacturer shall be made available, Member States shall consider accepting another official language of the Union in which the information is made available, taking into consideration the technical knowledge, experience, education or training of the average intended user(s).';

~~(ii) the second subparagraph is deleted;~~

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(g) paragraph 14 is replaced by the following:

'14. Where manufacturers have their devices designed or manufactured by another legal or natural person, the information on the identity of that person shall be part of the information to be submitted in accordance with Article 26(1).';

(h) in paragraph 15, '85/374/EEC' is replaced by '(EU) 2024/2853';

(10) Article 10a is amended as follows: [25]

(a) paragraph 1 is replaced by the following:

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

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

[25] ~~The Presidency suggests reordering the paragraphs as follows: paragraph 5 proposed by the Commission would become paragraph 2, the new paragraph 5a would become paragraph 3, paragraph 6 proposed by the Commission would become paragraph 4, the current (unchanged) paragraphs 2 and 3 would become paragraphs 5 and 6 and the paragraph 4 proposed by the Commission would become paragraph 7.~~

(b) the following paragraphs 4, 5, 5a and 6 are added:

‘4. The Commission, ~~where necessary~~ in cooperation with the Agency, **and in consultation with the MDCG,** shall set up, maintain, and manage an IT system to facilitate the reporting and information exchange regarding cases of interruption or discontinuation of the supply of devices in accordance with paragraphs ~~[~~1, 2, 4, 5, 5a and 6~~]~~. That IT system shall be integrated in or interoperable with the European database on medical devices referred to in Article 30~~.~~ **and shall be accessible to manufacturers, competent authorities, health institutions, healthcare professionals.** It shall also enable health institutions and healthcare professionals to inform competent authorities about the unavailability or the immediate risk of unavailability of devices needed for the exercise of their professional activity. ~~This IT system shall be accessible to manufacturers, competent authorities, health institutions and healthcare professionals.~~ Information ~~relating~~**referred** to **in paragraph 6** ~~manufacturing sites, production volumes, and related operational data~~ shall be accessible exclusively to the Commission, the Agency and the competent authorities.

5. The Agency, in ~~collaboration with the MDCG~~ **particular through** ~~and~~ **the** Executive Steering Group on Shortages of Medical Devices (MDSSG) established by Article 21 of Regulation (EU) 2022/123, **and in collaboration with the MDCG** shall develop a methodology to identify the devices, or categories of devices, for which it is reasonably foreseeable that an interruption or discontinuation of supply could result in serious harm or a risk of serious harm to patients or public health as referred to in paragraph 1. Based on that methodology, the Agency, in **particular through** ~~collaboration with~~ the MDSSG **and in collaboration with the MDCG,** and in agreement with the Commission, shall **propose** ~~draw up, publish and keep up to date~~ a list of devices, or categories of devices, **that are deemed to meet that criteria. The Commission shall, by means of implementing acts and taking into account the list proposed by the Agency, adopt, publish and keep up to date a list of devices, or categories of devices, for which an interruption or discontinuation of supply could result in serious harm or risk of serious harm to patients or public health in one or more Member States,** to which paragraphs ~~[~~1, 2, 3, 4, 5a and 6~~]~~ shall apply. The methodology shall be **drawn up and published** ~~developed~~ within one year from the date of application of this Regulation. The list of devices, or categories of devices, shall be developed within one year from the date of the development of the methodology. The list shall be reviewed and updated regularly, to ensure its continued relevance and accuracy. For the purpose of this paragraph, the MDCG, representatives of manufacturers, other relevant actors in the supply chain for the medical device sector and representatives of healthcare professionals, of patients and of consumers may be consulted as necessary.

For the purposes of ~~[~~paragraphs 1, 2, 3, 4, 5a and 6~~]~~, the obligations shall only apply to devices included in the list drawn up in accordance with this paragraph, when available.

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5a. Economic operators shall establish, maintain and keep up to date a shortage prevention plan for the devices included in the list drawn up in accordance with ~~[~~paragraph 5~~]~~. Shortage prevention plans shall be made available to the competent authority upon request. They shall be developed on the basis of a risk-based approach and shall identify specific measures and actions to be taken in the event of an actual supply interruption.

6. The competent authorities of the Member States or the Commission may request the manufacturers of devices included in the list drawn up in accordance with ~~[~~paragraph 5~~]~~ to provide all necessary information regarding risks and weaknesses within the supply chain which may affect the supply of such devices, including production capacity and volume of sales. Manufacturers of those devices shall register on the IT system referred to in ~~[~~paragraph 4~~]~~ and be identifiable as such to the Commission and the competent authorities.

*** Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/123/oj).';

(11) in Article 11, paragraph 4 is replaced by the following:
'The mandate referred to in paragraph 3 of this Article shall not delegate the manufacturer's obligations laid down in Article 10(1), (2), (3), (4), (5), **(6),** (8), (9), (10) and (11).';

(12) in Article 14, paragraph 2 is amended as follows:
~~(a) in the first subparagraph, point (d) is replaced by the following:~~
~~'(d) that, where applicable, a UDI has been assigned by the manufacturer in accordance with Article 24(3).';~~

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

'In order to meet the requirements referred to in the first subparagraph the distributor may apply a sampling method that is representative of the devices supplied by that distributor.';

(13) Article 15 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of in vitro diagnostic medical devices.

The person responsible for regulatory compliance shall be able to demonstrate that they have acquired and keep up to date the knowledge necessary to perform the tasks referred to in this Article.

The requisite expertise shall be demonstrated by either of the following:

(a) successful completion of a university degree in law, medicine, pharmacy, engineering or another relevant discipline, or an equivalent qualification in relevant studies, and at least one year of professional experience in regulatory affairs or in quality management systems relating to **in vitro diagnostic** medical devices;

(b) two years of professional experience in regulatory affairs or in quality management systems relating to **in vitro diagnostic** medical devices.';

(b) paragraph 2 is replaced by the following:

'2. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC**** shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person at their disposal.

_____

**** Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).';

PUBLIC

(c) in paragraph 3, point (c) is replaced by the following:

'(c) the post-market surveillance obligations are complied with in accordance with Article 78;';

(d) paragraph 6 is replaced by the following:

'6. Authorised representatives shall have at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for in vitro diagnostic medical devices in the Union. **The availability of the person responsible for regulatory compliance shall be proportionate to the number of manufacturers represented by the authorised representative as well as to the risk class of the devices manufactured by them.**

The person responsible for regulatory compliance shall be able to demonstrate that they have acquired and keep up to date the knowledge necessary to perform the tasks referred to in this Article.

The requisite expertise shall be demonstrated by either of the following:

(a) successful completion of a university degree in law, medicine, pharmacy, engineering or another relevant discipline, or an equivalent qualification in relevant studies, and at least one year of professional experience in regulatory affairs or in quality management systems relating to **in vitro diagnostic** medical devices;

(b) two years of professional experience in regulatory affairs or in quality management systems relating to **in vitro diagnostic** medical devices.';

(14) Article 16 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in the first subparagraph, the introductory wording is replaced by the following: 'A distributor, an importer or another natural or legal person who makes a ~~product~~ **device** available on the market, or places a ~~product~~ **device** on the market or puts it into service shall assume the obligations incumbent on manufacturers if it does any of the following:'

PUBLIC

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

'The first subparagraph shall not apply to any healthcare professional or any other person who, while not considered a manufacturer, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.';

(b) paragraph 4 is replaced by the following:

'4. At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities referred to in points (a) and (b) of paragraph 2 shall submit to the competent authority a certificate **or a declaration** ~~, issued by an independent conformity assessment body,~~ attesting that the quality management system of the distributer or importer complies with the requirements laid down in paragraph 3.';

(15) Article 17 is amended as follows:

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

'The EU declaration of conformity shall state that the requirements specified in this Regulation have been fulfilled in relation to the device that is covered by that declaration.';

(b) the following paragraph 2a is inserted:

'2a. Declarations of conformity in accordance with paragraphs 1 and 2 may be provided in electronic form.';

(16) The following Article 19a is inserted:

'Article 19a

Kits

A kit shall contain **multiple components with** 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~~ **The components of a kit may include the following**:

(a) accessories to an in vitro diagnostic medical 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.';

(…)

(22) Article 29 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. For class C 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 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 (f), (g) and (h) are deleted;

(…)

PUBLIC

(27) Article 47 is ~~amended as follows~~**replaced by the following**:

'1. Devices shall be divided into classes A, B, C and D, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII.

2. Upon a duly substantiated request by a manufacturer or an authorised representative established within a Member State, or on its own initiative, the competent authority of that Member State (the 'responsible competent authority') shall, after obtaining information from the manufacturer and, where applicable, the notified body that issued the certificate for that device, determine the class of the device of the requesting manufacturer, taking into account this Regulation, in particular Annex VIII and any harmonised criteria established at Union level.

3. Where the competent authority has justified doubts during the determination referred to in paragraph 1, it may consult the competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) of Regulation (EU) 2017/745.

4. A manufacturer or a notified body may refer any dispute between them arising from the application of Annex VIII to the responsible competent authority. Where the notified body concerned is established in a Member State other than that of the manufacturer or the authorised representative, the responsible competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.

5. Where a competent authority (the 'initiating competent authority'), on the basis of information obtained through vigilance activities, market surveillance activities or any other relevant information, has justified doubts as to the classification of a device for which neither the manufacturer nor the authorised representative is established within its Member State, it shall refer the matter to the responsible competent authority.

6. Following consultation with the initiating competent authority and after having obtained information from the manufacturer or authorised representative and where applicable, the notified body that issued the certificate for that device, the responsible competent authority shall determine the classification within 6 months. Where the initiating and the responsible competent authorities agree on the classification of the device, the responsible competent authority shall issue the determination and communicate it to the initiating competent authority and the competent authorities of the other Member States in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) of Regulation (EU) 2017/745.

7. Where a competent authority does not agree with the determination taken by the responsible competent authority and continues to have justified doubts regarding the classification of the device, the responsible competent authority shall consult the national competent authorities in the framework of the coordination activities referred to in Article 106b paragraph (1) point (a) of Regulation (EU) 2017/745 who shall issue an opinion on the classification of the device.

8. Where a majority of the Member States' competent authorities referred to in point 7 consider it justified, they may refer the case for the consideration of the MDCG. The MDCG shall provide its opinion on the classification and may request the Commission to decide on the classification of the specific product, by means of implementing acts.

9. During the consideration referred to in paragraph 8, the MDCG, or the Commission in agreement with the MDCG, may consult the relevant expert panel. The manufacturer or authorised representative, as well as the notified body that issued the certificate, if applicable, will be provided with the opportunity to present their positions on the classification of the product to the competent authorities, MDCG or the relevant expert panel, as applicable.

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10. Within 60 days of the request referred to in paragraph 9, the relevant expert panel shall provide advice to the MDCG or the Commission.

11. Within 90 days of the request referred to in paragraph 8, the MDCG shall issue an opinion on the classification of the product. Where an expert panel is consulted in accordance with paragraph 9, the clock shall stop until the advice from the expert panel is received.

12. Within 180 days of the request from the MDCG referred to in paragraph 8, the Commission shall propose to the Committee referred to in Article 107(1) a decision on the classification of the product. That decision shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 107(3). In adopting its decision, the Commission shall take the utmost account of the advice and opinions issued by the expert panel and the MDCG.

13. At the substantiated request of the MDCG, the Commission shall, decide by means of implementing acts, that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII, taking into consideration the principle of proportionality and classification of devices at international level.

14. In order to ensure the uniform application of the rules set out in Annex VIII, and taking account of the relevant opinion of the MDCG and the scientific opinion of the relevant expert panel, the Commission is empowered to adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.

15. The implementing acts referred to in paragraphs 13 and 14 of this Article shall be adopted in accordance with the examination procedure referred to in Article 107(3).

PUBLIC

16. The outcomes of the coordination activities of the competent authorities in accordance with this Article, the opinions of the MDCG, and the advice of the expert panel delivered in accordance with this Article shall be made publicly available, without disclosing any confidential information as referred to in Article 102.';

~~(a) paragraph 2 is replaced by the following:~~

~~'2. The competent authorities of the Member States shall, when necessary, exchange experience, cooperate and coordinate their activities, with the support of the Agency as referred to in Article 106b(1) point (a) of Regulation (EU) 2017/745, when determining the classification of a device, or a category or group of devices. The results of the coordination activities of the competent authorities, including the result of any decision or measure adopted by a competent authority in accordance with Article 47a or 47b and any opinion issued by an expert panel in relation to classification shall be made publicly available, without disclosing any confidential information as referred to in Article 102.';~~

~~(b) in paragraph 3, point (b), is replaced by the following:~~

~~'(b) that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII, taking into consideration the principle of proportionality and classification of devices at international level.';~~

~~(c) paragraph 5 is replaced by the following:~~

~~'5. In order to ensure the uniform application of the rules set out in Annex VIII, and taking account of the relevant scientific opinions of the relevant scientific committees or expert panels, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.';~~

~~(d) the following paragraph 7 is added:~~

~~'7. The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend Annex VIII in order to adapt it to technical or scientific progress or to take into account developments regarding classification of devices at international level.';~~

PUBLIC

(28) the following Articles 47a and 47b are inserted:

'Article 47a

Classification in the event of a dispute between manufacturer and notified body

1. A manufacturer or a notified body may refer any dispute between them arising from the application of Annex VIII to the competent authority of the Member State in which the manufacturer has its registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State in which the authorised representative referred to in Section 2.2., second paragraph, point (b), last indent, of Annex IX has its registered place of business.

   The competent authority of the Member State in which the manufacturer has its registered place of business shall notify the MDCG and the Commission of its decision. The decision shall be made available upon request.

2. Within 60 days of receipt of the referral referred to in paragraph 1, the competent authority shall consult the other competent authorities in accordance with the coordination activities referred to in Article 47(2) regarding its draft classification decision.

   The authority may within these 60 days ask for clarification or additional information about the referral, and the 60-day clock will stop until all relevant information has been received.

   At the time of consultation of the competent authorities, the initiating competent authority may request the opinion of an expert panel with the support of the Agency. If the requisite information is not provided within 60 days of it being requested by the authority, the referral may be considered as lapsed.

PUBLIC

3. Where, within 30 days of sending the consultation referred to in the paragraph 2, no substantiated disagreement is raised, the competent authority shall adopt its decision within 30 days of the expiry of the deadline of the consultation referred to in paragraph 2.

4. Where, within 30 days of sending the consultation referred to in paragraph 2, a substantiated disagreement has been raised regarding the draft classification decision, the matter shall be referred to the relevant expert panel as referred to in Article 106 of Regulation (EU) 2017/745. That expert panel shall deliver a technical or scientific opinion on the matter within 30 days to be used by the competent authority to resolve the dispute between the notified body and the manufacturer. The competent authority may ask the expert panel for clarifications on its opinion.

5. Within 30 days of receipt of the expert panel opinion, or any requested clarification, the competent authority shall adopt its decision, giving utmost consideration to the expert panel opinion. It shall notify the other Member States and the Commission of its decision without undue delay.

Article 47b

Challenges to the classification of CE marked devices

1. Where a competent authority, as part of its market surveillance activities considers that a device that is CE marked in accordance with Article 18, is not classified in accordance with Annex VIII, it shall consult the other competent authorities in accordance with the coordination activities referred to in Article 47(2) regarding its envisaged decision on the classification of the device.

2. Where, 30 days of sending of the consultation referred to in paragraph 1, no substantiated disagreement has been raised by a competent authority of a Member State, the initiating competent authority may decide on the classification of the device in question and shall notify the other Member States and the Commission of its decision giving the reasons for the decision.

PUBLIC

3. Where, within 30 days of sending of the consultation referred to in paragraph 1, a substantiated disagreement is raised regarding the notified envisaged measure on the classification, the matter shall be referred to an expert panel referred to in Article 106 of Regulation (EU) 2017/745, which shall deliver an opinion on the classification of the device within 30 days. The competent authority may ask the expert panel for clarifications on its opinion.

4. The competent authority shall give utmost consideration to the expert panel opinion. The competent authority shall, where necessary, conduct an evaluation in accordance with Article 94. Where the competent authority adopts a measure on the classification, it shall notify the other Member States and the Commission of its measure without undue delay.

4a. The Commission may, after consulting the MDCG, by means of implementing acts, lay down further details of the procedure for the application of Article 47a and of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';

(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.

PUBLIC

The representative device shall be chosen in accordance with the approach outlined in the third paragraph of Section 2.3 of Annex IX.

Where, having applied the approach in the third paragraph of Section 2.3 of Annex IX, a notified body considers it necessary, on justified grounds, to assess the technical documentation of additional representative devices due to their specific characteristics or properties, it shall document its rationale as part of the sampling plan to be drawn up in accordance with Annex VII Section 4.5.2(a).

The sampling plan shall be made available to the authority responsible for notified bodies upon request.';

(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**, II** 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.~~

The representative device shall be chosen in accordance with the approach outlined in the third paragraph of Section 2.3 of Annex IX.

Where, having applied the approach in the third paragraph of Section 2.3 of Annex IX, a notified body considers it necessary, on justified grounds, to assess the technical documentation of additional representative devices due to their specific characteristics or properties, it shall document its rationale as part of the sampling plan to be drawn up in accordance with Annex VII Section 4.5.2(a).

The sampling plan shall be made available to the authority responsible for notified bodies upon request.';

(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 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 representative device**(s)** for the assessment of the technical documentation as referred to in Section 2.3 of Annex IX;

(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, ~~in particular~~ 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;

(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.';

PUBLIC

(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, 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**, and may, upon request by the manufacturer, be** subject to the specific arrangements set out in this Article.

2. A device shall be considered a breakthrough device if it meets ~~all~~ the following criteria:
   (a) 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; **and**
   (b) 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; **and**
   (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.

PUBLIC

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 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 opinion ~~with respect to confirming~~ **on the notified body's assessment of** 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 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.

6. For 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 the conformity assessment of that device,** offer priority access to supports to the manufacturer throughout the conformity assessment procedure **and apply, where appropriate, a rolling review with a view to reduce assessment timelines.**

~~These supports may include, where appropriate:~~

~~(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~~ **may** issue a certificate pursuant to Article 51 where, **all applicable requirements of this Regulation are fulfilled and,** based on their assessment of the performance evaluation report, the pre-market clinical evidence, even if based on limited clinical performance data, provided that each of the following 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**, pursuant to an appropriate PMCF plan**.

   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 **in a digital format** the technical documentation and any reports or other documents required pursuant to this Regulation**. That** ~~in~~ digital format **may be a**~~, 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 with the notified body or competent authority or national authorities responsible for notified bodies as applicable.

2. Where necessary to ensure that the digital format **referred to in paragraph 1** ~~of the technical documentation, reports or other documents~~ is reliable, interoperable and standardised, the Commission may **establish**~~, by means of CS as referred to in Article 9, lay down~~ minimum requirements or functional specifications for the digital format **by means of common specifications as referred to in Article 9**.';

(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, **and having consulted the authority responsible for notified bodies,** 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 **necessary to provide its advice** ~~needed for its assessment. The expert panel may request an assessment from the respective authority responsible for notified bodies~~.

2. The MDCG~~, a competent authority~~ or the Commission may, based on reasonable concerns, **and having consulted the authority responsible for notified bodies** request advice from one or more EU reference laboratories, based on their expertise related to 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 **necessary to provide its advice** ~~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 upload them **within 30 days of issuance** in Eudamed ~~in a timely manner~~. The minimum content of the certificates shall be as set out in Annex XII.

2. The EU technical documentation assessment certificates **or EC type examination 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.

Notwithstanding subparagraphs 1 and 2, the notified body 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.’;

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(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, in accordance with Section 4.8 of Annex 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, point(**f**~~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~~ **limited** number of devices **for a limited period of time**, 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.';

PUBLIC

(b) the following paragraphs 1a, 1b and 1c are inserted:

'1a. By way of derogation from Article 6(2), on a duly justified request, any competent authority may authorise for a limited period of time or for a ~~defined~~ **limited** number of devices **for a limited period of time**, the use of a **specific** 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 **specific** 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 **specify and** impose **additional** ~~and specify~~ conditions or limitations to the ~~exemption~~ **derogations**~~as~~ ~~applicable~~, such as conditions on labelling, **serious** incident reporting, and traceability~~, and limitations on time and number of devices~~.

1c. Where **necessary to support the decision-making processes referred to in paragraphs 1 and 1a, for a request for use other than for a single patient** ~~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 **or EU reference laboratory established under this Regulation**.';

(c) paragraph 2 is replaced by the following:

'2. The Member State shall inform the Commission**, the Agency,** and the other Member States 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 the provision of a service, in accordance with paragraph 1a, where such authorisation is granted for use other than for a single patient.

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

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, **where applicable,** 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~~ **such Union-wide** 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, a competent authority may authorise for a limited period of time or a limited number of devices **for a limited period of time**, 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 **specific** 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~~**referred to in** 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 **for a limited period of time**, 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 may establish one or more regulatory sandboxes to which the application of certain requirements of Chapters V or VI or of **Chapters II and III of** Annexes I, **or** VIII, IX, X, XI, XIII or XIV would not be appropriate from a technical**,** ~~or~~ scientific **or regulatory** 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 shall set out **technical,** clinical, scientific and regulatory justification for the necessity to establish a regulatory sandbox including at least:
   (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**;**
   (e) identification of the responsibilities and obligations of each participant in the regulatory sandbox, including the person or persons responsible for the conduct and oversight of the regulatory sandbox;
   (f) procedures for the reporting, assessment and management of incidents, serious incidents, or serious adverse events, including the implementation of appropriate corrective and preventive measures, taking into consideration paragraph 5 of this Article.

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;
   (b) the application of the requirements of this Regulation referred to in paragraph 1 would not be appropriate due to **technical, clinical,** scientific or regulatory challenges arising from characteristics or methods related to.

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.

PUBLIC

5. Any participant in the regulatory sandbox shall **report**, without undue delay, ~~inform~~ **to** the competent authority that is responsible for the supervision of the regulatory sandbox and the competent authority according to Article 84(2)**,** ~~about~~ any serious incidents **or serious adverse events that have** 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 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.

Article 54c

Union regulatory sandboxes

1. The Commission, on its own initiative**, and in consultation with the MDCG,** 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:

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(a) would 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 the MDCG about the establishment of a regulatory sandbox and keep it informed about its outcome.

4. The Commission 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 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).

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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.';

(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.

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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.';

(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.';

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(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 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 **conducting** ~~demonstrating~~ 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 **or other procedures posting significant risk** for the subjects of the studies, **with the exception of low risk procedures such as routine blood sampling or taking a specimen from a natural body orifice.**';

(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 subjects for the performance study are to be enrolled, in accordance with this Regulation, unless otherwise stated;';

PUBLIC

(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 ~~patients~~ **subjects** for the performance study are to be 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.';

(43a) in Article 68, the following sentence is added at the end of paragraph 1:

*'**The sponsor remains responsible for ensuring all performance study activities, including those conducted by third parties and sites inside or outside the Union, comply with the approved performance study plan and this Regulation.**';*

PUBLIC

(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 *******, 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 (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 as soon as the Member State concerned has notified the sponsor of its authorisation, or-following expiry of the period defined in paragraph 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';

(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 '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;

(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, shall be carried out in accordance with Article 14c of Regulation (EU) No 536/2014.

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.';]

(…)

PUBLIC

(55a) The following Article 82b is inserted:

'Article 82b

Reporting of serious incidents under Regulation (EU) 2024/1698

For in vitro diagnostic medical devices that incorporate AI systems according to Regulation (EU) 2024/1689, serious incidents in accordance with Article 3(49), point (c), of Regulation (EU) 2024/1689, related to the infringement of obligations under Union law intended to protect fundamental rights, shall be reported to the national competent authority chosen for that purpose under that Regulation by the Member States where the incident occurred.';

(…)

(60) Article 88 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices and on the compliance of economic operators with the obligations set out in this Regulation including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.';

(b) the following paragraph 1a is inserted:

'1a. Member States shall ensure that their national competent authorities are provided with adequate and sufficient technical, financial and human resources, and with infrastructure to fulfil their tasks effectively under this Regulation.';

(c) paragraph 2 is replaced by the following:

'2. The competent authorities shall draw up annual surveillance activity plans, taking into account the European market surveillance programme, which shall be developed and maintained by the MDCG, and local circumstances.';

(d) the following paragraph 12 is added:

'12. The competent authorities may exchange information in relation to their market surveillance activities and, where relevant, engage with the authorities responsible for notified bodies and the authorities responsible for vigilance.

Where appropriate, the competent authorities may also cooperate and exchange relevant information with other authorities, including in the fields of cybersecurity, artificial intelligence, and other areas where regulatory interplay exists, whose responsibilities are relevant to the performance of their market surveillance activities.

In respect of devices that are high-risk AI systems as referred to in Article 6(1) of Regulation (EU) 2024/1689, the competent authorities shall cooperate with market surveillance authorities of their Member State designated in accordance with Article 70 of Regulation (EU) 2024/1689.';

(61) Article 89 is replaced by the following:

'Article 89

Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

The competent authorities of a Member State, either alone or in cooperation with the competent authorities of other Member States, shall carry out an evaluation of a device covering the relevant requirements laid down in this Regulation relating to the risk presented by the device or to any other non-compliance of the device, where they, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe either of the following:

(a) a device may 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;

(b) a device otherwise does not comply with the requirements laid down in this Regulation.

The relevant economic operators and, where applicable and requested, the notified body that issued a certificate for the device in question shall cooperate with the competent authorities.';

(62) Article 90 is amended as follows:

(a) paragraph 3 is replaced by the following:

‘3. The economic operators referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken within the period referred to in that paragraph throughout the Union in respect of all the devices concerned that they have made available on the market.’;

(b) paragraph 7 is replaced by the following:

‘Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of the notified measures taken by a Member State, those measures shall be deemed to be justified.

In that case, all Member States shall ensure that corresponding appropriate restrictive or prohibitive measures, including withdrawing, recalling or limiting the availability of the device on their national market are taken without delay in respect of the device concerned.

Corresponding measures adopted by the other Member States pursuant to this paragraph shall be based on the notification referred to in paragraph 4. Those measures shall not be subject to the procedure set out in paragraph 4.’;

(63) Article 91 is amended as follows:

(b) in paragraph 2, the second sentence of the first subparagraph is replaced by the following:

‘If the Commission considers the national measure to be unjustified, the Member State concerned, as well as any Member State that has taken corresponding restrictive or prohibitive measures, shall withdraw the measure.’;

PUBLIC

(64) Article 92 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Where, having performed an evaluation pursuant to Article 89, the competent authorities of a Member State find that a device ~~or an economic operator~~ does not comply with the requirements laid down in this Regulation but 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, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.’;

(b) in paragraph 2, the first sentence is replaced by the following:

‘Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1, the Member State concerned shall, without delay, take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the national market.’;

(c) the following paragraph 2a is inserted:

‘2a. The economic operator shall take any appropriate corrective action pursuant to paragraph 1 throughout the Union in respect of all the devices concerned that they have made available on the market, unless a competent authority takes other appropriate measures.’;

(…)

(66) the heading of Chapter VIII is replaced by the following:

‘COOPERATION BETWEEN MEMBER STATES AND EU REFERENCE LABORATORIES’;

PUBLIC

(67) in Article 96, the first and second sentences are replaced by the following:

'The Member States shall designate the competent authority or authorities responsible for the implementation and practical application of this Regulation. They shall ensure that those authorities are entrusted with sufficient powers, resources, equipment and knowledge necessary for the effective and efficient performance of their tasks pursuant to this Regulation, in practice. The Member States shall communicate the names and contact details of the competent authorities to the Commission which shall publish a list of competent authorities.';

(67a) in Article 97, paragraph 1 is replaced by the following:

'*1. The competent authorities of the Member States shall cooperate with each other* ***and the authorities responsible for notified bodies shall cooperate with each other. Both shall also cooperate with each other*** *and with the Commission. The Commission shall provide for the organisation of exchanges of information necessary to enable this Regulation to be applied uniformly.'*

(68) in Article 97, paragraph 2 is deleted;

(69) Articles 98 and 99 are deleted;

(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;';

(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 by the Commission, the MDCG, competent authorities, or notified bodies with due consideration of comparative test results or other studies;';

(iii) point**s (e) and** (j) ~~is~~**are** 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 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.';

(71) Article 101 is deleted;

(72) Article 103 is amended as follows:

'(a) in paragraph 1, the reference to 'Directive 95/46/EC' is replaced by 'Regulation (EU) 2016/679';

PUBLIC

(b) in paragraph 2, the reference to 'Regulation (EC) No 45/2001' is replaced by 'Regulation (EU) 2018/1725 of the European Parliament and of the Council*********.

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********* Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: http://data.europa.eu/eli/reg/2018/1725/oj).'

(73) the following Article 103a is inserted:

'Article 103a

Submission of information or documents

The submission of information or documents in accordance with this Regulation ~~shall~~ **may** take place electronically.

Member States may require that information or documents in accordance with this Regulation shall be submitted electronically to the relevant authority.'

(74) Article 104 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. This Regulation shall be without prejudice to the possibility for Member States and the Commission to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost-recovery principles.';

(b) in paragraph 2, second sentence, the words 'on request' are deleted;

(75) Article 105 is deleted;

~~(76) in Article 108(6), first and second sentences, the words 'three months' are replaced by the words 'two months';~~

~~(77) Article 109 is deleted;~~

(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.

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.

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.

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.

PUBLIC

~~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 label~~ling~~, instructions for use and, where appropriate, any other accompanying documentation.

At least every 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.

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

(79) Article 111 is amended as follows:

(a) in the first sentence, the date '27 May 2027' is replaced by the date …'[OP, please insert the date = five years after the date of entry into force of this Regulation]';

(b) the second sentence is deleted;

(80) in Article 113(3), point (f), the following subparagraph is added:

'After the date of application of the provisions referred to in the first subparagraph of this point, where Member States maintain national databases, the relevant information available in Eudamed for those national databases shall be retrieved from Eudamed. This shall be without prejudice to the possibility for Member States to maintain or develop complementary national functionalities and data elements necessary for national market surveillance or other regulatory tasks, avoiding duplication of Union data, where possible.;'

(1) Annex I is amended as follows:

(a) Section 16.4. is replaced by the following:

'Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures and cybersecurity, including **appropriate technical, operational and organisational measures to ensure an appropriate level of cybersecurity** ~~protection against unauthorised access,~~ necessary to run the software as intended **such as protection against unauthorised access and handling of vulnerabilities**.';

(aa) Section 16.5 is added as follows:

'16.5. In vitro diagnostic medical devices that incorporate AI systems according to Regulation (EU) 2024/1689 shall be designed and developed taking into account the following principles:

- **human oversight;**
- **record keeping;**
- **representativeness of data and data governance, including with regard to training, validation and testing;**
- **transparency and provision of information to deployers and users;**
- **accuracy and robustness.';**

(b) Section 20.1. is amended as follows:

(i) the second sentence of the first paragraph is replaced by the following:
'Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:';

(ii) in point (c), the following sentence is added:
'Labels may be provided in digital form to the extent, and only under the conditions, set out in implementing rules adopted pursuant to this Regulation.';

(iii) point (e) is replaced by the following:
'(e) Where multiple devices, with the exception of devices intended for self-testing, are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.';

(iv) point (f) is replaced by the following:
'(f) When the device is intended for professional use only, instructions for use may be provided to the user in non-paper format (e.g. electronic).';

PUBLIC

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

'(k) For devices that are used exclusively with a medicinal product in accordance with Article 19 of [Proposal for a Directive on the Union code relating to medicinal products for human use, and repealing Directive 2011/83/EC and Directive 2009/35/EC] and packaged together with a medicinal product, the instructions for use may be included, where needed, as part of the co-packaging of the medicinal product with the device. Moreover, the information on the label of the device may be limited to the particulars referred to in Section 20.2., points (a) and (c), where, following agreement of the competent authority responsible for the authorisation of the medicinal product, the following conditions are met:

(i) the information necessary for safe use and correct functioning of the device is provided to the user with the summary of product characteristics and/or package leaflet of the medicinal product under the responsibility of the marketing authorisation holder set out in [Proposal for a Directive on the Union code relating to medicinal products for human use, and repealing Directive 2011/83/EC and Directive 2009/35/EC;

(ii) the traceability and identification of the device is ensured by the marketing authorisation holder.';

(c) Section 20.2. is amended as follows:

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

'(e) an indication that the device is an in vitro diagnostic medical device or an accessory for an in vitro diagnostic medical device, or if the device is a 'device for performance study', an indication of that fact;';

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

'(j) where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination thereof, or other terms which accurately reflect the contents of the package;';

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

'(r) where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion thereof;';

PUBLIC

(d) Section 20.4.1. is amended as follows:

(i) in point (c), subpoint (viii) is replaced by the following:

‘(viii) for companion diagnostics, the International Non-proprietary Name(s) (INN) or description of the specific group of the associated medicinal product(s) for which it is a companion diagnostic.’;

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

‘(d) an indication that the device is an in vitro diagnostic medical device or an accessory for an in vitro diagnostic medical device, or, if the device is a ‘device for performance study’, an indication of that fact;’;

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

‘(h) a description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the critical ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;’;

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

‘(w) analytical and clinical performance characteristics as referred to in Section 9.1, points (a) and (b);’;

(v) point (x) is deleted;

(vi) point (z) is replaced by the following:

‘(z) information about the use of available reference measurement procedures and materials by the use;’;

(vii) point (ae) is replaced by the following:

‘(ae) date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use;’;

(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;’;

PUBLIC

(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.';

(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.';

PUBLIC

(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.';

(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 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;’

(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~~.’;

PUBLIC

(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**, and giving due consideration to the size and diversity of the manufacturer's portfolio**,';

(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:';

PUBLIC

(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,';

(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 **of Regulation (EU) 2017/745** 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.';

(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.';

PUBLIC

(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.

Those procedures shall require the manufacturer in question to submit at predefined intervals a summary of changes and scientific findings for the device **or QMS**, including:

(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. ~~and Articles 48(7) and 48(9)~~ **for a representative device in accordance with Article 48**.

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.

For class B and C devices, other than for self-testing or companion diagnostics, ~~T~~**t**he notified body may include a**n** ~~'for cause'~~ assessment of the technical documentation of additional representative devices on duly justified grounds identified during the quality management system assessment.

If the quality management system and the technical documentation of the assessed representative device conforms~~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 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 or subcontractors. On justified grounds, a surveillance audit may be conducted remotely instead of on-site. The notified body shall inform the authority responsible for notified bodies ~~on~~ **of** the justified grounds ~~and~~ **for** the ~~conducted~~ remote audits **conducted**. 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.

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 may carry out the surveillance audits and assessments only once every 24 months.';

PUBLIC

(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 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.';

(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~~ **shall** include an assessment of the technical documentation as specified in Section 4 for the device or devices concerned on the basis of further samples chosen in accordance with the rationale documented by the notified body in accordance with the third paragraph of Section 2.3. **or based on the compliance history of the generic device group or category of devices as applicable, and giving due consideration to the size and diversity of the manufacturer's portfolio.**';

(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 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.';

(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** sentence**s are**~~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.';~~

PUBLIC

(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.';

(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 (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.';

(7) Annex X is amended as follows:

(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);’;

(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.';

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.';

(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.';

(b) Chapter II is amended as follows:

(i) Section 6 is replaced by the following:

'6. where applicable, date of expiry;';

(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;

PUBLIC

(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.';

(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**n equivalent** 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~~ **or of an equivalent device**~~be demonstrated~~;
- other clinical experience published in peer-reviewed scientific literature with the device concerned or **of** a**n equivalent** 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.

PUBLIC

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.';

(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;

(ha) Section 2.3.2, first paragraph, is amended as follows:

Clinical performance studies shall be performed on the basis of a clinical performance study plan (CPSP). ***Performance studies shall be conducted at sites, including specimen collection sites, testing sites and laboratories, that operate in accordance with documented good study practices. The sponsor shall define those practices in the performance study plan and verify compliance throughout the study.***

(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;';

(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 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;';

(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

(aa) Chapter II is amended as follows:

(i) Section 4 is amended as follows:

'4. The sponsor shall appoint a monitor that is independent of the investigation site to ensure that the clinical performance study is conducted in accordance with the Clinical Performance Study Plan, the principles of good clinical practice and this Regulation. ***The sponsor shall maintain documented evidence that investigation sites and outsourced activities comply with applicable good study practice requirements and shall make such documentation available to competent authorities upon request.';***

PUBLIC

Amendments to Regulation (EU) 2022/123

Article 30 of Regulation (EU) 2022/123 is amended as follows:

(1) the first subparagraph is replaced by the following:
'The Agency shall provide the secretariat for the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745 (the 'expert panels') and shall provide the support necessary to ensure that those expert panels can efficiently perform the tasks set out in that Regulation and in Regulation (EU) 2017/746.';

(2) the second subparagraph is amended as follows:
(a) the introductory wording is replaced by the following: 'The Agency shall, in particular:'
(b) point (a) is replaced by the following:
'(a) select and appoint the experts in accordance with Article 106(2) and (5) of Regulation (EU) 2017/745 and provide administrative and technical support to the expert panels for the provision of opinions and advice;';
(c) points (c), (d) and (e) are replaced by the following:
'(c) ensure that the work of the expert panels is carried out in an independent manner in accordance with Article 106(3) and Article 107 of Regulation (EU) 2017/745. For that purpose, the Agency shall establish systems and procedures to actively manage and prevent potential conflicts of interest;
(d) maintain and regularly update a webpage for the expert panels and make all necessary information not already publicly available in Eudamed publicly available on that webpage;
(e) publish the opinions of the expert panels in accordance with Regulation (EU) 2017/745 or Regulation (EU) 2017/746, while ensuring confidentiality in accordance with Article 109 of Regulation (EU) 2017/745 or Article 102 of Regulation (EU) 2017/746;';

PUBLIC

(d) in point (f), the reference to ‘Article 106(14)’ is replaced by the reference to ‘Article 106(10)’;

(e) the following point (i) is added:

‘(i) submit to the Commission a substantiated recommendation for the fees to be paid by manufacturers or notified bodies for the opinions or advice provided by expert panels, as referred to in Article 106(9) and (10) of Regulation (EU) 2017/745.’;

PUBLIC

Amendments to Regulation (EU) 2024/1689

Annex I to Regulation (EU) 2024/1689 is amended as follows:[26]

(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).’

Entry into force and application (Article 5 of the Commission proposal)

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

2. It shall apply from …[OP please insert the date = six months after the date of entry into force of this Regulation].

3. By way of derogation from paragraph 2:

(a) Article 1, points (47) and (95), Article 2, points (33), (40) and (78), Article 3 and Article 4 shall apply from …[OP please insert the date = the date of entry into force of this Regulation];

(b) Article 1, points (27) to (40) and Article 2, points (24), (25) and (26), shall apply from… [OP please insert the date = 12 months after the date of entry into force of this Regulation];

[26] See recital (23) in support of this provision.

(c) Article 1, point (69), and Article 2, point (55), shall apply from …[OP please insert the date = three years after date of entry into force of this Regulation];

(d) Article 1, point (15), shall apply from …[OP please insert the date = five years after the date of entry into force of this Regulation].

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