AMDR comments to the Spanish Royal Decree Regulating Medical Devices

DG/24/21 Contributions from Association of Medical Device Reprocessors (AMDR)

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The Association of Medical Device Reprocessors (AMDR) appreciates the opportunity to comment on the Spanish Ministry of Health's public consultation on implementation of the Regulation (EU) on medical devices. AMDR is providing comments exclusively on section III., Reprocessing and reuse of single-use products, articles 11 to 15.

Context

Article 17 of the European Union's Medical Device Regulation (MDR) of 2017 put 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. Absent Member State action to affirmatively allow reprocessed and remanufactured SUDs, such products are presumptively not allowed. This deprives hospitals and health systems of an urgently needed sustainable solution for medical devices. Therefore, AMDR appreciates the Ministry's efforts in promulgating these rules allowing such products.

Going forward, any reuse of SUDs must both adhere to the safety and efficacy requirements of the MDR and comply with these proposed Spanish requirements. The safety and regulatory requirements ensure that that reprocessors 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, such as Spain has done, may also elect to allow hospitals to reprocess 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 supply chain resiliency benefits of such products, 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, green house gas emissions 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 Spain'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 Specifications (CS) approaches for allowing SUD reuse to reduce cost, waste, and improve supply chain resiliency.

Technical AMDR comments

AMDR respectfully comments on Chapter III, Articles 11 to 15 - the reprocessing of single-use devices. Our primary concerns are the following:

1. The draft regulation provides a negative list of devices, or devices which are proposed to be excluded from Common Specification reprocessing. This is not required since the EU MDR and the CS ensure that only devices that can be safety reprocessed or remanufactured, are reprocessed or manufactured.

2. The draft regulation proposes to exclude Common Specification reprocessing by entities outside of Spain. This would discriminate against AMDR members from other EU countries and be counter to EU law. Also, AMDR is not aware of any commercial medical device reprocessing or remanufacturing company in Spain and so such an exclusion would result in a de facto ban on such reprocessing, driving up waste and costs for hospitals.

3. The draft regulation requires informing patients of use of reprocessed devices. As the reprocessing regulations ensure that a reprocessed device is just as safe as a virgin device, there is objectively no need to provide such information. Any regulation proposing to do so would unfairly discriminate against reprocessed devices.

Article 11: Reprocessing of Single-Use Products

Section 2: AMDR respectfully requests that Spain NOT include any of the restrictions outlined in Section 2, listing of SUDs that may not be reprocessed. CE marked devices, whether original or reprocessed, must adhere to the relevant requirements of the MDR and be certified by Notified Bodies. Compliance with this or the Common Specifications for hospital reprocessing ensures the safety and effectiveness of reprocessed devices, so this additional restriction is unnecessarily burdensome. There is no reason such products should be excluded and such exclusion would only promote greater costs, waste and greenhouse gas emissions.

By way of examples, subsection (a) eliminates the potential for all class I devices. Any reprocessing or remanufacturing of a Class I S/M/R devices is subject to Notified Body certification to ensure compliance with the EU MDR. This is needlessly restrictive.

Article 14: External Reprocessors

Section 1: AMDR urges the striking of section 1 which requires external reprocessors to have "facilities established in Spain." This discriminates against reprocessors from other EU member countries. Also, AMDR is aware of no commercial medical device reprocessing or remanufacturing entities in Spain and given the complexity and cost associated with compliance with the EU MDR, does not envision there being commercial reprocessor in every single EU member country.

Section 3: AMDR urges the striking of section 3 prohibiting reprocessors from engaging in outsourcing. Reprocessors and remanufacturers, like any other medical device manufacture, must outsource certain functions such as sterilization, replacement parts and component construction and other functions. Reprocessors should not be prohibited from outsourcing typical medical device manufacturing functions provided that they comply with the EU MDR.

Article 15: Use of Reprocessed Single-Use Products

Section 2: As with our comments above in Article 14, section 1, we respectfully urge the Ministry to strike section 2 under article 15, requiring the reprocessor to be based in Spain.

Section 3: AMDR respectfully urges the Ministry to strike this section. CE marked remanufactured SUDs, by definition, meet the EU MDR's requirements and are therefore not investigational or experimental. They need to meet the same safety standards as virgin devices. As to CS reprocessed devices, 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. Requiring the information of the patient would unfairly discriminate against reprocessors.

To illustrate this point, consider the following: Informing a patient of the clinical use of one brand of CE marked devices versus another is also not required by the regulation and doing so would unfairly suggest a different level of risk associated with the two products. The very purpose of the regulation and its requirements is to ensure that reprocessed or remanufactured devices do <u>not</u> present an elevated risk to patients. Further, by meeting the requirements, these devices are not investigational or experimental, so there is no legal or ethical basis for such a requirement.

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.

Conclusion

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

COVID has shined a light on the vulnerabilities of our health care supply chain, our over-reliance on non-European 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 also respectfully request that the proposed fees for reprocessor and remanufacturers be eliminated as this would create the wrong incentive to our healthcare institutions and patients. We should encourage maximizing the life of existing assets before asking our healthcare institutions to tap into a global supply chain to buy more.

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 over 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 and remanufacturing industry, AMDR continues to push the global medical technology sector 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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