

Position Paper Patient Safety

Reprocessing in Europe – Focus on Patient Safety

When it comes to human safety and personal health no compromise is acceptable. Especially in terms of those who need utmost protection. Having access to high-quality healthcare when and where it is needed is a priority issue for European citizens, which is also recognized in the Charta of Fundamental Rights of the EU. This is why national and international organizations and competent bodies set up different regulatory frameworks for the protection of consumers. Today, increased movements of patients together with the dissemination of new medical technologies such as pharmaceuticals and medical devices pose new challenges to law-makers and competent authorities. Health issues do not longer respect the borders of single States – if they ever did so. Consequently the European Union focuses more than ever on regulation concerning health issues, and health systems as well as health policies across the EU are becoming more and more interconnected.

However and despite these desirable efforts that have been made, it is still a fact that patient safety is at stake when we speak about reprocessing medical devices in Europe – which has nothing to do with technical or hygienic reasons. It is the sole decision of the manufacturers of medical device to declare their medical device as either 'single-use' or 'multiple-use'. Though the single-use label says little about the actual reprocessability of a medical device, many national regulations still recommend to follow this label. Reprocessing includes all the steps needed to treat a medical device after use in a patient to prepare it for a safe reuse in the next patient. Actually, thanks to scientific and technological opportunities, professional third-party reprocessing service providers created conditions that enable hospital officials to profit from cost effectiveness as well as patients to have broader access to innovative and safe medical treatment. What puts patient safety at stake instead is the fragmented market itself: In some member states reprocessing is accepted and regulated under high quality standards, in some not recommended or explicitly prohibited, and in some member states a regulation does just not exist - despite the fact that reprocessing is common practice throughout all Europe. Thus prohibition has proven to not favour safety. The reason for this inconsistency lies in misleading implications of single-use labelling.

Serving as best practice, Germany has invented a coherent framework concerning reprocessing which does not refer to the type of labelling but defines

quality standards for reprocessing that have to be fulfilled and certified by an accredited body. These quality standards apply for any type of medical device, no matter which label the manufacturer has chosen. Validated reprocessing methods guarantee that the reprocessed medical devices leave their premises in an impeccable hygienic and functional condition. They follow documented and well-defined reprocessing procedures, thus fulfilling a level of patient safety comparable to the original product.

Under this framework and in compliance with already existing international standards (ISO, EN) reprocessing companies were in a position to develop state-of-the-art- methods guaranteeing that the reprocessed medical devices leave their premises in an impeccable hygienic and functional condition. Validation, documentation and traceability form the core of these reprocessing procedures. The highly reputed German Robert-Koch-Institute states that professional reprocessors fulfil all national and international guidelines concerning the decontamination of medical devices in order to prevent any transmission of infections. From that very patient point of view – as far as reprocessing is concerned – safety would no longer be a question of technical or scientific prerequisite. But a question of creating binding guidelines that fully accomplish the quality of the reprocessing of medical devices.

With regards to current developments at EU level and the forthcoming directive on cross-border health services, the reprocessing of medical devices should be in the political focus as well: When patients who are seeking cross-border treatment shall receive health care similar to what they would have been entitled to in their home country, member states will be in charge of ensuring the quality and exchanging safety standards also when it comes to reprocessing medical devices. This is not only because the question of liability and procedures to be followed in the event of medical malpractice will gain importance, but definitely also a patient safety topic.

About EAMDR

The European Association for Medical Device Reprocessing (EAMDR) was created in 2003. EAMDR represents and promotes the interests of associations and research institutes, companies, opinion leaders on hygiene and microbiology, reprocessing service providers as well as members of the medical device industry involved in the reprocessing of medical devices throughout Europe.

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