



NEW GUIDELINES FOR MEDICAL DEVICES AND IN VITRO DIAGNOSTIC PRODUCTS

Introduction

The European Medicines Agency (EMA) has recently released a revised [guidance document](#) for applicants, marketing authorization holders, and notified bodies regarding medical devices and in vitro diagnostic products.

The guidance is provided to support the application of the regulations on medical devices (Regulation (EU) 2017/745 - MDR) and on in vitro diagnostic devices (Regulation (EU) 2017/746 - IVDR); the two regulations that changed the European legal structure for medical devices, introducing new responsibilities and requirements for EMA and national competent authorities in the assessment of certain categories of medical devices used in combination with medicines.

The revised guidance document, formulated as a Q&A, provides practical considerations on the implementation of the medical devices and in vitro diagnostic regulations for combinations of medicinal products and medical devices.

Applicable Framework Governing Borderline

Products combining a medicinal product and a medical device are regulated based on their main mode of action.

In this context, the Medical Device Coordination Group (MDCG), a regulatory body established under the new regulations on medical devices and composed of representatives from all EU Member States, has already issued a [Manual](#) on borderline and classification of medical devices under the above Regulations. Main purpose of this Manual is to standardize the classification process by guiding the competent authorities of the Member States towards the uniform application of the classification rules, including borderline cases. However, this Manual serves only as a supplementary guide for implementing EU legislation, with national competent authorities and courts responsible for making decisions at the national level.



The aspects concerning the borderline between medical devices and other types of products, also known as **qualification of a product**, are generally governed by Article 4 of the MDR and the corresponding Article 3 of the IVDR. **Borderline** cases are those for which it is not clear from the outset whether a given product is a medical device, or an in vitro diagnostic medical device, or not. Where a given product does not fall within the definition of medical device or is excluded from their scope, other EU or national legislation may be applicable. According to Recital 8 of the MDR, when determining the regulatory status of products in borderline cases involving medicinal products, human tissues and cells, biocidal products, or food products, the Commission should consult appropriately with the EMA, the European Chemicals Agency, and the European Food Safety Authority, as applicable.

Once a product is qualified as a medical device, it is assigned a risk class (I, IIa, IIb, or III), whereas for IVDs, the risk classes are A, B, C, and D. These classifications are governed by MDR Article 51 and IVDR Article 47, respectively.

New Guidelines and Recommendations

The recent guidance document should be read in conjunction with the Manual. It provides further clarity on the application of MDR and IVDR, whereas its revision is based on the experience gained since the implementation of the new Regulations and actual cases encountered.

More specifically, the document covers regulatory and procedural guidance for:

- integral drug-device combinations (medical devices that form an integral product with a medicine, such as pre-filled syringes) and their lifecycle management;
- medicinal products that include a medical device in their packaging (referred to as co-packaged) and how these should be labelled;
- the consultation procedure for medical devices with an ancillary medicinal substance (a substance that supports the proper functioning of the device) and;
- the consultation procedure for companion diagnostics, diagnostic tests that are essential for the correct use of a specific medicine.

Key Topics

Key topics addressed in the Q&As have as follows:

- **Regulatory Framework and Lifecycle Management:** Guidance is provided on regulatory requirements and lifecycle management for products like pre-filled syringes.
- **Labeling Requirements:** Moreover, the Q&As provide instructions for labeling medicines that include a device.
- **Consultation Process:** Procedures for products with a pharmaceutical substance supporting device function and for diagnostic products essential for correct medicine use are provided.
- **Ambiguous Products:** Companies should consult national authorities and notified bodies and may seek opinions from the EMA's Innovative Task Force (ITF). Minor product changes affecting quality, safety, or efficacy should be reported, whereas changes in indications, concentration, and form may require new certification.



Conclusion

Navigating the intricate landscape of medical device regulations demands vigilance and a comprehensive understanding of the evolving guidelines. The recent release of revised guidance by the European Medicines Agency underscores the importance of staying abreast of regulatory updates, particularly concerning the convergence of medical devices, pharmaceuticals and software.

The clarity provided by the revised guidance document regarding integral drug-device combinations, co-packaged products, and consultation procedures for ancillary medicinal substances and companion diagnostics offers invaluable insights for stakeholders across the medical device and pharmaceutical industries.

Furthermore, it is essential for companies to proactively engage with national authorities, notified bodies, and regulatory agencies such as the EMA's Innovative Task Force (ITF) to address any ambiguities or uncertainties surrounding product classification and regulatory requirements. This collaborative approach ensures alignment with regulatory expectations and mitigates the risk of non-compliance.

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