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LOGFILE Feature 29/2020 – Substance-based medical devices

6-7 Minuten

21.07.2020

Certainty and challenges due to the new EU Medical Device Regulation

5 minutes reading time

by Felix Tobias Kern

The differentiation between medical devices and medicinal products is a constant challenge for pharmaceutical manufacturers. Does my product meet the definition of a medical device according to the EU Medical Device Directive (MDD) or the definition of a medicinal product according to EU-Directive 2001/83 for medicinal products? This is based on the main effect of the product. In contrast to medicinal products that act pharmacologically, immunologically or metabolically, the main effect of medical

devices is achieved primarily by physical means. If both medical device and medicinal product are combined in one product, the corresponding principal effect is decisive for the classification of the product.

What are substance-based medical devices?

Substance-based medical devices are not initially perceived by patients as medical devices, as they are similar to a medicinal product in terms of their form of administration and appearance. An example of this is the tablet. When is a tablet a medicinal product and when is it a substance-based medical device? This is also based on the main effect of the product. For example, if the active ingredient in the tablet creates a physical barrier over the mucous membranes so that irritations are reduced, the tablet may be a material medical device. If, on the other hand, it causes a reduction in bacterial growth, for example through an antibiotic effect, the tablet is a medicinal product.

Examples of substance-based medical devices:

Solid, semi-solid and liquid preparations, such as:

- Lozenges, Ultrasound gel,
- Tear or saliva substitute fluids,
- Seawater nasal spray,

which have no pharmacological effect on humans, but are used to detect and treat diseases.

How have substance-based medical products been treated so far?

Substance-based medical devices have not yet been duly recognised. The EU Commission had even considered removing them completely from the medical device law. In fact, the products are very relevant, especially in terms of health economics. Many of these products are over-the-counter and suitable for self-medication. They relieve the health care system extremely because patients try to treat themselves at their own expense before going to the doctor.

What is the Medical Device Regulation (MDR)?

The MDR is a European regulation that does not have to be transposed into national law and is directly applicable in the member states of the European Union. The MDR replaces the two EU directives 93/42/EEC on medical devices and 90/385/EEC on active implantable medical devices. The introduction of MDR is intended, among other things, to harmonize European medical device law, provide legal certainty for manufacturers of medical devices and facilitate access to the European market for new medical devices.

What will the Medical Device Regulation (MDR) change with regard to substance-based medical products?

1. The existence of the substance-based medical devices is confirmed and explicitly mentioned in the MDR with a new classification rule (Rule 21). This provides certainty for the manufacturers of these products that they can actually produce a substance-based medical device.

2. Significant tightening of the classification of substance-based medical devices with the introduction of its own classification rule (now classification at least in Class IIa/IIb or Class III).
3. Expected shortage of Notified Bodies: Due to the tightened classification of these products a conformity assessment procedure by the manufacturer himself is no longer sufficient. No substance-based medical devices will be assigned to Class I by the new classification rules. Accordingly, a new certification must be carried out together with a Notified Body. The number of Notified Bodies for substance-based medical devices in the EU is very limited.
4. Extended requirements for quality management: This concerns, for example, risk management, post market follow-up system and stricter clinical trials and evaluations.
5. Extended personnel requirements: This concerns, for example, the obligation to designate a responsible person and to prove their qualification to the authorities.

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