The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

Proposed amendments to the Commission's Proposal for a targeted revision of EU rules on Medical devices and in vitro diagnostics

The CPME statement on medical devices may be accessed here and the CPME statement on medical devices – electronic instructions for use may be accessed here.

Amendment 1	
Recital 23, page 26	
Text Proposed by the Commission	**CPME Proposed Amendment**
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 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) 2024/168915 of the European Parliament and of the Council could lead to overlaps of requirements and stifle innovation. To prevent those overlaps and to simplify the regulatory framework for artificial intelligence-enabled devices, the application of Regulation (EU) 2024/1689 to those devices should be limited to those provisions referred to in Article 2(2) of that Regulation.	~~**The parallel application of Regulations (EU) 2017/745 and (EU) 2017/746, as applicable, and Regulation (EU) 2024/168915 of the European Parliament and of the Council could lead to overlaps of requirements and stifle innovation. To prevent those overlaps and to simplify the regulatory framework for artificial intelligence-enabled devices, the application of Regulation (EU) 2024/1689 to those devices should be limited to those provisions referred to in Article 2(2) of that Regulation.**~~
The references to Regulations (EU) 2017/745 and (EU) 2017/746 in Annex I to Regulation (EU) 2024/1689 should therefore be moved from Section A to Section B. Where needed, the Commission may use its implementing and delegated powers to lay down specific requirements regarding artificial intelligence, taking into account the requirements set out in Chapter III, Section 2, of Regulation (EU) 2024/1689. Moreover, notified bodies that are designated to	~~The references to Regulations (EU) 2017/745 and (EU) 2017/746 in Annex I to Regulation (EU) 2024/1689 should therefore be moved from Section A to Section B. Where needed, the Commission may use its implementing and delegated powers to lay down specific requirements regarding artificial intelligence, taking into account the requirements set out in Chapter III, Section 2, of Regulation (EU) 2024/1689. Moreover,~~ **N**otified 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.	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.

Justification

This provision should be deleted, since it would render inapplicable important requirements and safeguards on high-risk AI systems used for medical purposes , such as ensuring human oversight, risk-management system focusing on AI-specific risks relating to outputs (e.g., bias, performance drift, ethical use of AI, deployers' training, etc), as well as on transparency, accuracy, robustness and cybersecurity foreseen in Section 2 of Chapter III of the AI Act. The current regime of the AI Act should continue to apply. The AI Act already foresees simplification requirements for medical devices and IVD MD (Article 8(2) of the AI Act), and the European Commission even published guidance on the interplay between the AI Act and MDR/IVDR. Further guidance should continue to be developed to support the industry without changing current frameworks. Stability of EU legislation is necessary. The clarification of the obligations of notified bodies is welcomed.

Amendment 2

Article 4, page 127
Amendments to Regulation (EU) 2024/1689

Text Proposed by the Commission	CPME Proposed Amendment
Article 4 Amendments to Regulation (EU) 2024/1689 Annex I to Regulation (EU) 2024/1689 is amended as follows: (1) in Section A, points 11 and 12 are deleted; (2) in Section B, the following points are added: '21. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p.1); 22. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).'.	~~Article 4~~ ~~Amendments to Regulation (EU) 2024/1689~~ ~~Annex I to Regulation (EU) 2024/1689 is amended as follows:~~ ~~(1) in Section A, points 11 and 12 are deleted;~~ ~~(2) in Section B, the following points are added:~~ ~~'21. Regulation (EU) 2017/745 of the European Parliament and of the Council of~~ ~~5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC)~~ ~~No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives~~ ~~90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p.1);~~ ~~22. Regulation (EU) 2017/746 of the European Parliament and of the Council of~~ ~~5 April 2017 on in vitro diagnostic medical devices and repealing Directive~~ ~~98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).'.~~

Justification

This provision should be deleted, since it would render inapplicable important requirements and safeguards on high-risk AI systems used for medical purposes, such as ensuring human oversight, risk-management system focusing on AI-specific risks relating to outputs (e.g., bias, performance drift, ethical use of AI, deployers' training,

etc.), as well as on transparency, accuracy, robustness and cybersecurity foreseen in Section 2 of Chapter III of the AI Act. The current regime of the AI Act should continue to apply. The AI Act already foresees simplification requirements for medical devices and IVD MD (Article 8(2) of the AI Act), and the European Commission even published guidance on the interplay between the AI Act and MDR/IVDR. Further guidance should continue to be developed to support the industry without changing current frameworks. Stability of EU legislation is necessary.

Amendment 3

Article 1, Amendments to Regulation (EU) 2017/745 Article 59c(52), pages 71-72	
Text Proposed by the Commission	**CPME Proposed Amendment**
Article 61 is amended as follows (a) paragraphs 1 and 2 are replaced by the following: '1. Manufacturers shall plan, conduct and document a clinical evaluation in accordance with this Article and with Part A of Annex XIV to confirm the safety and performance of the device under normal conditions of use in accordance with the intended purpose of the device, and shall evaluate any undesirable side-effects and the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I. The manufacturer shall specify and justify the level of clinical evidence necessary to confirm the safety and performance of the device. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose, taking into consideration paragraph 10. The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report as referred to in Section 4 of Annex XIV, which, except for custom-made devices, shall be part of the technical documentation referred to in Annex II relating to the device concerned. 2. For class IIb and class III devices, a manufacturer may, prior to its clinical investigation or clinical evaluation, consult an expert panel as referred to in Article 106, with the aim of reviewing the manufacturer's intended clinical development strategy or proposals for clinical investigation. The manufacturer and the notified body involved in any future conformity assessment procedure shall, in the clinical evaluation report and the clinical evaluation assessment report, give due consideration to the	Article 61 is amended as follows (a) paragraphs 1 and 2 are replaced by the following: '1. Manufacturers shall plan, conduct and document a clinical evaluation in accordance with this Article and with Part A of Annex XIV to confirm the safety and performance of the device under normal conditions of use in accordance with the intended purpose of the device, and shall evaluate any undesirable side-effects and the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I. The manufacturer shall specify and justify the level of clinical evidence necessary to confirm the safety and performance of the device. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose, taking into consideration paragraph 10. The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report as referred to in Section 4 of Annex XIV, which, except for custom-made devices, shall be part of the technical documentation referred to in Annex II relating to the device concerned. 2. For class IIb and class III devices, a manufacturer may, prior to its clinical investigation or clinical evaluation, consult an expert panel as referred to in Article 106, with the aim of reviewing the manufacturer's intended clinical development strategy or proposals for clinical investigation. The manufacturer and the notified body involved in any future conformity assessment procedure shall, in the clinical evaluation report and the clinical evaluation assessment report, give due consideration to the

advice of the expert panel and where they do not follow the advice, they shall provide duly justified reasons.'; (b) in paragraph 4, first subparagraph, the introductory wording is replaced by the following: 'In the case of implantable class IIb devices and class III devices, other than custom-made devices, clinical investigations shall be performed, except if:'; (c) paragraph 5 is replaced by the following: '5. A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by it, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the original clinical evaluation has been performed in compliance with the requirements of this Regulation and the manufacturer provides clear evidence thereof to the notified body.';	advice of the expert panel and where they do not follow the advice, they shall provide duly justified reasons.'; (b) in paragraph 4, first subparagraph, the introductory wording is replaced by the following: 'In the case of implantable class IIb devices and class III devices, other than custom-made devices, clinical investigations shall be performed, except if:'; ~~**(c) paragraph 5 is replaced by the following:**~~ ~~**'5. A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by it, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the original clinical evaluation has been performed in compliance with the requirements of this Regulation and the manufacturer provides clear evidence thereof to the notified body.';**~~
Justification	
The core of the Medical Devices Regulations is the requirement for robust clinical evidence for high-risk medical devices. This was introduced to address the shortcomings of the previous Medical Devices Directives (MDD) framework, which relied too heavily on equivalence claims. The proposal for replacement article 61(5) would relax these requirements, poses significant safety risks. Some key concerns include the following: - Evidence from the CORE-MD project demonstrates that current clinical data for many high-risk devices are limited, with studies often being small or poorly comparable, leading to uncertainty about safety and effectiveness. - Cohort studies ("Comparison of rates of safety issues and reporting of trial outcomes for medical devices approved in the European Union and United States: cohort study") show that flexible approval routes in the EU raise patient risks. High-risk devices approved under these routes have a 2.9 times higher likelihood of safety alerts and recalls compared to similar devices in the United States[1]. - Allowing manufacturers to rely on clinical data from other sources undermines transparency and increases risks, as manufacturers often lack full access to raw data, follow-up information, or insights into production processes. Considering the above mentioned, we are against the relaxation of clinical evidence requirements for high-risk devices (class III), we emphasize that direct clinical evidence from the manufacturer is essential to ensure	

[1] "Comparison of rates of safety issues and reporting of trial outcomes for medical devices approved in the European Union and United States: cohort study"

patient safety and maintain public trust. Consequently, paragraph 5 should not be replaced.

Amendment 4

Article 2(10), page 42
Amendments to Regulation (EU) 2017/746

Text Proposed by the Commission	CPME Proposed Amendment
Article 10a is amended as follows:	Article 10a is amended as follows:
(a) in paragraph 1, the second subparagraph is replaced by the following:	(a) in paragraph 1, the second subparagraph is replaced by the following:
'The information referred to in the first subparagraph shall be provided at least six months before the anticipated interruption or discontinuation or, if this is not possible, without undue delay after the manufacturer becomes aware of the anticipated interruption or discontinuation. The manufacturer shall specify the reasons for the interruption or discontinuation in the information provided to the competent authority.';	'The information referred to in the first subparagraph shall be provided at least six months before the anticipated interruption or discontinuation or, if this is not possible, without undue delay after the manufacturer becomes aware of 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 and 6 are added: '4. The Commission, where needed in cooperation with the EMA, 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 and 3. That IT system shall be integrated in or interoperable with the European database on medical devices referred to in Article 33. 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.	(b) the following paragraphs 4, 5 and 6 are added: '4. The Commission, where needed in cooperation with the EMA, 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 and 3. That IT system shall be integrated in or interoperable with the European database on medical devices referred to in Article 33. 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. **The new IT system with information on shortages of devices shall be publicly available.** **Information on this topic shall be made available in a timely manner for service providers for them to be able to adapt to the change.**
5. The EMA, in collaboration with the Executive Steering Group on Shortages of Medical Devices (MDSSG) established by Article 21 of Regulation (EU) 2022/123, 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	5. The EMA, in collaboration with the Executive Steering Group on Shortages of Medical Devices (MDSSG)

harm to patients or public health as referred to in paragraph. Based on that methodology, the EMA, in collaboration with the MDSSG and in agreement with the Commission, shall draw up, publish and keep up to date a list of devices, or categories of devices, to which paragraphs 1, 2 and 3 shall apply. 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.	established by Article 21 of Regulation (EU) 2022/123, 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. Based on that methodology, the EMA, in collaboration with the MDSSG and in agreement with the Commission, shall draw up, publish and keep up to date a list of devices, or categories of devices, to which paragraphs 1, 2 and 3 shall apply. 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.
Justification	
These amendments on the obligations in case of interruption or discontinuation of supply chains are welcome, as they will ensure the administrative efforts are focused where they are really need, but information about discontinuation or interruption of relevant device marketing should be made publicly available. Also, information on this topic should be made available in a timely manner for service providers for them to be able to adapt to the change.	
Amendment 5	
Article 1(52), pages 71-72 **Amendments to Regulation (EU) 2017/745**	
Text Proposed by the Commission	**CPME Proposed Amendment**
Article 61 is amended as follows: (a) paragraphs 1 and 2 are replaced by the following: '1. Manufacturers shall plan, conduct and document a clinical evaluation in accordance with this Article and with Part A of Annex XIV to confirm the safety and performance of the device under normal conditions of use in accordance with the intended purpose of the device, and shall evaluate any undesirable side-effects and the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I. The manufacturer shall specify and justify the level of	Article 61 is amended as follows: (a) paragraphs 1 and 2 are replaced by the following: '1. Manufacturers shall plan, conduct and document a clinical evaluation in accordance with this Article and with Part A of Annex XIV to confirm the safety and performance of the device under normal conditions of use in accordance with the intended purpose of the device, and shall evaluate any undesirable side-effects and the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I. The manufacturer shall specify and justify the level of

clinical evidence necessary to confirm the safety and performance of the device. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose, taking into consideration paragraph 10. The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report as referred to in Section 4 of Annex XIV, which, except for custom-made devices, shall be part of the technical documentation referred to in Annex II relating to the device concerned. 2. For class IIb and class III devices, a manufacturer may, prior to its clinical investigation or clinical evaluation, consult an expert panel as referred to in Article 106, with the aim of reviewing the manufacturer's intended clinical development strategy or proposals for clinical investigation. The manufacturer and the notified body involved in any future conformity assessment procedure shall, in the clinical evaluation report and the clinical evaluation assessment report, give due consideration to the advice of the expert panel and where they do not follow the advice, they shall provide duly justified reasons.'; (b) in paragraph 4, first subparagraph, the introductory wording is replaced by the following: 'In the case of implantable class IIb devices and class III devices, other than custom-made devices, clinical investigations shall be performed, except if:'; (c) paragraph 5 is replaced by the following: '5. A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by it, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the original clinical evaluation has been performed in compliance with the requirements of this Regulation and the manufacturer provides clear evidence thereof to the notified body.'; (d) paragraph 6 is amended as follows: (i) the introductory wording is replaced by the	clinical evidence necessary to confirm the safety and performance of the device. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose, taking into consideration paragraph 10. The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report as referred to in Section 4 of Annex XIV, which, except for custom-made devices, shall be part of the technical documentation referred to in Annex II relating to the device concerned. 2. For class IIb and class III devices, a manufacturer may, prior to its clinical investigation or clinical evaluation, consult an expert panel as referred to in Article 106, with the aim of reviewing the manufacturer's intended clinical development strategy or proposals for clinical investigation. The manufacturer and the notified body involved in any future conformity assessment procedure shall, in the clinical evaluation report and the clinical evaluation assessment report, give due consideration to the advice of the expert panel and where they do not follow the advice, they shall provide duly justified reasons.'; (b) in paragraph 4, first subparagraph, the introductory wording is replaced by the following: 'In the case of implantable class IIb devices and class III devices, other than custom-made devices, clinical investigations shall be performed, except if:'; (c) paragraph 5 is replaced by the following: '5. A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by it, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the original clinical evaluation has been performed in compliance with the requirements of this Regulation and the manufacturer provides clear evidence thereof to the notified body. **Clinical investigations may only be exempted if the equivalent device was itself subject to a clinical investigation**';

following: 'The requirement to perform clinical investigations pursuant to paragraph 4 shall not apply to implantable class IIb devices and class III devices:'; (ii) point (b) is replaced by the following: '(b) that are well-established technology devices for which the clinical evaluation is based on sufficient clinical evidence and is in compliance with the relevant product-specific CS, where such CS are available.';	(d) paragraph 6 is amended as follows: (i) the introductory wording is replaced by the following: 'The requirement to perform clinical investigations pursuant to paragraph 4 shall not apply to implantable class IIb devices and class III devices:'; (ii) point (b) is replaced by the following: '(b) that are well-established technology devices for which the clinical evaluation is based on sufficient clinical evidence and is in compliance with the relevant product-specific CS, where such CS are available.';
Paragraph 5 opens equivalency evaluation, provided that the original clinical evaluation has been performed in compliance with the requirements of the Medical Devices Regulation. Paragraph 5 should be amended to ensure that clinical investigations may only be exempted if the equivalent device was itself subject to a clinical investigation.	
Amendment 6	
Annex II, pages 24-25 of the annexes	
Text Proposed by the Commission	**CPME Proposed Amendment**
(1) Annex I is amended as follows: (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). ';	(1) Annex I is amended as follows: (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). '; **(g) Electronic Instructions for Use (eIFU) shall not be extended beyond what is foreseen in Implementing regulation 2021/2226** **(h) Medical device instructions for use (IFU) shall be maintained to be used in case non-paper formats are not available**
CPME believes that Electronic Instructions for Use (eIFU) could be helpful for healthcare professionals, since it would be easy and quick to find information in the electronic form. Also, from an environmental perspective, eIFU could contribute to have more sustainable healthcare systems without compromising patient safety. However, the environmental cost of digital health also needs to be considered[2]. Medical device instructions for use (IFU) should be kept to be used in case of electricity blackout, or when there is not a robust digital	

[2] http://www.cpme.eu/api/documents/adopted/2022/11/cpme.2022-065.FINAL.CPME.position.EHDS.pdf, point 14, final paragraph.

infrastructure in place or in emergencies. Considering the Implementing regulation - 2021/2226, allowing Electronic Instructions for Use (eIFU) for certain medical devices intended for professional users, we stress that eIFU should not be extended beyond what is foreseen in that Regulation. Consequently, such safeguards should be included in this provision.

Amendment 7

Annex II, pages 24-25 of the annexes

Text Proposed by the Commission	CPME Proposed Amendment
(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, EN 26 EN 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.';	(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~~ **shall** 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, EN 26 EN 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.'; **(iii) electronic instructions shall provide approved information only** **(iv) the software used for the electronic instructions shall comply with regulation 2016/679, and profiling of patients shall be forbidden.**

Justification

For devices that are used exclusively with a medicinal product and packaged together with a medicinal product,

the instructions for use must be included, where needed, as part of the co-packaging of the medicinal product with the device. Also, electronic instructions shall provide approved information only and the software used for the electronic instructions shall comply with regulation 2016/679 (General Data Protection Regulation), and profiling of patients shall be forbidden. Consequently, these elements should be reflected in this provision.

Amendment 8

Article 59c Union regulatory sandboxes, page 71

Text Proposed by the Commission	CPME Proposed Amendment
1. The Commission, on its own initiative or upon a substantiated request by a Member State, may establish, by means of implementing acts for a limited time and pursuant to a specific plan, Union regulatory sandboxes, which shall inform whether the existing requirements appropriately regulate a specific type of device with particular characteristics or emerging technologies, and there is a risk that the existing requirements: (a) would impede or significantly delay the development of such devices and access by healthcare professionals or lay users to those devices; or (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 the placing on the market or putting into service of devices which do not comply with this Regulation 2. The Commission shall request an expert panel as referred to in Article 106 to provide scientific, technical or regulatory advice on the design of a Union regulatory sandbox. 3. The Commission shall inform the MDCG about the establishment of a regulatory sandbox and keep it informed about its outcome. 4. The Commission may, by means of implementing acts, specify common principles or the detailed	1. The Commission, on its own initiative or upon a substantiated request by a Member State, may establish, by means of implementing acts for a limited time and pursuant to a specific plan, Union regulatory sandboxes, which shall inform whether the existing requirements appropriately regulate a specific type of device with particular characteristics or emerging technologies, and there is a risk that the existing requirements: (a) would impede or significantly delay the development of such devices and access by healthcare professionals or lay users to those devices; or (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 the placing on the market or putting into service of devices which do not comply with this Regulation 2. Union regulatory sandboxes may also serve as environments to test and validate real-world evidence (RWE) governance systems across the full product lifecycle, ensuring traceability, accountability, and involvement of stakeholders, including clinicians and patients contributing data. 2. The Commission shall request an expert panel as referred to in Article 106 to provide scientific, technical or regulatory advice on the design of a Union regulatory sandbox.

arrangements for the establishment, operation and supervision of regulatory sandboxes pursuant to Article 59b or of Union regulatory sandboxes pursuant to this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). 5. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this Article or Article 59b in order to adapt it to scientific, technical or regulatory progress and to take into account developments regarding regulatory sandboxes, including in areas other than medical devices.';	3. The Commission shall inform the MDCG about the establishment of a regulatory sandbox and keep it informed about its outcome. 4. The Commission may, by means of implementing acts, specify common principles or the detailed arrangements for the establishment, operation and supervision of regulatory sandboxes pursuant to Article 59b or of Union regulatory sandboxes pursuant to this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). 5. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this Article or Article 59b in order to adapt it to scientific, technical or regulatory progress and to take into account developments regarding regulatory sandboxes, including in areas other than medical devices.';
Justification	
The increased reliance on real-world evidence (RWE) in the MDR revision is welcome but requires robust governance to ensure its reliability and applicability. The "valleys of death" in medical device development — gaps between research, development, and clinical adoption — are not bridged by lighter regulation but by continuous stakeholder involvement. We emphasize that RWE must be governed by design, with robust systems for traceability and stakeholder involvement across the entire product lifecycle. Regulatory sandboxes are the ideal environment to develop and test these systems.	
Amendment 9	
Annex I, annex VII, pages 12-13	
Text Proposed by the Commission	**CPME Proposed Amendment**
(g) Section 6.3 is replaced by the following: '6.3 Rule 11 Software which is intended to generate an output that confers a clinical benefit and is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition is classified as class I, unless the output is intended for a disease or condition: - in a critical situation with a risk of causing death or	(g) Section 6.3 is replaced by the following: '6.3 Rule 11 Software which is intended to generate an output that confers a clinical benefit and is used for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition is classified as class I, unless the output is intended for a disease or condition: - in a critical situation with a risk of causing death or

an irreversible deterioration of a person's state of health, in which case it is classified as class III; - in a serious situation with a risk of causing a serious deterioration of a person's state of health or a surgical intervention, or to drive clinical management in a critical situation in which cases it is classified as class IIbl In a non-serious situation, or to drive clinical management in a serious situation or to inform clinical management in a critical or serious situation in which cases it is classified as class IIa;	an irreversible deterioration of a person's state of health, in which case it is classified as class III; - in a serious situation with a risk of causing a serious deterioration of a person's state of health or a surgical intervention, or to drive clinical management in a critical situation in which cases it is classified as class IIb - in a non-serious situation, or to drive clinical management in a serious situation or to inform clinical management in a critical or serious situation in which cases it is classified as class IIa; **- standalone software updates that do not materially change the risk to patients, such as updates to decision-support systems or electronic patient records, shall be considered low-risk and shall not require reassessment by a notified body** **- the medical professional remains ultimately responsible for clinical decisions.**
Justification	
The MDR currently applies the same regulatory scrutiny to software updates as it does to high-risk devices. This approach is disproportionate, particularly for software updates related to decision-support systems or electronic patient records, where a medical professional remains ultimately responsible. proportional regulatory requirements that streamline approval processes for software updates, reducing costs and timeframes for low-risk innovations while maintaining safeguards for high-risk applications.	