GMED LNE GROUP Newsletter

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CLINICAL EVALUATION: THE STRATEGIC PATH OF WELL ESTABLISHED TECHNOLOGIES (WET) FOR LEGACY DEVICES

Demonstration of compliance with general safety and performance requirements must be based on clinical data providing sufficient clinical evidence. The manufacturer must specify and justify the level of clinical evidence required for the device under evaluation.

For legacy devices[1], MDCG 2020-6 provides guidance to manufacturers on the level of evidence required and accepted for these devices. This guide introduces a strategic route for legacy devices based on a well-known and stable technology, referred to in the text as Well Established Technologies (WET).

What is allowed when using this approach? When and how to apply it? What are the pitfalls to avoid? GMED answers these questions in this latest edition of its newsletter.

A WHAT IS ALLOWED WHEN USING THIS ROUTE? TO WHICH DEVICES DOES IT APPLY?

The route called "Well Established technologies for legacy devices" is only really addressed in the MDCG 2020-6 guide. This document highlights the provision related to paragraphs 1 and 6.a of Article 61 of Regulation (EU) 2017/745, on sufficient clinical data for "legacy devices". It paves the way for the use of low-level evidence data for so-called "standard of care devices[2]", otherwise known as "Well Established technologies (WET) legacy devices".

The MDCG 2020-6 guide states that a "legacy device" can only be claimed as a WET in exceptional cases. Use of this route should therefore be considered with great care.

[1] *Devices which, in accordance with Article 120(3) of Regulation (EU) 2017/745 (RDM), are placed on the market from the date of entry into force of the regulation and until the dates referred to in Article 120(3a) and (3b) of the RDM, if certain conditions are met.*
These devices can be:

- *Class I devices in accordance with Directive 93/42/EEC, for which an EC declaration of conformity was issued before May 26, 2021, and for which the conformity assessment procedure in accordance with the MDD requires the intervention of a notified body, or;*
- *Devices covered by a valid CE certificate (in accordance with article 120 paragraph 2 of the RDM) issued under Directive 90/385/EEC or 93/42/EEC before May 26, 2021.*

[2] *Treatment recognized by medical experts as appropriate for a certain type of illness and widely used by healthcare professionals.*

This route is applicable to all device classes, even implantable and Class III legacy devices, according to Appendix III of MDCG 2020-6: *"Class III legacy devices and implantable legacy devices which are not well-established technologies should have sufficient clinical data as a minimum at level 4. Those devices which are well-established technologies may be able to confirm conformity with the relevant GSPRs via an evaluation of cumulative evidence from additional sources as listed below. Reliance solely on complaints and vigilance is not sufficient."*

This route is to be distinguished from the notion of Well Established Technologies in the regulatory text. These WETs listed in Regulation (EU) 2017/745, Article 61(6.b) consist of an exhaustive list of DMs exempted from the obligation to conduct clinical investigations.

Even if the semantics are the same, they don't point to the same concept, and this can be a source of confusion.

B WHAT ARE THE CRITERIA FOR USING THE WET STRATEGIC ROUTE ?

In order to declare a legacy device as a WET according to the MDCG 2020-6 guide and claim the use of low level of evidence cumulative clinical data, it must be demonstrated that the legacy device meets the following four criteria cited in section 1.2 of the guide:

- A relatively simple, common design, with minor evolutions;
- A generic group whose security is well known and which has not been associated with security problems in the past;
- Well-known clinical performance and that its generic group corresponds to "standard of care devices" with little evolution in indications and state of the art;
- Significant market experience.

GMED offers further explanations of these criteria:

- **A relatively simple, common design, with minor evolutions, implies two aspects**:
  - A simple, familiar design with commonly used materials;
  - Minor changes have been made to the device since it was first marketed, but these do not affect the way it functions.

  These two aspects will have to be demonstrated both for the device under evaluation and for similar products in the generic group identified within the state of the art.

- **Demonstrating that the device belongs to a generic group whose safety is well known and not associated with past safety problems** must include, as a minimum, the collection of data from the post-marketing surveillance (PMS) process, from vigilance databases, guides, or assessment reports from the French National Commission for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS), a body of the French High Authority for Health (HAS), the MAUD database, the Federal Institute for Drugs and Medical Devices (BfArM), the Medicines and Healthcare products Regulatory Agency (MHRA), and the National Institute for Health and Care Excellence (NICE), for example, and literature searches of scientific articles. This demonstration requires an exhaustive approach, the application of best practices, details of key words and their relevance, as well as the inclusion and exclusion criteria used. This applies both to similar devices in the generic group and to devices under evaluation. It must also be demonstrated that the generic group safety is favorable and known, and that the device under evaluation safety is comparable to that of the generic group.

- **Demonstration that the device has known clinical performance and that its generic group corresponds to "standard of care devices" with few changes in indications and state of the art**, must be established based on state-of-the-art data available for similar devices. It must be demonstrated that the device under evaluation is sufficiently close to similar devices in the generic group to be able to use its data. This should include performance data taken, for example, from evaluation reports such as those drawn up by CNEDiMTS, NICE, etc. The device under evaluation must also have the same indications as similar devices in the same generic group, as well as the same user(s). **Different indications, different target populations or different users will call into question whether the device is a WET**.

- Lastly, it must be demonstrated **that the device has significant experience on the market**, by showing the date of CE marking of the device under evaluation and that of similar devices belonging to the same generic group. CE marking dates for different indications should be specified, if applicable.

All Member States in which the device under evaluation and similar devices are made available must be considered. If the coverage of the European market is different and is reduced to 1 or 2 countries, this calls into question the principle of "Well Established Technology".

For a device to qualify as a "WET legacy device", the available clinical data must cover the entire lifetime of the device, for each claimed indication.

C WHAT CLINICAL DATA CAN BE USED WHEN THE DEVICE IS A "WET LEGACY DEVICE"?

Once correspondence to the criteria has been demonstrated and the device has qualified as a "WET legacy device", both for the under evaluation device and for similar devices in the generic group, it is then possible to use this route.

It is then possible to use low-level evidence clinical data, or even to consider such data as clinical data, even though they are not formally recognized as such by the regulations. This strategy also requires the accumulation of low-level evidence from different sources. These data are defined in the table in Appendix III of the MDCG 2020-6 guide, and correspond to level 5 to 12 clinical data. It should be noted that **the accumulation of vigilance and complaints data alone is not sufficient**: "*Those devices which are well-established technologies may be able to confirm conformity with the relevant GSPRs via an evaluation of **cumulative** evidence from additional sources as listed below. **Reliance solely on complaints and vigilance is not sufficient***."

Conclusion

The "WET legacy devices" route is one of the strategic routes available for collecting clinical data. However, it is only applicable to legacy devices. The manufacturer can only use it if the device under evaluation meets the “WET legacy device” criteria defined in MDCG 2020-6. Understanding the framework and what it underlies will avoid any free interpretation that would not be accepted by the notified body.

Furthermore, this approach does not allow clinical demonstration to be based solely on data from similar devices or on post-marketing data (complaints, vigilance, sales volume, etc.). It is based on an accumulation of low-level evidence from different sources, including PMS data and clinical data relating to similar devices. Only in the case of "WET legacy devices" can clinical data on similar devices be used to demonstrate device compliance.

See the next page to go further

To go further

TRAININGS FOR AMERICA REGION

The Clinical Evaluation Report (CER) Requirements under the EU MDR 2017/745
8-hour training session | October 30-31 | Virtual classroom

→ CHECK OUT THE PROGRAM

Post Market Surveillance and Vigilance - New Requirements under the European Medical Device Regulations
8-hour training session | November 01-02 | Virtual classroom

→ CHECK OUT THE PROGRAM

European Medical Devices Regulation (EU) 2017/745
2-day training session | September 27-28, 2023 | December 7-8, 2023 | Virtual classroom

→ CHECK OUT THE PROGRAM

TRAININGS FOR OTHER REGIONS

Understand the regulatory requirements for clinical evaluation to choose the right route
SA65 | 1-day training session | On demand

Conduct clinical evaluation of medical devices using the literature route
SA09 | 1-day training session | On demand

Meet regulatory requirements for post-market surveillance and vigilance
SA45 | 1-day training session | On demand

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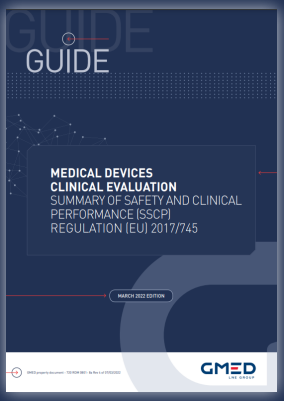
GUIDE

Medical Devices Clinical Evaluation – Summary of Safety and Clinical Performance (SSCP) – Regulation (EU) 2017/745

It is the manufacturer's responsibility to specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements under Regulation (EU) 2017/745.



This guide recalls the principles of clinical evaluation and describes the different elements to be included in:

- The clinical evaluation plan
- The clinical evaluation report
- The post-market surveillance plan including the post-market clinical follow-up (PMCF) plan
- The PMCF evaluation report

All these documents are part of the technical documentation, within the framework of CE marking procedures for medical devices, regardless of the medical device class.

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