AMDR comments to the Slovenian Ministry of Health Proposal:

0070-110/2019; EVA 2019-2711-0067

Regulation implementing the Regulation (EU) on medical devices – comments to Article 8.

5 February 2021

The Association of Medical Device Reprocessors (AMDR) appreciates the opportunity to comment on the Slovenian Ministry of Health public consultation on its implementation of the Regulation (EU) on medical devices. AMDR provides comment on section II. PROCESSING OF DEVICES AND INFORMATION REGARDING IMPLEMENTED DEVICES, Article 8 (disposable devices and their reprocessing): 070-110/2019

Context

Article 17 of the European Union's Medical Device Regulation (MDR) of 2017 puts in place stringent new EU-wide requirements for the reuse of "single-use" devices (SUDs). EU Member States have discretion on which path or paths to take, as outlined in the provisions of article 17, and the EU MDR is to be fully implemented by May of this year (2021). In short, any reuse of SUDs must both adhere to the safety and efficacy requirements of the MDR and be allowed by national provision. The safety and regulatory requirements require that that reprocessor adhere to the same standards as applied to original equipment manufacturers and obtain a CE mark – often dubbed in Europe, "remanufacturing of SUDs." Or, Member States may elect to allow hospitals to reuse SUDs so long as it is compliant with the European Commission's 2020 "Common Specifications."

As AMDR represents commercial, professional medical device reprocessing and remanufacturing, we support the safety, efficacy, sustainability and resiliency benefits of reprocessed and remanufactured single used devices, as confirmed by two decades of research done in this area. See AMDR's bibliography here. This is also confirmed by two decades of US FDA and German regulation of the practice where all data indicates that reprocessed and remanufactured SUDs that comply with the regulatory requirements are safe and effective – with no increased risk to patients.

Remanufacturing SUDs is proven to reduce costs and waste. A groundbreaking new life cycle assessment published in the journal ***Sustainability*** indicates that "using a remanufactured as an alternative to a newly-manufactured catheter shows that the global warming impact is reduced by 50.4% and the abiotic resource use by 28.8%."

AMDR appreciates Slovenia's action in this regard and urges other EU Member States to take similar swift action to opt-in to the EU MDR's CE marking and/or Common

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Specifications approaches for allowing SUD reuse to reduce cost, waste, and improve supply chain resiliency.

Technical AMDR comments

AMDR respectfully comments on the reprocessing of SUD provisions (Article 8), as indicated above, and fees (Article 5.2.7). We thank you for the opportunity.

Article 8

AMDR is pleased with the action the Ministry is taking, giving hospitals in Slovenia the power to promote more circular, sustainable, resilient and cost-saving healthcare supply chain solutions like medical device reprocessing.

8.1 For absolute clarity, we urge the Ministry to clarify in Article 8.1 that Slovenia is opting in to allow the 17.2, 17.3 and 17.4 provisions of the EU MDR. AMDR suggests inserting parentheses after "Article 17" and adding "subparagraphs 2, 3 and 4."

8.2 8.2 seems to undermine or contradict 8.1, therefore we urge the Ministry to strike this provision. As AMDR understand the EU law, Member States may elect to "opt in" to allowing reprocessed or remanufactured devices in accordance with the article. 17.1 of the EU law gives Member States that authority. If Member States elect to allow such devices, they may also elect to "opt in" to 17.3 and 17.4 allowing less than all of the rules as it relates to in-hospital reprocessing. Member States may also elect to add additional standards (discussed below). But so far as AMDR understands the EU law, section 17.2 of the EU MDR is not a provision Member States can opt in or out to. Thus, if the Ministry's intent was to mirror the requirements of the EU MDR in its' Article 8, there's nothing to be said with regard to 17.2 as Slovenia has opted in to 17.1, as other Member States are doing. We urge striking 8.2 entirely.

8.3 As noted, this subsection seems to reference subsections 17.3 and 17.4 of the EU MDR, as does Article 8.1 with 17.1. We urge the Ministry to clarify such by inserting "pursuant to EU MDR Article 17.3 and 4 after "devices are permitted" and before "if the devices are reprocessed . .". This would be consistent with what the Ministry has done in 8.4, referencing the specific subsections of the EU MDR intended.

8.4 Consistent with the above, we urge the Ministry to clarify section 8.4 references EU MDR Article 17 subsection 3 subparts a and b.

8.5 AMDR respectfully urges the Ministry to strike 8.5. CE marked remanufacture SUDs, by definition, meet the EU MDR' requirements and are therefore not investigational or experimental. Informing a patient of the clinical use one brand of CE marked device versus another is not required by the regulation and would needlessly suggest a different level of risk associated with the two products. If the Ministry intends to require providing patients with this information in regard to 17.3 and 17.4 "in-house" reprocessed devices, AMDR urges the Ministry to specify such, making clear that CE marked devices, or 17.2 compliant devices, do not require such disclosure. However, as the European Commission and its group of experts spent considerable time formulating the Common Specifications applicable in 17.3/4 to in-house reprocessing,

and they did not include such a requirement, we respectfully urge the ministry to withdraw this subsection. To inform patients would needlessly send the message that reprocessed devices present a greater safety risk when, in fact, the very purpose of the regulation and its requirements is to ensure that reprocessed or remanufactured devices do not present an elevated risk to patients. Further, by meeting the requirements, these devices are not investigational or experimental, and so AMDR is unaware of a legal or ethical basis for such a requirement.

Alternatively, AMDR requests the word "shall" be stricken and replaced with "may."

Of course, while not relevant for Article 8, reprocessed or remanufactured devices that ARE part of a clinical investigation should be subject to the same informed consent rules as any other medical device under experiment or investigation.

Article 5.2.7

Article 5.2.7 places an annual fee of 4,500 Euros on healthcare institutions and external processors. As noted in the introduction, reprocessed and remanufactured devices cost less than original equipment. They help keep limited financial resources IN our healthcare institutions, rather than being committed to medical device makers. Further, medical device reprocessing and remanufacturing extends the life span of existing equipment, further reducing consumption and spending on new equipment. This is on top of the environmental and supply chain resiliency benefits.

COVID has shined a light on the vulnerabilities of our health care supply chain, our over-reliance on international manufacture of "disposable" medical equipment and supplies, and on the wastefulness of our accepted practices. Now is the time to encourage more responsible medical device and supply consumption. We therefore respectfully request that the fees for reprocessed and remanufacturers be stricken as it sends the wrong incentive to our healthcare institutions and patients. We should encourage maximize the life of existing assets before asking our healthcare institutions to tap into a global supply chain to buy more. Alternatively, AMDR asks that the fee applicable to external reprocessors or remanufacturers be the same as applied to any other medical device manufacturer, as outlined in 5.2.2. After all, the EU MDR went to great lengths to hold remanufacturers to the same standards as manufactures, they should pay the same fees as any other entity that places CE marked medical devices onto the market.

AMDR appreciate this opportunity comment. If we can be of further technical service, please do not hesitate to contact us.

About AMDR

The Association of Medical Device Reprocessors is the global trade association for the regulated, professional single-use device reprocessing and remanufacturing industry. For 20 years, AMDR has promoted reprocessing remanufacturing as an important healthcare strategy that helps hospitals and healthcare providers increase quality, reduce costs, and strengthen the supply chain. AMDR protects the interests of its members in regulation, legislation and standard-setting.

AMDR members include Innovative Health, Medline Renewal, NEScientific, ReNu Medical, Stryker Sustainable Solution, Sustainable Technologies (a Cardinal Health Business), and Vanguard AG.

Having played a key role in the establishment of the reprocessing industry, AMDR continues to push the global medical technology industry and lead the way for remanufacturing to play a defining role in the evolution and use of new device technologies.

Sincerely,

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Recent findings from the peer-reviewed literature:

Combining Life Cycle Assessment and Circularity Assessment to Analyze Environmental Impacts of the Medical Remanufacturing of Electrophysiology Catheters, Schulte, Maga and Thonemann, *Sustainability*, January 2021.

Transforming the Medical Device Industry: Road Map to a Circular Economy, MacNiell, Hopf, et. al., *Health Affairs*, December 2020.

Health Care Pollution and Public Health Damage in the United States: An Update, Eckelman, Huang, Lagasse, et. al., H*ealth Affairs*, December 2020