European Commission's Call for Evidence for an Impact Assessment: Single Market Emergency Instrument

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

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COVID-19 and climate change have put a laser focus on the vulnerability and wastefulness of the healthcare supply chain. As the European Commission seeks to promote the Single-Market and remove barriers that may restrict more resilient, sustainable practices, we hope the Commission will include the healthcare supply chain in its focus, and the low-hanging fruit solution medical device reprocessing and remanufacturing offers. Current European Union (EU) policy, as described below, places a prohibitively *higher* burden on remanufactured medical devices than exists for even original equipment. This is wrong, frustrates the cultivation of a robust Single Market, and hamstrings Member States as they seek to put in place more resilient supply chain tools that help cut the carbon footprint.

The Association of Medical Device Reprocessors (AMDR) represents the worldwide interests of commercial reprocessors (known in Europe as "remanufacturers") of "single-use" medical devices (SUDs) as a circular economy solution for healthcare. Commercial remanufacturers are regulated under the EU Medical Device Regulation (2017), and in the United States by the Food and Drug Administration (FDA). FDA has regulated SUD reprocessing for over two decades. Over 300 kinds of devices labelled for "single-use" by their manufacturer have been evaluated as safe and effective after reprocessing by FDA and now also by European Notified Bodies. More than 10,300 hospitals worldwide use professional, commercially available remanufactured SUDs. Devices range from non-invasive EKG leads, tourniquet cuffs and pulse oximeter sensors, to invasive devices used in laparoscopic surgery and cardiac imaging devices.

AMDR applauds the Commission's efforts to address weaknesses of the Single Market in facing emergency situations. Given the supply chain disruptions for healthcare products during the worst of COVID-19, AMDR hopes the Commission will pay special attention to barriers and weaknesses in the Single Market that discourage adoption of more circular healthcare supply chain innovations like reprocessing and remanufacturing.

Further, healthcare delivery plays an outsized role in the generation of the greenhouse gases that cause climate change and adverse health effects in humans. In a field committed to health and the promise to "do no harm," it is unacceptable that the pollution generated from the health sector contributes to the climate change crisis and makes people sicker. Medical device remanufacturing spotlights new opportunities to pursue more resilient and less wasteful supply chain practices. Now is the time for the Commission to support this green technology to address public health emergencies, build supply chain resiliency, fight the threat of climate change, and support a circular economy for healthcare products.

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Medical Device Remanufacturing

Single-use device remanufacturing is strictly regulated in Europe, Canada, the United States, Japan, and the United Kingdom (UK). As an established practice, with solid regulatory oversight and an impeccable safety record, regulated remanufacturing should serve as a cornerstone activity in the promotion of sustainable healthcare practices. Medical device remanufacturing is a circular solution, advancing supply chain resilience by reducing consumption of new devices, lessening dependency on original equipment manufacturer (OEM) supplies, and extending the life of existing equipment. This translates directly to enormous cost savings, substantial reductions in waste and lower greenhouse gas emissions.

A growing body of academic research points to medical device remanufacturing as a well-established, proven circular solution that can ensure immediate, measurable benefits. Greater emphasis on SUD remanufacturing would transform the traditional "take-make-dispose" mentality dictating current resource consumption and replace it with a more sustainable, affordable, circular economy model for the larger industry to follow. A regenerative approach to product usage will allow us to consume less, protect the health of populations and the environment, decrease rising costs and, in the context of this Stakeholder Consultation, help build a more resilient supply chain for medical devices. But we need the Commission to step up now and play an active role. For an overview of SUD remanufacturing and the, see AMDR's backgrounder.

AMDR Comments, in Brief

We believe SUD remanufacturing is a critical circular solution that the Commission should embrace, consistent with the policy objectives of this initiative. We recommend, given the significant inconsistencies of Member States in correctly understanding Article 17 of the EU Medical Device Regulation (EU MDR), that the Commission further its **first aim** by providing **adequate information, coordination, and communication on this issue** between the EU, Member States, and stakeholders to increase supply chain resilience for healthcare products.

Further, SUD remanufacturing is a key solution in the health sector as, consistent with the Commission's **second aim**, as it provides a means to ensure resilience of healthcare products. Further, the Single-Market is under threat by the adoption of Article 17 of the **EU MDR as the opt in provision prevents the free circulation of goods, namely, EU wide availability** of remanufactured products which can help to build resiliency, reduce emissions, waste, and cost.

Specifically, AMDR urges the Commission, as per the **Crisis Response** pillar, to prioritize focus on the vulnerabilities of the healthcare supply chain. The EU MDR opt in requirement frustrates the Commission's goal to streamline placing on the market

considerations for remanufactured SUDs. A firm, EU level regulatory standard exists. As the Commission works to create a module to identify national measures restricting the free movement of goods, we urge you to focus on the EU MDR's provision which has allowed most Member States to restrict the placing on the market of remanufactured SUDs (Article 17).

AMDR urges the Commission to reopen this provision of the EU MDR to remove the "opt in" provision (17.1). Alternatively, we call on the Commission to include SUD remanufacturing in its modules examining National level frustrations and in placing on-the-market considerations. Specifically, the Commission should include in any future "blacklist" of efforts that restrict the free movement of goods, those Member States that fail to "opt in" to article 17 of the EU MDR. Further, we advise the Commission to promote national EU Member State policies that maximize circular economy technologies in healthcare like SUD remanufacturing.

Expanding SUD remanufacturing gives the Commission a simple, immediate way to push back on multiple crises within the healthcare system while advancing key sustainability goals. But for overly restrictive regulation at the EU level, frustrating the Single-Market, SUD remanufacturers would be providing their goods at far greater levels, like in the U.S.

AMDR urges the Commission, as per the **Crisis Preparedness** pillar to help avoid **supply chain disruptions**, to focus on the vulnerabilities in the healthcare supply chain. Given the particularly toxic and vulnerable nature of the healthcare supply chain (see elaboration below), immediate solutions like SUD remanufacturing would build resiliency into the supply chain, and, as such, should be promoted.

Article 17 of the EU MDR, as explained further below, needlessly impedes development of the Single-Market, hampers the ability of hospitals to control their medical device assets, and runs counter to the Commission's Circular Economy Action Plan, continuing the toxic cycle of needless waste, consumption, and spiking emissions. We call on the Commission to re-open this "opt in" requirement. Short of that, we encourage the Commission to include SUD remanufacturing as a healthcare **supply chain mitigating measure** for increasing the supply of goods and reducing consumption of new medical devices.

Removing the barriers to SUD remanufacturing will:

- Improve diversification of supplies for medical devices;
- Extend the life of existing medical device inventories;
- Provide substitution products in the event of device shortages; and
- Slash consumption of raw materials.

Taking these steps now will help save costs, cut waste, and reduce emissions in unprecedented ways.

Further Background:

SUD Remanufacturing is Regulated

As noted, remanufactured SUDs must meet all the same requirements as any other medical device, ensuring the collection, repair, cleaning, disinfection or sterilization and testing functions of remanufacturing results in products with no change in safety or effectiveness. SUD remanufacturing is a prime example of a repair industry in healthcare that makes no compromises in safety or effectiveness while achieving consumer benefits such as lower emissions, less waste, less cost, and a more secure supply chain. As SUD remanufacturing is already regulated and requires Conformite Europeenene (CE) marking, promotion of SUD remanufacturing should be a Commission objective.

The Urgent Need to Create a Circular Economy in the Health Sector

Hospitals across Europe throw out millions of medical devices after just a single use. These devices, labelled for "single-use only," are not intended by their original manufacturer to be reprocessed or reused *by the health facility*. However, regulatory authorities in the EU, U.S., Canada, Japan, and elsewhere have cleared or approved hundreds of models of SUDs to be remanufactured when done so by regulated, commercial firms. Once remanufactured, liability for the device shifts from the OEM to the commercial remanufacturer. Remanufacturing of SUDs has not resulted in increased patient risk, nor lesser device functionality, and regulation governing the practice demands remanufacturers produce evidence to demonstrate substantial equivalence to original devices.

Consumption of goods in the health sector accounts for almost 5 percent of all worldwide carbon dioxide emissions. If it were a country, the health sector would be the fifth-largest emitter, and its C02 emissions are *more than twice* those of the entire airline industry.[1] A closer look reveals that over 80 percent of greenhouse gas emissions generated by the health sector comes from its supply chain alone (known as "Scope 3 emissions"),[2] a source directly impacted by the reuse and repair of medical devices.

Action is needed now, and governments are taking notice. Over forty countries have committed to reducing greenhouse gas emissions from the health sector.[3] Given the extent of the sector's impact on global health, governments and healthcare providers have

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[1] Health Care Climate Footprint Report, **Health Care Without Harm,** September 2019.
[2] Eckelman MJ, Haung K, et. al (2020) Healthcare Pollution and Public Health Damage in the United States: An Update, **Health Affairs** 39:12. 2071-2079.
[3] Winston Choi-Schagrin, More than 40 Nations Pledge to Cut Emissions from their Health Industries, *The New York Times*, November 8, 2021

a responsibility to not only identify sources of greenhouse gas emissions in the supply chain but find lower emission alternatives.

Programs to Remanufacture SUDs Cut Greenhouse Gas Emissions, Build Supply Chain Resiliency, and Lower Costs

Expanding the circularity of products and materials used in healthcare needs to be supported to successfully transition to a more sustainable healthcare economy. Remanufacturing represents a relatively easy, immediate, and quantifiable innovation.

Researchers from the Fraunhofer Institute for Environmental, Safety, and Energy Technology UMSICHT published a life cycle assessment of one remanufactured device (an electrophysiology catheter) and found it to reduce ozone depleting emissions by nearly 90 percent, and climate change-specific emissions by over 50 percent compared to using an original device.[4] While AMDR actively encourages funding life cycle assessment for additional remanufactured SUDs, we already have evidence that remanufacturing at least one SUD decreases greenhouse gas emissions substantially, relative to using a device just once and throwing it away.

In a twist to the common notion that the EU is far ahead of the U.S. in addressing sustainability, fewer than 1,000 hospitals have regulated, commercial remanufacturing programs in Europe while over 9,000 hospitals and surgical centers do so in North America. We urge the Commission to promote medical device remanufacturing in the health sector as part of its broader effort to shore up the Single-Market and build resiliency into the supply chain.

Providing the clear and compelling evidence along with instructions to migrate to the circular economy in healthcare will reduce greenhouse gas emissions, improve human health, build supply chain resiliency, and help mitigate the effects of climate change. In a rare triple win, the use of remanufactured SUDs not only slashes CO_2 and boosts the reliability of the supply chain, but also costs less. We implore the Commission to take specific steps to educate and incentivize Ministries of Health and hospital consumers to use remanufactured medical devices, consistent with the Crisis Response pillar this Impact Statement proposes in the objectives and policy options.

The EU MDR Opt-In Process Unfairly Discriminates Against a Healthier EU

The EU MDR that governs medical device manufacturing AND the safe and effective remanufacturing of SUDs also requires that EU Member States "opt-in" to allow remanufacturing of SUDs within their borders. AMDR is aware of no other CE marked

[4] Schulte A, et. al., Combining Life Cycle Assessment and Circularity Assessment to Analyze Environmental Impacts of the Medical Remanufacturing of Electrophysiology Catheters, ***Sustainability,*** 2021, *13*(2), 898.

product subject to this additional regulatory burden. This has a chilling effect on remanufacturing because many hospitals may prefer the practice for all its benefits but may be unable to utilize them – despite CE certificates having been issued for such products, indicating that the device has met the Regulation's requirements. This places a stifling regulatory burden on medical device remanufacturing, thus discouraging a circular economy in the medical device sector.[5]

This anti-competitive measure runs counter to sound science and good environmental policy. To allow Member States to supplant their judgment, without evidence or any review of the scientific data ordinarily required of a product seeking to be placed on the market, undermines the purposes of the EU MDR, and circumvents the Notified Body procedure. This also runs afoul of decades of EU law that allows the free circulation of CE marked products to be marketed across the Union.[6] Allowing Member States to prohibit reprocessing or even export of devices to be reprocessed violates the fundamental freedoms of the internal market[7] and cannot be justified on public health protection grounds as the EU MDR contains a safeguard clause.

AMDR can find no other example where a carveout exists in EU regulations whereby Member States are allowed to prospectively reject CE-marked products, absent any existing safety concerns (The Safeguard Clause, Article 8, MDD).[8][9] We believe strong manufacturer pressure, relying on a volume-based sales culture in healthcare, has

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[5] See Article 17.1, "reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this Article", Regulation (EU) 2017/745 of the European Parliament and of the Council, 5 April 2017, On Medical Devices, Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and Repealing Council Directives 90/385/EEC and 93/42/EEC.

[6] Article 26, TFEU, "The Union shall adopt measures with the aim of establishing or ensuring the functioning of the internal market, in accordance with the relevant provisions of the Treaties," and "[t]he internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties."

[7] Articles 34 and 45, TFEU prohibit quantitative restrictions, and measure having an equivalent effect, on imports and exports between the Union's Member States. The prohibition of such restrictions covers all commercial rules enacted by the Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade.* A ban on the market of a specific product, which has been done here, is the most restrictive measure a Member State can adopt from a free movement perspective. See in particular, Case 8/74 Dassonville [1974] ECR 837, para 5; Case 178/84 Commission v Germany [1987] ECR 1227 ('Beer purity law'), para. 27; and Case C-12/00 Commission v Spain [2003] ECR I-459, para. 71.

[8] Article 8, European Council Directive 93/42/EEC 14 June 1993 concerning medical devices.

[9] Case law establishes that exceptions to the free movement of goods is to be interpreted strictly. Commission of the European Communities v Kingdom of Spain. Case C-88/07. It requires Member States impose a national ban on a product to show that the measure is necessary and that the marketing of the products poses a serious risk to the public health and that those rules are in conformity with the principlke of proportionality. This includes providing relevant evidence such as technical and scientific data and al other relevant information. Case C-270/02 Commission v Italy [2004] ECR I-1559.

resulted in the incongruent and restrictive regulatory playing field,[10] disfavoring remanufacturing. To advance a circular economy, this must change.

This additional national law requirement deprives many in the EU of access to safe, lower cost and environmentally friendly medical device options. This "opt-in" provision creates an enormous disincentive for European hospitals to be good environmental stewards or to build resiliency in the supply chain, by remanufacturing their devices. We strongly urge the Commission to have this section of the Regulation re-evaluated and/or provide guidance and instruction to Member States on the safety, efficacy and lower emissions associated with remanufactured, MDR-compliant devices.

AMDR Has an Open Door

On behalf of AMDR and our members, we are eager to participate further in this initiative and are available to contribute to future discussions and planning. Please contact us at any time if we can be of service. Thank you for your consideration.

Sincerely,

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[10] Restrictions on the free movement of goods must be proportionate to the am pursued and not attainable by measures less restrictive on intra-Community trade. Cassis de Dijon C-470/93.