Clarifying MDR Terminology: The Problematic Definition of 'Similar Device'

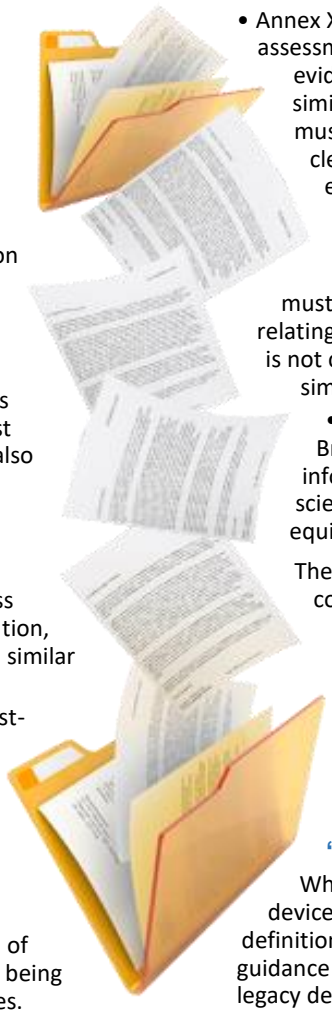
One of the most challenging aspects of demonstrating compliance with the Medical Device Regulation (MDR; 2017/745) and meeting Notified Body expectations concerns a lack of clarity of certain terminology used in the MDR. An example is 'similar device,' which is referred to in the MDR multiple times but defined only in European guidance. This article examines references to 'similar device' in the MDR, a misalignment of its definition in EU guidance, and an approach for addressing this issue.

Maria E. Donawa, M.D.

Range of MDR requirements for 'similar device' but no definition

The MDR includes a range of regulatory requirements concerning 'similar devices,' 'similar medical devices,' and 'similar products,' but does not define what these terms mean. The following MDR provisions refer to these terms:

- Annex II, Section 1.2: The device description and specification must include an overview of identified similar devices available on the Union or international markets, where such devices exist.
- Annex II, Section 6.1(a): The results of tests and evaluation of published literature must cover not only the device in question but also similar devices, with respect to pre-clinical safety and conformity with the specifications.
- Annex III, Section 1(a), fifth indent: The post-market surveillance plan must address the collection and use of available information, including publicly available information on similar medical devices.
- Annex III, Section 1(b), first indent: The post-market surveillance plan must describe a process that enables comparison between the device and similar products available on the market.
- Annex VII, Section 4.5.5: During clinical evaluation assessment, the notified body must conduct an in-depth review of the clinical evaluation, including consideration of clinical literature relevant to the condition being treated with the device or to similar devices.
- Annex VII, Section 4.10: Where listed as part of the conditions for certification, the notified body must conduct an in-depth review of the clinical evaluation as most recently updated by the manufacturer, based on post-market surveillance, PMCF, and clinical literature relevant to the condition being treated with the device or to similar devices.



- Annex X, Section 3(d): Concerning conformity assessment based on type-examination, where clinical evidence is based partly or totally on data from similar or equivalent devices, the notified body must assess the suitability of using such data and clearly document its conclusions on the claimed equivalence [the term "similar" is not repeated] and on the relevance and adequacy of the data for demonstrating conformity.
- Annex XIV, Section 6.2 (f): The PMCF plan must include an evaluation of the clinical data relating to equivalent or similar devices. (If equivalency is not claimed, an evaluation of clinical data relating to similar devices is required).
- Annex XV, Chapter II: The Investigator's Brochure for a clinical investigation must include information on existing clinical data from relevant scientific literature on the device and/or on equivalent or similar devices.

These requirements illustrate the extent to which compliance with the MDR relies on identifying similar devices to inform and support MDR-related assessments of safety and clinical performance. A precise and consistent understanding of what constitutes a 'similar device' is therefore essential for compliance with these MDR provisions.

Need for correcting the definition of 'similar device' in MDCG guidance

While the MDR does not define the terms 'similar device,' 'similar medical device' or 'similar product,' a definition for 'similar device' can be found in European guidance MDCG 2020-6[1] on clinical evidence concerning legacy devices. MDCG 2024-10[2], the guidance on clinical evaluation of orphan medical devices, adopts the same definition.

It is important to note, however, that the definition of 'similar device' in MDCG 2020-6 is inconsistent with the obvious need for such a device to have both the same or similar intended purpose and a commonality of technology.

Maria E. Donawa, M.D.

Dr. Donawa is President of Donawa Lifescience, a leader in providing US and European regulatory and quality management system consultancy services. The company is also a full service CRO for medical device and IVD studies intended to support CE marking in Europe and marketing submissions in the US. Dr. Donawa is a stakeholder member of the European Commission's Clinical Investigation and Evaluation, Performance Studies and Evaluation (CIEPSE) and is also a member of ISO TC 194, WG 4, which is currently developing an international standard on clinical evaluation.

The definition of 'similar device' in MDCG 2020-6 and MDCG 2024-10 is:

*'similar device': devices belonging to the same generic device group. The MDR defines this as 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.* (MDR Article 2(7)) [text is underlined and bold for emphasis].

This aligns with an earlier definition of 'generic device group' under the Medical Device Directive (MDD; 93/42/EEC), where the term was similarly defined in guidance to inform Notified Bodies planning technical documentation sampling for conformity assessment purposes[3], based on commonality of intended purpose **or** technology.

The conjunction 'or' following the word 'purposes' in the definition of 'similar device' indicates that only one of the two qualifiers — 'same or similar intended purpose' or 'commonality of technology' — is required to establish a 'similar device.'

Thus, if this definition is adopted by manufacturers when presenting clinical evidence for their own device, conclusions reached regarding device safety or clinical performance may be flawed. This is because, to meet MDR requirements and reach valid conclusions regarding safety and clinical performance based on similar devices, these devices must have the same or similar intended purpose **and** a commonality of technology.

For example, two balloon catheters may belong to the same generic device group because they share a commonality of technology. If one is intended for dilating blood vessels and the other for widening the esophagus, they cannot be considered similar for the purposes of evaluating safety and clinical performance according to MDR requirements because they have differing intended purposes. This is just one example of why the definition of 'similar device' in MDCG 2020-6 and MDCG 2024-10 needs to be addressed.

MDR requirements concerning 'generic device group' and sampling

Considering the fact that the MDR definition of 'generic device group' has been used in a European guidance document to define 'similar device,' it is relevant to understand MDR requirements concerning 'generic device group.'

This term is defined in MDR Article 2(7) as:

'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.

As discussed previously, this means that a generic device group may represent the same or similar intended use or a commonality of technology, or both these conditions may also exist.

The following are the only two MDR requirements concerning 'generic device group:'

- Article 11(2), which requires the authorised representative's mandate to cover at least all devices of the same generic device group, and
- Article 52(4), which requires that for class IIb devices, other than custom-made or investigational devices, at least one representative device per generic device group must be reviewed during conformity assessment.

Thus, the MDR specifies requirements related to 'generic device group' for manufacturers requiring an Authorized Representative or manufacturers with class IIb devices.

Issues concerning identification of devices within the same 'generic device group'

It is important to note that the process of identifying devices within the same generic device group is not explained in MDCG 2020-6 or MDCG 2024-10. Instead, the identification of generic device group for the purpose of sampling devices during the assessment of technical documentation by the Notified Body is explained in general terms in MDCG 2019-13 Rev 1[4].

That is, MDCG 2019-13 Rev 1 states:

"3.2. Generic device group (Ref 2): is to be understood:

- *in respect of the MDR (Ref 3,4) as the 4th level of the European Nomenclature on Medical Devices (EMDN) (Ref 5, 6) (i.e. a combination of one letter plus 6 digits);"*

The following references in this section of the guidance are important for understanding the process of identifying a generic device group:

> *"Ref 2: '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' (Art. 2 (7) MDR and Art. 2(8) IVDR).*
>
> *Ref 3: In cases, where the 4th level for the MDR does not exist the notified body should use the next higher level.*
>
> *Ref 4: If the notified body considers that for a particular device level 4 for the MDR/level 3 for the IVDR is not sufficiently specific to define a generic device group, it can use the next lower level if available.*
>
> *Ref 5: EMDN nomenclature can be found currently at: http://www.salute.gov.it/imgs/C_17_pagineAree_328_listaFile_itemName_15_file.pdf*[5]
>
> *Ref 6: In case where more than one EMDN code applies to one device, only the most appropriate one of these EMDN codes will be assigned for sampling purposes. The technical documentation related to that particular device will be assessed in its entirety."*

The following illustrates how this process can be applied in practice for sample selection for conformity assessment purposes. If we locate 'PTCA Balloon Dilation Catheter' in the list of EMDN codes (use the link in footnote 5), the corresponding code is C010401020101, which is a Level 7 entry.

To determine the generic device group, we identify its Level 4 ancestor, which in this case is C010401 – CARDIAC ANGIOGRAPHY DEVICES. Under MDCG 2019-13 Rev 1, §3.2, this Level 4 code constitutes the generic device group for MDR purposes. Accordingly, for sampling of technical documentation, devices classified at Levels 5-7 which descend from C010401 are all considered to belong to the same generic device group.

This grouping is not appropriate, however, for identifying 'similar devices' for the purpose of evaluating safety or clinical performance, because the range of devices within this generic device group is too broad and includes multiple intended purposes and technologies.

For example, within this same generic device group (descendants of C010401) are:

- C010401020402 - CORONARY ARTERY ATHERECTOMY SYSTEMS, ROTATIONAL (Level 7), and
- C010401020102 - CORONARY STENT IMPLANTATION DILATION CATHETER (Level 7).

These clearly have very different intended purposes and technologies and therefore cannot be considered 'similar' in the context of safety or clinical performance evaluation.

Empirical identification of 'similar devices'

As discussed in this article, identifying a generic device group is problematic for determining 'similar devices' for safety and clinical performance purposes. Manufacturers may therefore wish to identify 'similar devices' empirically, without reference to a specific generic device group. In general, this will involve conducting searches of the scientific literature, competitor websites, and other competitor device information. Such searches are often performed during the device design phase, even before clinical evaluation considerations have begun.

If an empirical method is used, it is recommended that a definition for 'similar devices' is documented. An example of such a definition may be: 'similar devices': medical devices having the same or similar intended purposes and a commonality of technology, useful for evaluating safety or clinical performance data.

In addition, manufacturers using an empirical approach should be able to justify the method employed. Documenting the basis for concluding that one or more devices can be considered to be a 'similar device' is advisable. Thus, a table listing similar devices may include, for example: product name, intended purpose, any indications, intended users, patient population, ~~and~~ medical condition, or other information where relevant. This will provide a clear explanation of the approach taken concerning the basis for identifying 'similar devices.'

Need for clearer definition of 'similar device'

The analysis presented in this article demonstrates that the definition of 'similar device' used in current MDCG guidance does not align with MDR principles. For clinical evidence from another device to be valid in demonstrating safety or clinical performance, the devices must share both the same or similar intended purpose and a commonality of technology. The article also highlights that identifying a relevant generic device group, as a possible means of defining similar devices, is problematic in practice. Clarification of the definition of 'similar device' in future guidance should resolve the problems described.

Note: This article has been provided to the Medical Device Coordination Group Working Group, Clinical Investigation and Evaluation, Performance Studies and Evaluation (CIEPSE), which is responsible for developing and issuing the guidance documents referenced in this article. The author is a stakeholder representative in this group.

Maria E. Donawa, M.D.
Donawa Lifescience
Piazza Albania 10, 00153 Rome, Italy
Tel. +39 06 578 2665,
medonawa@donawa.com
www.donawa.com

[1] 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)

[2] MDCG 2024-10, Clinical evaluation of orphan medical devices (June 2024)

[3] NBOG BPG 2009-4, Guidance on Notified Body's Tasks of Technical Documentation Assessment on a Representative Basis (July 2009)

[4] MDCG 2019-13 Rev.1 Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation (December 2024 rev.1)

[5] A more valid link is https://webgate.ec.europa.eu/dyna2/emdn/build/EMDN%20V2_EN.xlsx