Proposed MDR Amendments and Clinical Data Requirements

An article published on LinkedIn in February 2025[1] discussed the blanket requirement under the current Medical Device Regulation (MDR; Regulation (EU) 2017/745) for clinical data for all devices, regardless of classification. The author submitted related comments to the European Commission during a recent targeted evaluation and call for evidence on the MDR/IVDR.[2] Although recently proposed amendments to the MDR introduce several provisions aimed at lessening overly burdensome requirements regarding clinical data, critical problems remain, which are likely to negatively impact decisions of small and medium-size manufacturers to market their medical devices in Europe. This article discusses the proposed amendments concerning clinical data-related requirements.

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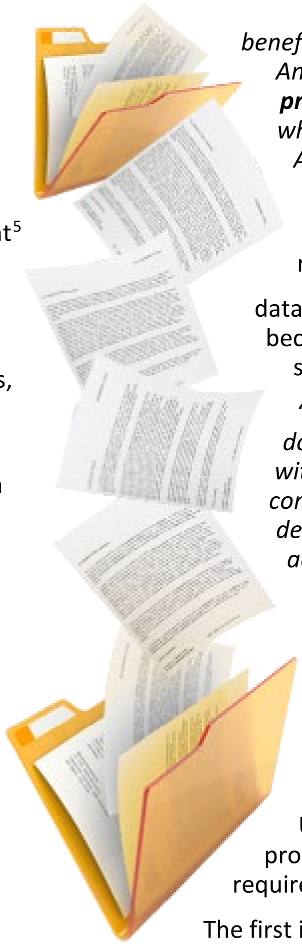
Proposed amendments

On 16 December 2025, the European Commission published a proposal for amending the MDR and In Vitro Diagnostic Medical Device Regulation (IVDR; Regulation (EU) 2017/746).[3] A separate document addresses amendments to MDR and IVDR Annexes.[4] A 195-page Commission document[5] provides the findings of targeted evaluation of the MDR and IVDR, which informed the proposed revisions. This article will address proposed amendments to the MDR concerning clinical data-related requirements, including relevant definitions.

The proposed amendments include 59 Recitals, which provide useful information on the rationale of the amendments being proposed. The Recitals primarily relevant to clinical data requirements, either directly or indirectly, include Recital 9 (clinical data definition), Recital 10 (well-established technologies), Recital 24 (Summary of safety and clinical performance), Recital 32 (clinical evaluation consultation procedure), Recital 38 (usefulness of non-clinical data), Recital 39 (clinical data from equivalent devices), and Recital 40 (Post-market clinical follow-up).



Blanket requirement for clinical data continues

The current MDR requires clinical data for all devices regardless of device classification, with limited exceptions discussed later. That is, MDR Article 61(1), subparagraph 1, states:

*"Confirmation of conformity with relevant general safety and performance requirements set out in Annex I under the normal conditions of the intended use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk- ratio referred to in Sections 1 and 8 of Annex I, **shall be based on clinical data providing sufficient clinical evidence**, including where applicable relevant data as referred to in Annex III."* [text highlighted for emphasis].

On initial examination of the proposed amendments, it appeared that the blanket requirement for clinical data would at long last be addressed. This is because the proposed text of Article 61(1), subparagraph 1, is:

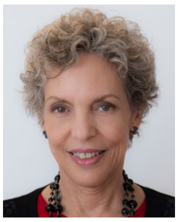
"Manufacturers shall plan, conduct and document a clinical evaluation in accordance with this Article and with Part A of Annex XIV to confirm the safety and performance of the device under normal conditions of use in accordance with the intended purpose of the device, and shall evaluate any undesirable side-effects and the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I."

That is, "*…**shall be based on clinical data providing sufficient clinical evidence…**"* has been removed.

Unfortunately, two other provisions in the proposed amendments maintain the blanket requirement for clinical data.

The first is the proposed text of Article 61(1), subparagraph 2, which is:

*"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." [text highlighted for emphasis].*



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Requiring that the level of clinical evidence be specified and justified is consistent with the current blanket requirement for clinical data because clinical evidence, as defined in Article 2(51) of the MDR (no change proposed), necessarily includes clinical data, namely:

"…***clinical data*** *and clinical evaluation results*…" [text highlighted for emphasis].

Thus, despite the proposed removal of the reference to clinical data in Article 61(1), subparagraph 1, clinical data are still required for all classes of devices as a general rule, unless the requirements of Article 61(10) can be met, under which clinical data must be considered not appropriate.

The second provision reinforcing the blanket requirement for clinical data is the text of Annex XIV, Section 1, point (a), first indent (in italics below) which is that to plan, continuously conduct and document a clinical evaluation, manufacturers shall establish and update a clinical evaluation plan, which shall include at least:

"— an identification of the general safety and performance requirements that require support from relevant clinical data, or adequate justification that confirmation of safety and performance based on clinical data is not deemed appropriate in accordance with Article 61(10)."

The above text therefore requires support from relevant clinical data unless confirmation of safety and performance based on clinical data is justified as not appropriate in accordance with Article 61(10).

Elimination of PMCF Evaluation Report and consolidation of updating

In Article 61(11), the MDR requires that clinical evaluation be updated throughout the life cycle of the device with clinical data obtained from the implementation of the PMCF plan; however, under the current MDR, for class III and implantable devices, the PMCF evaluation report and if indicated, the summary of safety and clinical performance (SSCP) must be updated at least annually. While Article 61(11) governs the obligation to update the clinical evaluation, the requirement for a PMCF evaluation report as a specific document is in Annex XIV, Part B of the MDR.

The proposed amendments to Annex XIV, Part B, which are discussed later in this article, eliminate the requirement for a PMCF evaluation report as a distinct document and consolidate the documentation of PMCF results within the clinical evaluation report and technical documentation. In parallel, the proposed revision of Article 61(11) simplifies the updating requirements by providing that the clinical evaluation and, where applicable, SSCP are to be updated throughout the life cycle of the device with data and findings from the implementation of the PMCF plan and post-market surveillance plan, whenever those data and findings provide information relevant for the confirmation of device safety and performance.

Elimination of contract regarding an equivalent device from a different manufacturer

The introductory text of Article 61(4) concerning the need to conduct a mandatory clinical investigation narrows the applicable device type from "implantable devices and class III devices" to "implantable class IIb devices and class III devices". No change is being proposed regarding exceptions to the need to conduct a clinical investigation for an equivalent device marketed by the same manufacturer.

A very important change is proposed regarding an equivalent device from a different manufacturer. The proposed amendment removes the requirement for a contract in order to rely on clinical data from such a device for the purposes of demonstrating equivalence. The revision provides that a manufacturer of a device demonstrated to be equivalent to an already marketed device from a different manufacturer may rely on Article 61(4) only if the original clinical evaluation was performed in compliance with the requirements of the Regulation, and the manufacturer is able to provide clear evidence of this to the notified body.

New definition for well-established technology device

An important clinical data-related proposed amendment is the introduction of a new definition, "well-established technology device." In spite of a limitation, which is discussed below, the new definition should help reduce overly stringent requirements applied to devices for which safety and clinical performance characteristics are well-known, based on long-standing clinical experience. Currently, the only reference to well-established technologies concerns a limited set of implantable and class III devices, which are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors. These devices are subject to specific exemptions from certain regulatory requirements under Articles 18, 52 and 61 of the current MDR.

Recital 10 of the proposed amendments notes that devices based on well-established technologies have a lower risk profile than other devices of the same risk class and may therefore be subject to certain exemptions or more proportionate requirements. To broaden the application of this concept, the proposed amendments introduce a new definition in Article 2(72). In addition, the specific list of well-established technology devices included in Article 18 (Implant card and information to be supplied to the patient with an implanted device), Article 52 (Conformity assessment procedures), and Article 61 (Clinical evaluation) is replaced in the proposed regulation by a reference to the newly defined term.

The new definition is:

'well-established technology device' means a device that belongs to a generic device group, which fulfils the following criteria:

(a) it has simple, common and stable design;
(b) it has not been associated with safety issues in the past;

(c) it has well-known clinical performance characteristics and comprises standard of care devices with little evolution in indications and the state of the art;
(d) it has a long history on the Union market

It is useful to understand the basis of the definition, which originates in MDCG 2020-6.[6] The definition of "well-established technology" in the guidance document was conceptually based on the types of device with very simple designs listed in MDR Article 61(6)(b) (sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors). The guidance pointed out that this list may be expanded in future by means of delegated acts. In anticipation of this expansion, the identified features of the listed devices have formed the basis of the new definition.

Certain WET devices exempted from clinical investigation

A critically important change is proposed in Article 61(6)(b), which currently lists specific implantable devices and class III devices (sutures, staples, dental fillings, etc.) that are exempt from the requirement to perform clinical investigations. The proposed revised point (b) of Article 61(6) states that the requirement to perform clinical investigations pursuant to Article 61(4), does not apply to implantable class IIb devices and class III devices that qualify as well-established technology devices and for which the clinical evaluation is based on sufficient clinical evidence and is in compliance with any relevant product-specific common specification.

Expansion of device classes qualifying for expert panel review

The proposed amendments expand the range of devices for which a manufacturer may consult an expert panel, on a voluntary basis. Currently, under Article 61(2), manufacturers of devices in class III and class IIb active devices intended to administer or remove a medicinal product may consult an expert panel to review the intended clinical development strategy and proposal for clinical investigation. The proposed amendments extend this option to all class IIb devices, while maintaining the inclusion of class III devices.

Clinical evaluation consultation procedure

The proposed amendments revise Articles 54 and 55, which govern the use of expert panels and scrutiny mechanisms for high-risk devices, with implications for the regulatory oversight of clinical evaluation and clinical data.

Under the proposed amendments, the revised Article 54, Clinical evaluation consultation procedure for certain class III and class IIb devices, will be narrower in scope. While the current MDR clinical evaluation consultation procedure applies to class III implantable devices and certain class IIb active devices intended to administer and/or remove medicinal products, the revised provision limits its application to class III implantable devices, excluding custom-made devices. At the same time, the Commission is empowered to extend the scope of this procedure to other device types through delegated acts. In addition, derogation from the clinical evaluation consultation procedure may be based not only on compliance of a clinical evaluation with an applicable common specification, but also on compliance with a harmonized standard for a specific kind of device.

Article 55, Mechanism for scrutiny of conformity assessments of certain class III and class IIb devices, is proposed to be replaced by Article 55, Mechanism for scrutiny of conformity assessments. The revised Article 55 provides that the MDCG or the Commission may, based on reasonable concerns, request advice from expert panels or expert laboratories regarding safety and performance of any device. The revised article also clarifies the exchange of information between notified bodies, expert panels, expert laboratories, and manufacturers.

Corrected definition of 'generic device group'

Another seemingly minor proposed amendment will have important consequences because it corrects what appears to be an error in the current MDR. This concerns the definition of "generic device group" in Article 2(7). This issue was the subject of a previous article[7] addressing the MDR definition of "similar," which highlighted the implications of the current wording for device grouping. In that article, it was noted that the existing definition required modification to eliminate the error. It is therefore encouraging that this issue has been addressed in the proposed amendments. The current definition is:

*'generic device group' means a set of devices having the same or similar intended purposes **or** a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.* [second "or" bolded for emphasis].

Specifically, the current definition allows devices to be grouped based either on the same or similar intended purpose or a commonality of technology. By contrast, the revised definition requires both elements to be present, namely that devices within a generic device group must have the same or similar intended purpose **and** a commonality of technology.

The revised proposed definition in Article 2(7) is:

*'generic device group' means a set of devices having the same or similar intended purposes **and** a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.* ["and" bolded for emphasis].

Reorganization of clinical data definition

The proposed amendments include a revision of the definition of "clinical data" in Article 2(48), reorganizing the definition so that each data source is explicitly linked to either the device concerned or a device for which equivalence to the device concerned can be demonstrated, as shown in the proposed revision below:

'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from any of the following:

- *clinical investigations of the device concerned or of a device for which equivalence to the device concerned can be demonstrated;*

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

Proposed changes to Annex XIV, Clinical Evaluation and Post-Market Clinical Follow-Up

Various changes, in addition to the ones already discussed, are proposed to Annex XIV, Part A, Clinical Evaluation and Part B, Post-Market Clinical Follow-Up. Most are clarifications, so not all are discussed here. See the proposed amendments for all proposed revisions.

Two proposed MDR amendments are being made to Section 3, Part A of Annex XIV and address the establishment of equivalence.

The first concerns biological equivalence and is:

"…the device uses the same ***or similar*** *materials or substances in contact with the same human tissues or body fluids…"* [text highlighted for emphasis].

In contrast, the MDR specifies that the device must use the same materials or substances. By allowing similar materials or substances to be considered, the proposed revision introduces a degree of flexibility, with a corresponding expectation that appropriate justification would be needed to support biological equivalence.

The second concerns clinical equivalence and is:

"…the device is used for the same ***or similar*** *clinical condition or purpose…"*

The MDR requires that the device must be used for the same clinical condition or purpose. As in the preceding case, allowing a similar clinical condition or purpose to be considered introduces a degree of flexibility, with a corresponding expectation that justification would be required to support clinical equivalence.

A proposed MDR revision to Section 5, Part B of Annex XIV, is to insert the following sentence after the introductory sentence:

"Where PMCF 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."

This addresses the absence in the MDR of an explicit mechanism for documenting the non-applicability of PMCF.

A proposed amendment to Section 7 addresses the elimination of a PMCF evaluation report by requiring that the manufacturer analyze the findings of PMCF and document the results in the clinical evaluation report and technical documentation. That is, there is no requirement to document these findings in a separate PMCF evaluation report but, if adopted, the obligation to analyze and document PMCF findings remains.

Conclusion

The proposed amendments to the MDR introduce a wide range of potential improvements but fail to address the blanket requirement for clinical data. This failure is likely to continue to lead many small and medium-size medical device manufacturers of critically needed medium and lower risk devices to market their products elsewhere, most notably in the United States.

It is particularly mystifying that the potential usefulness of consensus standards, in particular, harmonized standards, addressed in MDR Article 8, Use of harmonized standards, is not addressed in the proposed amendments. This omission is difficult to reconcile given the reference to standards provided by MEDDEV 2.7/1 revision 4,[8] which may be followed where it does not conflict with the MDR:

"It is important to recognise that there is considerable diversity in the types and history of technologies used in medical devices and the risks posed by them. Many devices are developed or modified by increments, so they are not completely novel. It may be possible to draw on the clinical experience and literature reports of the safety and performance of an equivalent device to establish the clinical evidence, thereby reducing the need for clinical data generated through clinical investigation of the device under evaluation. Similarly, it may be possible to use compliance with harmonised standards to satisfy the clinical evidence requirements for devices based on technologies with well established safety and performance characteristics."

The adoption of the proposed MDR amendments should improve the regulations but does not resolve the fundamental problem of requiring clinical data where this is not needed, thus continuing to contribute to a reduction of potentially beneficial medical devices being available in Europe.

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[1] Donawa, M.E. MDR Clinical Data Mandate Threatening Device Access in Europe. Donawa Lifescience Regulatory Recap; February 2025. Originally published on LinkedIn and available on the Donawa Lifescience website.

[2] European Commission public consultation and call for evidence on the targeted evaluation of the Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Device Regulation (IVDR) (12 December 2024–21 March 2025).

[3] European Commission. *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.* COM(2025) 1023 final; 2025/0404 (COD). Strasbourg, 16 December 2025.

[4] European Commission. *Annexes to the 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.* COM(2025) 1023 final; 2025/0404 (COD). Strasbourg, 16 December 2025.

[5] European Commission. *Commission Staff Working Document – Evaluation on the targeted evaluation of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices*, accompanying the Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746, and amending Regulation (EU) 2022/123 and Regulation (EU) 2024/1689. SWD(2025) 1051 final, Strasbourg, 16 December 2025.

[6] 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).

[7] M.E. Donawa, Clarifying MDR Terminology: The Problematic Definition of 'Similar Device', October 2025 Originally published on LinkedIn and available on the Donawa Lifescience website.

[8] MEDDEV 2.7/1 revision 4, Guidelines on Medical Devices, Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC (June 2016).