European Commission's Call for Evidence for an Impact Assessment: Sustainable Consumption of Goods – Promoting Repair and Reuse

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

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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 now for over two decades and, 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 European Notified Bodies. Over 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 European Commission's efforts to consider amendments to the Sale of Goods Directive and potentially create separate legislation on the right to repair. Healthcare delivery plays an outsized role in the generation of the greenhouse gases that cause climate change, yet administrative and legislative initiatives focused on sustainability and competitiveness have been largely unsuccessful in including – and indeed focusing – on this part of our economy, usually due to the sensitivity associated with instruments and devices used in patient care. However, in a field committed to health and the promise to "do no harm," it is unacceptable that the pollution generated from the health sector makes populations sicker and contributes to climate change and its ancillary adverse impacts on health.

The right to repair issue in healthcare potentially impacts a number of areas of healthcare including the repair or servicing of capital equipment, regulated, commercial remanufacturing of single-use devices, and hospital reprocessing of reusable devices in their own sterile processing departments. These practices all fundamentally relate to the repair and reuse of medical devices/instruments, yet are regulated in separate and very different ways. While the repair of equipment is largely un-regulated, single-use device remanufacturing is strictly regulated in North America, Europe, Japan, the UK. As an established practice, with solid regulatory oversight and an impeccable safety record, regulated remanufacturing should serve as both a template for the regulation of other repair-related industries within healthcare, and as a cornerstone activity in the promotion of sustainable healthcare practices. AMDR is committed to promoting medical device remanufacturing because our circular solution helps to build supply chain resilience by reducing consumption of new devices and lessening dependency on only OEM supplies, saving costs, and cutting waste and emissions.

AMDR urges the Commission to view hospitals as "consumers" and contemplate inclusion of healthcare products in the re-evaluation of the Goods Directive and potential repair legislation. With remanufactured devices, hospitals and patients can slash their enormous environmental

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impact, lower costs, create a stronger supply chain and encourage a more competitive market for healthcare products. But we need the European Commission to play an active role. We urge the Commission to consider healthcare products in its Sustainable Consumption of Goods initiative and we hope medical device remanufacturing will be given special attention due to its immediate potential to transform the health sector with its sustainable, circular solution.

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, US, Canada, Japan, and elsewhere have cleared or approved hundreds of models of SUDs to be remanufactured and used again when done so by regulated, commercial firms. Once remanufactured, liability for the device shifts from the original equipment manufacturer (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 (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 impacts of the sector's impact on global health, government-run and government-reimbursed healthcare facilities have 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, 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 solution. 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

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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
[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.

remanufacturing at least one SUD decreases greenhouse gas emissions substantially relative to using a device just once and throwing it away.

The European Commission, in its call for evidence for an "impact assessment on sustainable consumption of goods – promoting repair and reuse," provides an opportunity for digging deeper into the wasteful hospital practice and opens a pathway to expand remanufacturing programs that are already established (but underutilized) at over 10,300 hospitals worldwide.[5]

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 expand the right to repair and more sustainable consumption of goods.

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, and help mitigate the effects of climate change. In a rare double win, the use of remanufactured SUDs not only reduces CO2, but also costs less. We hope the Commission will take specific steps to educate and incentivize Ministries of Health and hospital consumers to use remanufactured medical devices. Further and to provide more direct advice, we have identified several barriers that we hope amendments to the Sale of Goods Directive or Right to Repair regulations will address.

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

The EU Medical Device Regulation (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 product subject to this additional regulatory burden. This has a chilling effect on remanufacturing because many hospitals may prefer the practice for all of its benefits but may be unable to utilize them – despite the issuance of Conformite Europeenene (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.[6]

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 CE marked products to be marketed across the Union.

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

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[5] http://amdr.org/reprocessing-by-the-numbers/

[6] 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.

concerns (The Safeguard Clause, Article 8, MDD).[7] We believe strong manufacturer pressure, relying on a volume-based sales culture in healthcare has resulted in the incongruent regulatory playing field, 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 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.

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. AMDR takes no position on the level of regulation required for *other* repair activities in the health space but as SUD remanufacturing is already fully regulated and requires CE marking, promotion of SUD remanufacturing should be a Commission objective.

Reliable and Relevant Information at Point of Sale

AMDR previously encouraged the Commission to include medical devices in the revision of any existing policy instruments on products' environmental performance.[8] Our comments reiterate the portion of our response that remain relevant for this inquiry. In healthcare, as in other sectors, consumers often lack reliable, consistent, or relevant environmental characteristics data. Further, there is a false perception that remanufactured SUDs may be inferior to new devices, despite both being subject to the same safety and efficacy standards. Educational information from the Commission to healthcare consumers on the value and benefits to the circular economy for the use of remanufactured SUDs would greatly assist already overwhelmed hospitals as they make medical device purchasing decisions.

Clear Labelling for the Availability of Repair Services

AMDR supports more information on the availability of repairing, reprocessing, or remanufacturing for medical devices. Broadly speaking, if a remanufactured equivalent of an existing medical device achieves a CE mark, indicating conformity with health, safety, and environmental protection standards for products sold in the EU, AMDR supports making that information available to all healthcare consumers, perhaps making this information required in the labeling of both new and remanufactured medical devices. This would encourage medical device makers to extend the life of medical devices, rather than generate more wasteful,

[7] Article 8, European Council Directive 93/42/EEC 14 June 1993 concerning medical devices.
[8] AMDR Comments to the European Commission's Inception Impact Assessment on Empowering the Consumer for the Green Transition

disposable options. Such a move would foster the growth of European remanufacturing operations rather than rely on the import of disposables from Asia.

Chipping and Software Upgrades/Updates

A primary threat to a circular economy for medical devices is some OEM use of software "updates" or "upgrades" that prevent remanufactured versions of these devices from working with consoles or generators. OEMs make both the consoles/generators and the devices used with them. By manufacturing the devices with microchips and updating the software on the generators, some OEMs are cutting out competition and increasing a hospital's reliance on the OEM product (and thus increasing consumption and waste) by preventing remanufactured versions of medical devices from working.

AMDR believes this activity has a deleterious impact on greenhouse gas emissions, is anti-competitive and wasteful. AMDR has received reports that hospitals' generators and consoles have had their software "upgraded" without the hospital's permission. AMDR has created the resource (and cited below) to address this issue in further detail and to provide instruction for hospitals on how to combat unwanted software upgrades.[9]

In addition to software upgrades or updates aimed at ensuring hospitals buy more unnecessary equipment, AMDR believes the use of "erasable programmable read-only memory" (EPROM) microchips in the handles of surgical and diagnostic medical devices are being used for the same purpose. Employed based on asserted "patient safety" claims, these chips are inserted to shut the device off after a single use. AMDR has evidence that an OEM with its own reprocessing/remanufacturing division, includes such chips, not just to discourage remanufacturing, but to discourage remanufacturing with competing vendors. AMDR has also created a resource on this topic to address the issue and provide instruction for hospitals on how to avoid unwanted device upgrades with new microchip-enabled forced obsolescence.[10]

New iterations of devices are consistently placed on the market, often with little evidence of improved performance, cost, or other positive variables necessitating adoption of newer generations. Healthcare consumers have had little option but to accept the latest model equipment, which often means accepting devices that have wasteful, built-in planned obsolescence. This tilting of the scales disfavors healthcare consumers, patients, and taxpayers, creating additional unnecessary manufacturing of new devices when more environmentally sustainable remanufacturing could be used. The incentives placed on manufacturers are to sell more, not develop better, longer lasting, and more environmentally sustainable products. Education for healthcare consumers on forced early failure efforts by device companies would provide a strong counterbalance to the power of the device industry and would encourage manufacturers to be more holistic in future medical device development and design.

AMDR supports Commission initiatives to strengthen healthcare consumers in their quest to find more sustainable consumption practices for medical devices, including medical device

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[9] AMDR, Software "Updates" Aimed to Thwart Reprocessing, 19 April 2018.
[10] AMDR, Forced Obsolescence Designed Into Devices, 19 April 2018.

remanufacturing. We call on the Commission to educate healthcare consumers on the adverse implications of OEM "forced obsolescence" measures as counter to the circular economy.

The WEEE Directive Fuels Wastefulness in Medical Device Design

Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) exempts electronic medical devices if they are "expected to be infective prior to end of life."[11] Commonly remanufactured single-use electronic devices include diagnostic and ablative cardiac catheters, laparoscopic electrosurgical instruments such as trocars and ultrasonic scalpels, and even pulse oximeter sensors and ECG leads.[12] AMDR does not believe a continued broad-based exclusion for medical devices is warranted, and provides further incentive for medical device makers to make more SUDs while discouraging more sustainable remanufacturing.

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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[11] Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on Waste Electrical and Electronic Equipment (WEEE), recast.
[12] Please see AMDR members' product pages: Vanguard (Berlin), Arjo/Renu, Innovative Health, Medline ReNewal, Northeast Scientific, Stryker Sustainable Solutions, and Sustainable Technologies a Cardinal Health Business.