
MEDICAL DEVICES: Guidance document

MEDDEV 2.12-2

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<p style="text-align: center;">GUIDELINES</p> <p style="text-align: center;">ON POST MARKET CLINICAL FOLLOW-UP</p>
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The present Guidelines are part of a set of Guidelines relating to questions of application of EC-Directives on medical devices. They are legally not binding. The Guidelines have been carefully drafted through a process of intensive consultation of the various interested parties (competent authorities, Commission services, industries, other interested parties) during which intermediate drafts were circulated and comments were taken up in the document. Therefore, this document reflects positions taken by representatives of interested parties in the medical devices sector.

**POST MARKET CLINICAL FOLLOW-UP OF
MEDICAL DEVICES UNDER
THE MEDICAL DEVICES DIRECTIVES**

Foreword : Rationale and Goals of PMCF

This document is intended to be a guide for manufacturers and notified bodies on how to carry out PMCF in order to fulfill post market surveillance obligation according to point 3.1 of annex II, point 3. of annex IV, point 3 of annex V, point 3.1 of annex VI or point 4 of annex VII of medical device directive (add ref. AIMDD)

While clinical evidence is an essential element of the premarket conformity assessment process, it is important to recognize the limitations inherent to these premarket clinical investigations. The extent of the data that can be gathered in the premarket phase does not enable the manufacturer to detect infrequent complications or problems only apparent after widespread use, or /long term performance issues. As part of the manufacturer's quality system, a program of appropriate post market surveillance is key to identifying and investigating risks associated with the use of medical devices placed on the market.

Manufacturers should have general systems in place to cover PMS as well as having a defined PMS strategy for each of their products/product ranges

Therefore, PMCF appears as a method of choice for this purpose. It will, for instance, enable patients' access to new therapies while establishing a review process for long term safety follow-up and detection of possible emergent risks that cannot be adequately detected by relying solely on pre-market clinical investigations (given the relatively short follow up required) or product experience /vigilance.

Implementation

Post market surveillance may include a number of strategies in addition to complaint handling and vigilance :

- active supervision by customer surveys,
- inquiries of users and patients,
- literature reviews,
- Post market Clinical Follow-up, etc..

Post market clinical follow-up (PMCF) through clinical studies and registries has a great importance among these strategies.

Post Market Clinical Follow-up (PMCF) should always be considered for devices where identification of possible emerging risks and the evaluation of long term safety and performance are critical. In identifying such emerging risk, the following criteria should be taken into account :

- **innovation**, when the design of the device, the material, the principles of operation, the technology, or the medical indication is new
- **severity** of the disease,
- **sensitive target population**
- **risky anatomical location**
- **well known risk** from the literature
- **well known risk** of similar marketed devices
- **Identification** of an acceptable risk during pre-CE clinical evaluation, which should be monitored in a longer term and/or through a larger population.
- **Obvious discrepancy** between the premarket follow up timescales and the expected life of the product

All PMCF should be planned. The PMCF plan can take the form of extended follow-up of patients enrolled in the pre-market trials, and / or a prospective study of a representative subset of patients after the device is placed on the market. It can also take the form of open registries. This plan will need to take into account :

- Results of the clinical investigation including Adverse events identified
- Average life expectancy of the device
- The claims made by the manufacturer for the device
- Performances for which equivalence is claimed
- New information becoming available

PMCF, when carried out, must always be performed for the use of the product within its intended indications according to Instructions for use. National regulations on post market clinical studies must be taken into account.

The involved Notified Body should review the appropriateness of the manufacturer's general PMS procedures, incorporating PMCF, as relevant, as well their PMCF plan(s) and results for specific products as part of conformity assessment procedures and quality management system auditing

The follow up duration should take into account the average life expectancy of the product in its indication. Therefore, in case of a device subject to short term premarket follow up and intended to stay in the patient for its lifetime, a longer follow up will be required.

PMCF will not be required for products for which the long term clinical performance and safety is already known from previous use of the device. In the case the assessment of a product is performed through the concept of equivalence , PMCF should always be considered .

Post Market clinical Requirements (Risk based matrix)

The following table sets out a 'triage approach' and suggests general advice for the evaluation of products under different circumstances.

Notified bodies should be part of the decision making with the manufacturer if applicable.

PMCF	Product specificities	Required actions
<u>no PMCF</u>	Products for which the medium/long term clinical performance and safety is already known from previous use of the device , or from fully transferable experience with equivalent devices (except **)	<ul style="list-style-type: none"> • All received complaints and adverse events data shall be systematically reviewed, and all product related adverse events such as those described in Annex II 3.1 of the MDD must be notified to the relevant Competent Authority (ies). This includes all sources of information known by the manufacturer, including published literature. • Monitoring of postmarket performance should take into account relevant data publicly available with similar devices especially when the CE marking was based on equivalence.
PMCF	<p>Always considered for devices where identification of possible emerging risks and the evaluation of long term safety and performance are critical</p> <p>(**)Products quoted as "equivalent" devices where reference product is subjected to PMCF</p>	<ul style="list-style-type: none"> • Same as above , <ul style="list-style-type: none"> ➤ Plus • Post-Market Clinical Follow-up (PMCF) in the form of follow up of all or a justifiable subset of patients already enrolled in pre-marketing Clinical Investigations; or on specific sub-groups and/or prospective study or registry of a sample of products. A formal protocol should describe the duration of PMCF; identify patient population and data to be collected. <p>(NOTE: The manufacturer must justify the design, nature, and duration of post-marketing follow-up, having regard to any published standards)</p> <p>PMCF report to be provided to the relevant NB for review and to competent authority if requested.</p>

*Equivalence has been precisely defined and should be demonstrated according to the criteria described in the document "Evaluation of clinical data: A guide for manufacturers and notified bodies" (see annex 1 of this document).

ANNEX 1 : The Demonstration of equivalence

From MEDDEV.2.7.1 : guidelines on medical devices Evaluation of clinical data : a guide for manufacturers and notified bodies -Section 4.3.1 d)relevance of data

- The manufacturer must demonstrate equivalence in all the following essential characteristics with the device, which is the subject of the published reports. Equivalence means :

➤ **Clinical:**

- used for the same clinical condition or purpose;
- used at the same site in the body;
- used in similar population (including age, anatomy, physiology);
- have similar relevant critical performance according to expected clinical effect for specific intended use.

➤ **Technical:**

- used under similar conditions of use;
- have similar specifications and properties (e.g. tensile strength, viscosity, surface characteristics)
- be of similar design;
- use similar deployment methods (if relevant);
- have similar principles of operation

➤ **Biological:**

- use same materials in contact with the same human tissues or body fluids;

To be equivalent, the devices should have similarity with regard to the clinical, technical and biological parameters with special attention to the performance, principles of operation and materials; or if there are differences identified, an assessment and demonstration of the significance these might have on safety and performance must be documented.

For example, where the device under consideration and the device referred to in the published study has a new principle of operation, then the two devices cannot be considered equivalent. A new mechanism and action does not necessarily result in a new clinical benefit and therefore a specifically designed clinical investigation will be needed to provide data to demonstrate (or otherwise) the clinical benefit of the new device



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