AMDR Reaction to Swedish Socialstyrelsen Report: Prerequisites for Reprocessing and Reusing Disposable medical Devices in Sweden (December 2020)

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The Association of Medical Device Reprocessors (AMDR) applauds the Swedish National Board of Health and Welfare (Socialstyrelsen) on its thorough and evidenced report of December 2020: Prerequisites for Reprocessing and Reusing Disposable Medical Devices (original here, AMDR's English version here).

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."

AMDR Response

AMDR therefore welcomes and appreciates the credible work taken on by the Swedish National Board of Health and Welfare. The content, credibility and thoroughness of this investigation is perhaps unparalleled in Europe thus far and AMDR believes Sweden's findings can be used as a basis for other Member States to expedite their own "opting in" to allow such products. The Socialstyrelsen concluded that reprocessing and reuse "of disposable medical devices that take place according to a validated protocol, according to current law in the field, can be considered patient safe." Ultimately, the report concludes that there should be no prohibitions or restrictions regarding external reprocessing (according to article 17.4) of the EU Medical Device Regulation.

As AMDR represents commercial, professional medical device reprocessing and remanufacturing, we support the safety, efficacy, sustainability and resiliency findings of the Socialstyrelsen report as it confirmed two decades of research done in this area. See AMDR's bibliography here. This is also confirmed by two decades of US FDA and

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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 from such products.

Remanufacturing SUDs is proven to reduce costs and waste. A groundbreaking new life cycle assessment published in ***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 urges EU Member States to take swift action to opt-in to the EU MDR's CE marking and/or Common Specifications approaches for allowing SUD reuse to reduce cost, waste, and improve supply chain resiliency.

About AMDR

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 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.

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