AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

AMDR Position on the Reprocessing Article of the Commission Proposal on a Medical Devices Regulation

AMDR welcomes the European Commission's Proposal for a Regulation for Medical Devices. The Proposal generally provides a sound balance between quality and safety of products and good patient care.

AMDR particularly welcomes the European Commission's commitment to setting clear regulatory rules for the reprocessing of medical devices as set out in Article 15.

Reprocessing and the reprocessing sector have undergone fundamental changes since the review of Medical Devices in 2007. In the absence of a regulatory framework providing clear EU-wide rules for reprocessing, hospitals and some third parties have been actively reprocessing "single-use" devices with at times inadequate processes.

AMDR represents manufacturers of medical devices that also engage in reprocessing, namely Sterilmed Inc., an affiliate of Ethicon-Endo Surgery, Inc. (a Johnson & Johnson company), and Stryker Sustainability Solutions, a division of Stryker Corporation. AMDR, therefore, only represents companies that have a most respectful reputation in the area of medical device development and manufacturing.

Whereas AMDR strongly supports a number of proposed measures laid out in the Commission's Proposal, a number of points would require improvement during the legislative procedure of the European Parliament and the Council of Ministers in order to strengthen clarity of the Regulation and further enhance safety and quality of reprocessed products.

CE Marking

AMDR strongly supports the Commission's proposal to define reprocessing of "single-use" devices as a manufacturing process, meaning that reprocessors need to comply with the same safety and quality standards as manufacturers and that a reprocessed product must therefore obtain a CE mark. Any organization not complying with the highest safety standards set out by the manufacturing requirements should be strictly excluded from conducting reprocessing.

AMDR therefore suggests to Members of the European Parliament and the Council of Ministers that this requirement of the Commission's proposal be adopted, which would exclude an organization from reprocessing that is not in full compliance with the manufacturing requirements of the Regulation.

Reprocessing of Critical Medical Devices

The European Commission notes that, the Commission shall, through implementing acts, develop lists of categories of critical devices that should not be reprocessed. Such provisions would be appropriate in a non-regulated environment. If the new provisions foreseen in this Proposed Regulations are in place, such potentially drastic exclusions would be inappropriate.

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AMDR agrees that certain critical devices cannot be reprocessed adequately, such as those used for neurological interventions. Reprocessors are not currently able to meet the manufacturer requirements for those devices because it is not possible to demonstrate conformance to the Essential Requirements; therefore, the regulatory framework already protects the public health by not allowing such devices to obtain a CE mark. Existing practice in the United States regulatory system, for example, follows this rationale and has proven effective and in accordance of high safety considerations.

AMDR therefore suggests to the European Parliament that this provision be reconsidered in favor of a limited and specifically defined criteria, to be developed during this legislative procedure, in order to bring the greatest possible clarity.

Labeling

AMDR supports the Commission Proposal in the respect that both the reprocessor as well as the original manufacturer should be named and identifiable for the user of the device. The Commission suggests placing the name of the reprocessor on the label and the name of the original manufacturer only in the accompanying instructions for use document.

AMDR suggests that, in the interest of convenience for the user of the device and hence patient safety, it would be beneficial to indicate that a product is a reprocessed device, name the reprocessor as well as the original manufacturer on the label of the device.

Member States Opt-Out Provision

The Commission Proposal notes that Member States can decide to prohibit reprocessing and the circulation of products from one Member State to another on the grounds on public health. Whereas AMDR recognizes that Member States may generally take any decision to protect the health of its citizens, it also believes that this clause will create major distortions of the single market and, therefore, does not comply with the EU principle of the free circulation of goods in the Community.

If the safety and quality measures, and therefore the manufacturers' requirements, are met fully in accordance to this Regulation, reprocessed products and newly manufactured should generally be subject to the same provisions.

A prohibition of use of a reprocessed product should therefore be no different to the prohibition of any other product manufactured in conformity with the manufacturers' requirements. Member States should therefore have to justify any prohibition on use of any product for any defined use if public health is endangered; this should be clearly outlined. AMDR suggests that Members of the European Parliament amend any general provision that would lead to a distortion of the principles of keeping a single market.

AMDR congratulates the European Commission for its commitment to establish a reliable regulatory framework for reprocessing of medical devices ensuring a high level of patient safety. AMDR urges the European Parliament and the Council of Ministers to take into account the recommendations made in this position to ensure the highest level of clarity in the Regulation.