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Short communication

The interplay between clinical evaluation, PMS and PMCF in the medical device lifecycle: challenges of the MDR Article 61(10)

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Introduction

Clinical Evaluation is a systematic and planned process to continuously generate, collect, analyse and assess clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer.

However, according to Article 61(10) of the Medical Device Regulation (EU) 2017/745 (MDR), the demonstration of conformity with General Safety and Performance Requirements (GSPRs) may be based on non-clinical data, provided that adequate justification is given by the manufacturer. This justification should be based on the results of risk management, the specifics of the interaction between the device and the human body, the intended clinical performance and the product-related claims.

In such cases, the manufacturer shall duly substantiate in the technical documentation why the demonstration of conformity with GSPRs, based solely on non-clinical testing methods (including performance evaluation, bench testing and pre-clinical evaluation), is considered adequate (MDR (EU) 2017/745).

The Article 61(10) pathway for clinical evaluation is mainly applicable to low-risk, non-invasive devices, particularly in cases where clinical benefits cannot be directly measured and safety and performance can be demonstrated through non-clinical data (e.g., bench testing, pre-clinical studies, mechanical testing, biological safety, usability, etc.). This pathway is not applicable to implantable devices and Class III devices (MDR (EU) 2017/745; MDCG 2020-6).

Contents of the justification for application of Article 61(10)

The demonstration of conformity with GSPRs of Annex I of the MDR without clinical data must be adequately justified in accordance with Article 61(10).

This justification is included in the technical documentation (prepared in accordance with Annexes II and III of the MDR) and should be based on at least the following elements:

- the specific interaction between the device and the human body,
- the intended clinical performance and the possibility to identify clinical benefits,
- the results of pre-clinical evaluation,
- the results of risk management,

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- relevant data from the state of the art and scientific literature (including similar or equivalent devices),
- post-market surveillance and vigilance data demonstrating an established safety profile,
- the claims of the manufacturer (IMQ, 2023).

To justify the use of Article 61(10), the manufacturer must identify potential device-related risks and demonstrate that these risks are not high. The elements of risk management should be sufficiently detailed in the clinical evaluation report to determine whether they support the use of non-clinical test methods. It should also be demonstrated that non-clinical test methods are appropriate in relation to the identified risks.

Furthermore, devices with a low level of innovation and well-established technology, for which sufficient data from similar devices are available, may be considered suitable for justification under Article 61(10). However, if relevant clinical data are available for the device itself or for similar or equivalent devices, this approach is unlikely to be accepted by the notified body (BSI, 2025; GMED, 2023).

Post-Market Surveillance (PMS) and Post-Market Clinical Follow-Up (PMCF)

All medical devices, including those evaluated under Article 61(10), require a clinical evaluation plan, clinical evaluation report, and PMS/PMCF plan.

PMS and PMCF activities are still performed under this pathway; however, they are typically limited to general PMCF activities, such as screening of scientific literature and collection of user feedback.

The purpose of these activities is to confirm that the device continues to comply with the current state of the art, to identify potential new risks and/or confirm existing risk estimations, and to verify that no relevant clinical data are available for the device, similar devices or equivalent devices. If new clinical data become available as part of PMS activities, the manufacturer may need to reassess the applicability of Article 61(10) (MDCG 2020-6, TEAM-NB).

Conclusion

The application of Article 61(10) requires a well-documented and scientifically justified approach demonstrating that conformity with GSPRs can be adequately established using non-clinical data.

Article 61(10) should be considered a possible evaluation pathway for certain low-risk devices and well-established technologies, where the generation of clinical data may not be necessary to demonstrate safety and performance.

The applicability of this pathway remains a subject of ongoing discussion, and in the absence of detailed guidance, there is still a degree of uncertainty among manufacturers, notified bodies and regulatory experts regarding its interpretation and implementation (GMED (2023), TEAM-NB).

References

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