GMED LNE GROUP Newsletter

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ARTICLE 117 OF REGULATION (EU) 2017/745: WHAT YOU NEED TO KNOW ABOUT PLACING COMBINED DRUG-DEVICE PRODUCTS ON THE MARKET

Many medicinal products are designed for use with a medical device or part of a medical device. Given the wide range of medical devices or parts of medical devices that may be used with a medicinal product, new provisions have been introduced in Article 117 of Regulation (EU) 2017/745 to demonstrate the conformity of these medical devices or parts of medical devices.

The implementation of these provisions is the responsibility of the pharmaceutical companies applying for marketing authorization.

In this newsletter, we will detail the requirements of Regulation (EU) 2017/745 relating to the marketing of combined drug-device products. We will discuss when the intervention of a notified body is required, as well as the steps to obtain a Notified Body Opinion (NBOP). Finally, we will guide you through the selection of a notified body and the available documentary resources.

A In which cases the applicant for marketing authorization must involve a notified body in the process under Article 117 of Regulation (EU) 2017/745?

The applicant for marketing authorization must use a notified body if the product combines a medicinal product and a medical device and meets the definition of a "combination drug-devices product":

- It is an integral product, where the medicinal product and the device is a single product. This single product is exclusively intended for use in that specific combination and cannot be reused;
- The primary mode of action comes from the medicinal product over the medical device.

B In which cases the applicant for marketing authorization does not need to involve a notified body in the process under Article 117 of Regulation (EU) 2017/745?

The applicant for marketing authorization does not need to involve a notified body in the following situations:

- The medical device has a valid CE marking certificate issued by a notified body in accordance with Regulation (EU) 2017/745;
- It is a non-sterile Class I medical device with no measuring function and is not reusable;
- The action of the medicinal product is ancillary to that of the medical device;
- It is a medicinal product containing a medical device in its secondary packaging (co-packaging).

C How to choose a notified body?

The notified body chosen must be designated for the classification code(s) applicable to the medical devices concerned. The applicant for marketing authorization may use any notified body designated for these specific codes.

Information on the scope of designation of each notified body is available on the European Commission's NANDO (New Approach Notified and Designated Organizations) website.

D What is an NBOP?

NBOP stands for "Notified Body Opinion." It is an assessment carried out by a notified body, which confirms the conformity of the device part of a drug-device combination with the general safety and performance requirements set out in Annex I of Regulation (EU) 2017/745.

The NBOP issued by the notified body is sent to the applicant or marketing authorization holder so that it can be included with the marketing authorization application or variation, as needed.

E Is an NBOP mandatory for a medicinal product already on the market?

Applications for marketing authorization for drug-device combinations submitted after May 26, 2021, must comply with the requirements of Annex I to Directive 2001/83/EC, point 12 of section 3.2, as amended by Article 117 of Regulation (EU) 2017/745.

In the event of a change, it is up to the marketing authorization holder to determine whether the intervention of a notified body is necessary.

F How to obtain an NBOP (Notified Body Opinion) from GMED?

The process for obtaining an NBOP is similar to that for certification for CE marking under Regulation (EU) 2017/745.

1) **Initial contact:** The applicant or marketing authorization holder contacts GMED and provides the information needed to define the certification project;
2) **Issuance of a quote:** GMED issues a quote for the project;
3) **Formal application:** The applicant submits a formal application for certification with the signed contract;
4) **Submission of technical documentation:** The applicant provides technical documentation demonstrating compliance with the safety and performance requirements of Annex I of Regulation (EU) 2017/745, as well as associated evidence (e.g., biological evaluation, test reports, etc.);
5) **Technical documentation assessment by GMED:** GMED assesses the technical documentation and determines whether the device complies with the General Safety and Performance Requirements. If necessary, GMED requests additional information;

[1]*Commission Implementing Regulation (EU) 2017/2185 of November 23, 2017 on the list of codes and corresponding types of devices established for the purpose of clarifying the scope of the designation as a notified body in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in the field of in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council.*

6) Verification and decision-making: After final verification, and in the absence of any major or minor non-conformity that has not been addressed by an appropriate action plan, GMED makes a decision and issues an NBOP.

If you are not yet a GMED customer, contact our sales department at **sales@lne-gmed.com** to start the process. If you are already a customer, please contact your certification project manager.

What guidance documents are currently available?

- EMA/37991/2019 Questions & Answers for applicants, marketing authorization holders of medicinal products and notified bodies with respect to the implementation of the Regulations on medical devices and in vitro diagnostic medical devices (Regulations (EU) 2017/745 and (EU) 2017/746) (01/30/2025);
- EMA/CHMP/QWP/BWP/259165/2019 Guideline on quality documentation for medicinal products when used with a medical device (June 22, 2021);
- MDCG 2022 – 5 Rev. 1 Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices (October 2024);
- MDCG 2019-14 Explanatory note on MDR codes (December 2019);
- Documents published by Team-NB (https://www.team-nb.org/) concerning the documentation to be submitted, the interpretation of changes related to the device part, and a template for the Notify Body Opinion.

Conclusion

The marketing of combined drug-device products involves strict compliance requirements under Regulation (EU) 2017/745. It is essential for pharmaceutical companies to understand when the involvement of a notified body is required, how to choose one, and what steps to take to obtain a Notified Body Opinion (NBOP).

By following best practices and relying on available information, you can optimize the market authorization process for your drug-devices combination products. For more information, please contact our teams.

Choose GMED

CHOOSE GMED FOR THE CONFORMITY ASSESSMENT OF YOUR COMBINED PRODUCTS

GMED has extensive experience supporting pharmaceutical companies in preparing Article 117 conformity assessments and issuing timely NB opinions. With a deep regulatory expertise in medical devices and strong collaboration with pharmaceutical stakeholders, we can bridge the regulatory gap between device conformity and medicinal product requirements. Pharmaceutical manufacturers working with us benefit from structured, responsive evaluations that align with EMA's expectations, helping to de-risk and streamline the marketing authorization process.

To go further

TRAININGS FOR AMERICAN REGION

European Medical Device Regulation (EU) 2017/745
2-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

Technical Documentation per (EU) Medical Device Regulation 2017/745
3 half-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

Risk Management Applied to Medical Devices (ISO 14971:2019)
2-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

Biocompatibility of Medical Devices
3 half-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

TRAININGS FOR OTHER REGIONS

Understand the requirements applicable to combined products under Article 117 of Regulation (EU) 2017/745
SA60 | 1-day training session | On demand

Apply the requirements of European Regulation 2017/745 on medical devices
SA56 | 2-day training session | On demand

Adapt your quality management system to the ISO 13485 v2016 standard
SA19 | 2-day training session | On demand

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