The instructions for use – more than just a duty

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The instructions for use is where the manufacturer and the user connect. Therefore, this document is of particular importance. The MDR did not only clarify the requirements for use but also made them stricter. The following article describes in detail when the instructions for use should be revised. In addition, the most important interfaces between instructions for use, clinical evaluation and risk analysis are discussed.

Terminology

Addressing the instructions for use begins with proper naming. The MDR defines „instructions for use“ in Article 2 (14) as “the information provided by the manufacturer to inform the user of a device‘s intended purpose and proper use and of any precautions to be taken”. The term is usually abbreviated as „IFU“. Terms that differ from this, such as „user manual“ or „direction for use“ should therefore be avoided.

When is an IFU obligatory?

Generally, the manufacturer is to provide information on the product (MDR, Article 10 and Annex I, Section 23). The content and legibility should be appropriate for the intended user. In this context the term „legibility“ certainly includes „comprehensibility.“

An exception applies to class I and IIa devices. For these devices, the MDR states that the instructions for use are expendable if the devices are self-explanatory and it can be assumed that the user is familiar with their safe use. This may be the case for simple products / instruments that are part of the standard armamentarium of the practicing physician. However, it should also be noted that the instructions for use may contain important information, e.g., on reprocessing.

More information is needed in IFUs for medical devices for lay use. In these cases, instructions for use can be considered mandatory.

Clinical evaluation

The clinical evaluation maps the risk profile of the medical device and includes, as an essential part, the comparison of the information presented in the instructions for use with the state of the art. It is mandatory that the instructions for use provide information on the intended purpose with indications, contraindications, the intended patient and user groups.

Especially in the case of generic products that are used for general patient populations, these requirements may seem somewhat excessive. Nevertheless, this information must be made fully available to the user, because it is used for the assessment of the benefit-risk ratio of a medical device in the clinical evaluation. This also applies to residual risks and possible complications, which must be disclosed to the user (and the patient) in the form of restrictions, precautions and warnings.

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Here, too, the clinical evaluation examines the agreement of the instructions for use with the current state of the art.

From our experience, recommendations for use that are stated quantitatively, such as a specific duration of use or a specific dosage, are also to be questioned. Such information must correspond to the scientific state of the art, as this also needs to be examined in a clinical evaluation.

Advertising claims

Closely related to the instructions for use, is the promotional presentation of the product. How is the product advertised on the website and in brochures? The statements made in the marketing material about performance, safety, indication and user must be both: verifiable and consistent with the information in the instructions for use.

Sometimes, marketing claims develop a life of their own and cannot be adequately substantiated by the state of the art or technical studies. Experience has shown, however, that it is precisely such claims that are readily questioned by the notified bodies. Article 7 of the MDR explicitly prohibits misleading claims regarding the intended purpose, safety and performance of the product in the instructions for use and in advertising.

Vigilance and risk analysis

If during the clinical evaluation new risks or complications are identified, they need to be discussed in the risk analysis. Consequently, the risk management often defines risk mitigating measures. It is vital that these measures and information do not get lost in the transition to the instructions for use. If new risks are discussed in the risk analysis, appropriate information, for instance, a warning or a restriction, which is addressed to the user / patient needs to be included in the IFU.

Of particular interest may be the paragraph 1 (a) of Article 87 (MDR), which deals with the reporting of serious incidents related to products made available on the Union market. Indeed, the reporting requirement does not apply if an event is an „expected adverse reaction“ that is already clearly documented in the product information. That means if a complication is stated in the instructions for use and is quantified in the technical documentation, i.e., risk analysis and clinical evaluation, and is subject of trending reports, the reporting requirement does not apply.

Instructions for use, risk analysis and the clinical evaluation must be consistent

Conclusion

In the course of the transition to the MDR regulations, a revision of the instructions for use in accordance with the extensive specifications of Annex I will be necessary in many cases.

It should be noted that the information in the instructions for use „fits together“ with the clinically relevant parts of the technical documentation: The information, measures and precise wording on intended purpose, indications, contraindications, patient population, users, warnings, possible complications, etc. must be coordinated in all parts of the technical documentation.

- There is a large number of interfaces between the IFU and the clinical evaluation, risk management, the usability and the vigilance system.
- The information in the instructions for use on application, intended purpose, indications, contraindications, patients, users, warnings, risks, etc. must be backed by the current state of science and / or b clinical data.
- Marketing claims are part of the technical documentation and must also be in line with the clinical evaluation and instructions for use.