German Summary:

Die Diskussion um die Wiederaufbereitung von Einmal-Medizinprodukten ist alt. Durch den nun vorliegenden Bericht der Europäischen Kommission an das EU-Parlament über die Wiederaufbereitung von Medizinprodukten in der Europäischen Union bekommt die Debatte wieder Nährstoff. Und mehr Fragen als Antworten. Der deutschsprachige Beitrag ist nachzulesen auf www.meditec.mi-verlag.de

Round two for single-use devices?

The discussion revolving around the reprocessing of single-use medical devices is anything but new. The report on the reprocessing of medical devices in the European Union, prepared by the European Commission for the EU Parliament and now available, is adding new fuel to the debate. And more questions than answers.

In product liability matters, there are different stages in which a manufacturer has the responsibility to avoid errors of diligence. Errors during the product design or development are usually especially serious, because they can lead to series or mass damages. So far this applies to all industries.

In the case of medical devices, the requirements placed on the manufacturers by the Medizinproduktegesetz (German Medical Devices Act) and the associated standards are even higher. And sensibly so, because here each product is developed for use more or less close to the patient. Medical devices allow no compromises in production safety, traceability or product liability. Damages that arise here are extremely sensitive, and naturally personal injuries are seen more often here than in other industries.

Given this precondition, we can only marvel at the fact that a medical device designed for single use and very deliberately intended to present an alternative to similar reusable products is permitted to be reprocessed and used in Germany. The manufacturers of these single-use medical devices are even obligated to point out risks and hazards that would arise if the product were to be reused. What distinguishes the device is precisely the fact that it was developed and produced for single use. For this reason - what a surprise - the reprocessing is per se associated with a risk. After all, a device is being used for a purpose other than the one intended when it was made.

"My advice is to fully and fundamentally steer away from the reprocessing of single-use devices," relates Johann Steinhauser, Head of the Medical Technology Service Centre and the central supply of sterile goods at the Tübingen University Hospital. "The expense and the benefits are out of all proportion. It is already costly enough to reprocess some reusable products in a validated process, even if the manufacturer has stipulated the process for these products."

The EU report quotes a report from the Netherlands, according to which the validation of a reprocessing method for single-use medical devices is a

task that can normally not be carried out in a hospital because of a lack of the necessary equipment, knowledge, experience and resources. Johann Steinhauser finds that the question of whether or not the hospitals are suitable for the job is irrelevant. "These are single-use products. Reprocessing them is quite simply not a matter for debate in our facilities."

In the opinion of Franz Döpp, Head of Quality Management, Regulatory Affairs and assistant medical device safety officer at Geuder AG, a manufacturer of ophthalmic surgical devices, everything would be right with the world if all users were to share this opinion. But he knows that there are more than just a few single-use products manufactured in his company that are in use in a reprocessed form. It is clear to him that in this case, users are fully responsible in terms of liability law. "It is the users who ultimately decide that they want to work with reprocessed single-use devices. And it is the users who decide how to reprocess these devices. The question of whether this takes place internally or with a service provider is neither here nor there, as I understand it." This corresponds to the logic that applies to his company as a medical device manufacturer, where it is obvious that there is full responsibility according to product liability law, even for the outsourced portions of the completely validated production process. In contrast, the EU report states that the sharing of liability between user and reprocessing service providers appears unclear.

It is clearly formulated in the EU report that the lower purchasing costs of a medical device can only represent one of many aspects in the assessment of the costs for the use of reprocessed single-use medical devices. Franz Döpp gets to the heart of the matter with simple questions. "How much does an eye infection cost? Or surgery that runs a longer course because a single-use instrument no longer functions correctly after being reprocessed?" The EU report nevertheless does not clearly deny that there are potential cost savings. Seen in the light of day, however, the expense for a validated reprocessing procedure is probably so high that only very minimum savings can be achieved. If the indirect costs, such as those that result from residual contamination, chemical substance residues and the product's altered performance caused by the reprocessing, are also added in, it becomes apparent that those whose final count shows savings must be suspected of a naïve assessment of the situation.

The sharing of liability between user and reprocessing service providers appears unclear

Franz Döpp, Head of Quality Management, Regulatory Affairs and assistant medical device safety officer at Geuder AG: "How much does an eye infection cost? Or surgery that runs a longer course because a single-use instrument no longer functions correctly after being reprocessed?"

The ethical considerations that are listed in the report include a question of whether or not the additional risk to patients result in an obligation with regard to patient information and prior informed consent. This would certainly take care of this topic. "Do you consent to being treated with a reprocessed single-use product if doing so means that you must accept an increased risk of infection?" Surely, the only way to obtain consent to this question would be by hedging it with restrictive clauses until it is no longer recognizable.

Ramona Riesterer ←

"The manufacturer's obligations do not end until its product has been disposed of"

Philipp Reusch validates the reprocessing of single-use medical devices from a lawyer´s point of view.

Mr. Reusch, what role does a manufacturer play when its single-use devices and products are reprocessed?
The rule for manufacturers is: if they visibly label their device or product with a statement indicating that single use is the intended use, there is no immediate cause for becoming involved in processing issues in the normal product liability law context. The manufacturer must observe the market, however, and keep an eye on user conduct; the manufacturer's obligations do not end until its product has been disposed of. An altered use acts in reverse, as it were, on the intended use.

Does this mean that the manufacturer must react if enough users use a product in a certain way, even if this type of utilization is not foreseen in the original purpose?
Exactly. And this is what leads to the obligation to point out the risks that are associated with the reprocessing of single-use devices and products.

Now that the EU report has been submitted, how do you think this situation will be addressed and regulated?
Directive 2007/47/EC clarified the term "single-use device" for the first time. Because different regulations apply in the various countries, for example, reprocessed single-use devices are not allowed at all in England and France and the regulations in the Netherlands are similar to those in Germany, the EU must ask what is the best solution in the context of consumer protection, or, in this case, patient protection. From the original manufacturer's point of view, the best solution would certainly be to prohibit reprocessing of single-use devices. If this is not the case, it must be ensured that all detailed questions that are still open are unambiguously regulated - for example, labelling obligations as to whether the patient must provide informed consent and other issues.

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