EU MDR - New Reporting and Documentation Requirements for Distributors and Importers of Medical Devices

Distributors and importers of medical devices have a lot to be prepared for when the transition period of the EU MDR - EU Medical Device Regulation 2017/745 ends on May 26, 2021. With EU MDR Article 13: "General Obligations of Importers" and Article 14: "General Obligations of Distributors", there are now sections that explicitly address importers and distributors.

This is a novelty - because the still valid MDD - Medical Device Directive 93/42/EEC hardly defines responsibilities and duties for these actors. For this reason, importers and distributors must now deal intensively with the new requirements and implement them consistently in order to work in compliance with the EU MDR.

What reporting requirements have been defined?

In addition to the obligation to ensure that the products placed on the market comply with the applicable requirements of the EU MDR, it defines in detail which notification obligations importers and distributors have in the event of non-compliance.

Importers and distributors are now obliged to inform the manufacturer and, if applicable, the EU Authorized Representative and, as a distributor, the respective importer as soon as a product (potentially) does not comply with the requirements of the EU MDR. It is irrelevant whether the product is already on the market or not. Forwarding the information to the manufacturer and/or the authorized representative is necessary in both cases.

This responsibility goes even further: if a product poses a (potentially) serious risk, the competent authorities of the member states, in Germany the BfArM - Bundesinstitut für Arzneimittel und Medizinprodukte, in which the product was made available, must also be informed.

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The same obligations await importers and distributors should there be a suspicion that a product is counterfeit. If such a product is already on the market, importers are also obliged to inform the Notified Body.

What does this mean in concrete terms?

Suppose an importer or distributor receives feedback from a customer that a patient developed arrhythmias immediately after insertion of a pacemaker and died.

This is a serious event associated with a marketed product. Possibly a serious hazard emanating from this product.

According to the new legal situation, the distributor is obliged in this case to inform the manufacturer and, if applicable, the importer as well as the EU authorized representative. The importer must also inform the Competent Authority and the Notified Body directly.

According to MDD requirements, the importer's/distributor's responsibility often ended after the notification to the manufacturer. Now, significantly more responsibility is assigned to importer and distributor.

To ensure product safety, the law further requires importers and distributors to keep records of recalls, withdrawals, complaints and feedback from the market, which must be submitted to the manufacturer upon request.

In addition, importers and distributors must immediately forward all feedback from healthcare professionals about suspected incidents to the manufacturer, its authorized representative if applicable, and as a distributor to the respective importer.

How can this be implemented?

Importers and distributors are now obliged to document all feedback from the market and to keep this information available. Depending on the circumstances, the feedback must be passed on to the supplier and, if applicable, to the supplier's authorized representative and the importer without being requested to do so.

Although seemingly a minor issue, this point could cause headaches for distributors and importers, as this requirement can quickly become an enormous amount of information. Which has to be organized and processed!

Particularly in the case of products directly for the end consumer, for example in the context of the supply of medical aids or medical products from the supermarket, large amounts of data can quickly accumulate here.

Therefore, the question arises for importers and distributors whether it makes sense or is even necessary to implement a quality management system for the systematic documentation of all feedback and complaints coming from the market. In any case, defined processes are required to ensure the necessary reporting chains - for example, from the patient to the application specialist to the manufacturer/EU representative - and to process and channel the mass of information. The handling of non-conformities would also be much easier to control and track with the help of a quality management system.

The gempex Medical Devices team offers support around the compliant market provision of products, is specialized in evaluating regulatory requirements also for distributors and importers individually and risk-based and in implementing a solution that equally ensures compliance and is economical in implementation. Together with the customer, the experts develop appropriate QM systems or derive measures specifically tailored to the individual case. Precisely tailored, with an eye to the specifics, compliance and efficiency of the solutions.