
AMDR Comments to the European Commission's Inception Impact Assessment on the *Sustainable Products Initiative*

16 November 2020

The Association of Medical Device Reprocessors (AMDR) appreciates the Commission's efforts to promote a cleaner and more competitive Europe. We welcome the opportunity to provide feedback to the Inception Impact Assessment on the [Sustainable Products Initiative](#).

- AMDR strongly agrees with the Commission's aim to widen the scope of the existing EcoDesign Directive beyond energy related products.
- We urge the Commission to include health care products and consumers within the scope of work when addressing the Sustainable Products Initiative. We look forward to the adoption of overarching product sustainability principles and hope they can be applied to health care products
- We further hope the Commission's efforts will create manufacturer incentives in the health and medical markets to make products used in hospitals and surgical centers more sustainable, including incentivizing and bringing awareness to medical device remanufacturing. We encourage the Commission's consideration of tools to make producers responsible for providing more circular products and intervention efforts aimed at preventing waste.
- We hope the Commission's efforts will bring attention to the "take-make-use-dispose" of culture in health care and specifically, decreasing medical product lifespans. We hope the Commission's efforts will educate health care consumers on specific tactics manufacturers use to promote linear production and consumption rather than more sustainable practices. We support mandatory sustainability labeling or disclosure or at least promotion of products that are environmentally preferable. We support the development of Commission guidance on promoting more circular products in public procurement including potential minimum requirements for product sustainability when the taxpayer is ultimately responsible for absorbing costs.
- We hope the Commission's efforts in regard to the Sustainable Products Initiative will provide a consistent, reliable mechanism for health care

consumers to easily identify products with the lowest environmental footprint. And,

- We hope the Commission will seek to harmonize medical device manufacturer and remanufacturer requirements so as to remove the current additional obstacles/disincentives to environmentally preferable remanufactured product.

Below and attached, AMDR provides further background information on the need to include health care in the scope of the Product Sustainability Initiative, an overview of remanufactured medical devices, and a discussion of current challenges to greater adoption of circular technologies in the health sector.

AMDR [members](#), located in Europe and the United States, are professional medical device reprocessing and remanufacturing companies, subject to the [European Union's Medical Device Regulation's](#) (MDR) (2017) requirements, ensuring that remanufactured medical devices meet the same safety and efficacy standards as original equipment. Specifically, Article 17 of the EU MDR sets forth requirements for "single-use" device (SUD) reprocessing and requires commercial firms to meet manufacturer standards, thus adoption of the term "remanufactured" in Europe. AMDR members are both stand alone, independent companies and subsidiaries of original equipment manufacturers (OEMs).

Our detailed comments can be found in the attached document.

The Need to Bring Circular Economy Initiatives to the Health Care Supply Chain

Health care delivery at hospitals is particularly unsustainable. Concerns over “infection control” have further contributed to a “take-make-use-dispose” of culture emblematic of our linear economy. A disposable culture exists in health care predicated on the false belief that many medical instruments can only be used once, or hospitals are at risk of exposing patients to infections. The shift to disposable products has contributed to a mountain of waste generated by hospitals. Expanding the circularity of products and materials used in the medical sector needs to be supported to transform to a more sustainable economy.

The COVID-19 crisis has fueled the health care waste crisis, further underscoring the need to green health care. The pandemic is generating tons of additional medical waste as clinicians dispose personal protective Equipment (PPE) and ancillary medical devices used on COVID patients.¹ The strain on the health care supply chain has led to shortages of desperately needed PPE and other medical devices. Further, beyond shortages, there are now additional costs associated with these unprecedented demands, additional waste, additional waste disposal costs and the obviously adverse environmental costs.

Sadly, health care was environmentally wasteful well before COVID-19. Health Care Without Harm (HCWH) estimates that “if the global health care sector were a country, it would be the fifth-largest greenhouse gas emitter on the planet.”² Their report notes that the “lion’s share of emissions—71% are primarily derived from the health care supply chain through the production, transport, and disposal of goods and services,” including “medical devices, hospital equipment, and instruments.” These findings are premised and corroborated in peer-reviewed publications.³ The European Environmental Agency recently identified air pollution as a top environmental health challenge in the EU. The health care sector is a major source of pollution. The World Health Organization points to the incineration of health care waste as a source of dioxins, furans, and particulate matter emissions that pollute our air.⁴ Additionally, health care’s contribution to greenhouse gas emissions (GHG)

¹ Calma, Justine, *The COVID-19 Pandemic Is Generating Tons of Medical Waste*, **The Verge**, 26 March 2020: <https://www.theverge.com/2020/3/26/21194647/the-covid-19-pandemic-is-generating-tons-of-medical-waste>

² *Health Care’s Climate Footprint: How the Health Sector Contributes to the Global Climate Crisis and Opportunities for Action*, **Health care Without Harm**, September, 2019: https://noharm-global.org/sites/default/files/documents-files/5961/HealthCaresClimateFootprint_092319.pdf

³ See, Eckelman MJ, Sherman J (2016) Environmental Impacts of the U.S. Healthcare System and Effects on Public Health. **PLOS ONE** 11(6): e0157014. doi:10.1371/journal.pone.0157014 and Eckelman MJ, Sherman JD and MacNeill AJ 2018 Life cycle environmental emissions and health damages from the Canadian health care system: an economic-environmental epidemiological analysis **PLOS Med.** 15 e1002623.

⁴ World Health Organization, *Health-Care Waste*, <https://www.who.int/news-room/fact-sheets/detail/health-care-waste> 8 February 2018.

has been studied and linked to acid rain, photochemical smog, and respiratory disease. These studies suggest health care itself is making people sicker.⁵

Health care consumers, for the purpose of these comments, include hospitals, providers and the individuals within these institutions making purchasing decisions over medical devices, supplies and equipment, have enormous impact on the sustainability of health care. Hospitals, and their patients, are both consumers, and they deserve to know the environmental impact of the medical decisions (and products used to implement these decisions) they make. Right now, AMDR is unaware of any significant use of the EcoDesign label for electrosurgical medical products. AMDR supports greater incentives for the MedTech industry to promote more sustainable medical equipment, including use of the EcoDesign label. We further support expansion of the EcoDesign Directive to non-electrical devices and equipment.

Hospitals can contribute to more sustainable consumption in their own activities to reduce environmental, occupational, and public health problems arising as a result of such activities. But right now, they lack the tools to evaluate and identify environmentally preferable products. Solutions such as medical device remanufacturing help promote a more resilient, cost-effective, and environmentally sustainable health care supply chain. Medical device remanufacturing also builds a circular health care economy, creating jobs in the EU and keeping financial resources at home, within health institutions, rather than spent on unnecessary supplies from a global supply chain. Unfortunately, Europe has been slow to adopt this solution.

Background on Medical Device Regulation and Labeling

With the advent of better plastics in the early 1980s, and the then threat of the little understood HIV virus, the market for disposable medical devices exploded. The Commission addressed the shift to single-use medical devices in the 1980s in its 2010 report on SUD reprocessing.⁶ A culture in health care has since enshrined the belief that disposables are safer, less expensive and more convenient.⁷ Only in recent years have environmental Life Cycle Assessments demonstrated this to often not be true. And now there are calls from within the MedTech industry finally calling for a circular economy for health care.⁸

⁵ Eckelman, MJ, Sherman, JD, 2018. *Estimated Global Disease Burden from US Health Care Sector Greenhouse Gas Emissions*, **American Journal of Public Health** 108 (S2), S120-S122 (April 2018):

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5922190/#bib2>

⁶ European Commission, Report from the Commission to the European Parliament and the Council, [Report on the Issue of the Reprocessing of Medical Devices in the European Union, in Accordance with Article 12a of Directive 93/42/EEC](#), 27 August 2010.

⁷ Chahaun, MN, et.al, *Use of Plastics Products in Theatres in NHS and Environment Drive to Curb Use of Plastics*, *World Journal of Surgery and Surgical Research*, http://www.surgeryresearchjournal.com/pdfs_folder/wjssr-v2-id1088.pdf, 9 January, 2019.

⁸ Thording, Lars, *The Circular Healthcare Economy: Suppliers, Lawmakers – Time's Up*, **Medical Device & Diagnostic Industry**, <https://www.mddionline.com/general-hospital/circular-healthcare-economy-suppliers-lawmakerstimes>, 27 October 2020.

From a regulatory perspective, medical device requirements have traditionally looked at devices as either “reusable” (multiple-use devices) or disposable (single-use devices). This black or white paradigm assumes no gray area; a medical device is essentially reusable indefinitely, assuming the reprocessing technicians in hospitals adequately disinfect, clean, and sterilize the equipment in compliance with the reprocessing instructions provided by the OEM. Alternatively, a device is marketed as disposable or for single-use and can only be used on one patient.

Manufacturers clearly develop many disposable medical devices out of infection control concerns. Inadequate reprocessing of devices in the hospital setting can create cross-contamination, and thus hospital-acquired infections amongst patients. But manufacturers also have an enormous incentive to label devices for single use. First, to market a device as reusable under the MDR, the manufacturer needs to submit validated cleaning and reprocessing instructions to a Notified Body.⁹ Simply labeling a device for single use is far less expensive and time consuming than labeling as reusable. Second, by marking devices for single use, manufacturers create an unending demand for their product. Medical device sales representatives and the companies that employ them make more money the more products they sell. Thus, in Europe and the United States, a medical device may become “single use” by default, because the manufacturer chose NOT to do a cleaning validation. As a U.S. Government Accountability Office Report concluded:

“ ... the decision to label a device as single-use or reusable rests with the manufacturer. If a manufacturer intends to label a device as reusable, it must provide data demonstrating to FDA’s satisfaction that the device can be cleaned and sterilized without impairing its function. Thus, a device may be labeled as single-use because the manufacturer believes that it cannot be safely and reliably used more than once, or because the manufacturer chooses not to conduct the studies needed to demonstrate that the device can be labeled as reusable.”⁹

Beginning in the 1980s, but later influenced by the European Medical Device Directive of 2007,¹¹ OEMs began to change the labels on some medical devices from “reusable” to “single-use.” Originally, this shift in labeling was not required by EU

⁹ Article 52, **Conformity Assessment Procedure**, subsection 7(c), Annex I, General Safety and Performance Requirements, Chapter II, Requirements Regarding Design and Manufacture, subsection 11.2, Chapter III, Requirements Regarding the Information Supplied with the Device, subsections 23.4(k) and 23.4 (n) from European [Regulation](#) 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, *hereinafter*, Directive *See also*, **Compliance and Enforcement Group (COEN)**, [Instructions For Use for Reusable and Re-Sterilisable Medical Devices](#), 2014.

¹⁰ U.S. Government Accountability Office, GAO-08-147, [Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk](#) (January 2008), at 1 (emphasis added) [hereinafter 2008 GAO Report].

¹¹ [Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, amended by Directive M5, 2007/47/EEC of the European Parliament and of the Council of 5 September 2007.](#)

authorities or the U.S. FDA. Indeed, to this day, no agency of which AMDR is aware, requires any device to carry a single-use label. As OEM documentation from this time demonstrates, in some cases, device labeling was changed from “reusable” to “single-use” without any significant design, performance or material changes to the devices that would preclude safe reuse.¹²

This change in labeling was perceived by many hospitals for what it was—a marketing strategy aimed at increasing sales of new products. It was clear that certain devices designated by OEMs as “single use” could be safely reprocessed/remanufactured. Hospital skepticism of the single-use label was noted in a 2000 GAO Report. According to the report, health care personnel “distrust the single-use label for some devices” because, among other things, the regulator “cannot require manufacturers to support the designation of a device as single-use,” and “they perceive that manufacturers have an economic incentive to market devices as single-use that could just as well be sold as reusable.”¹³

In part to address this hospital skepticism, the EU instituted new requirements with the Medical Device Directive amendments of 2007. To address inconsistencies in product labeling across the community, the 2007 amendment to the Directive requires that, “if the device is intended for single-use, ... [a] manufacturer’s indication of single-use shall be consistent across the Union.”¹⁴ This well-meaning regulatory requirement provides further incentive for device companies to market their devices for single-use.

The environmental impact of decisions to encourage single-use devices should not be minimized. In the U.S. and Canada, 7.2 million kilograms of single-use devices were diverted from landfills and incinerators through regulated reprocessing (remanufacturing) programs in 2018 alone.¹⁵

The Financial and Environmental Costs Associated with this Disposable Culture Are Astounding

Current European regulations create incentives to make devices disposable, and no incentives exist to make devices reusable—or to remanufacture them. Further, while the MDR now opens the door to the marketing of remanufactured medical devices (see Article 17.1 and 17.2), Member States can elect to NOT allow such

¹² AMDR records on file of manufacturer communications to hospital clients on change of labeling. See, e.g., Letter from Brian Dowling, Product Manager, USCI Cardiology & Radiology Products (July 24, 1980) (explaining that, although USCI was changing the label on its intracardiac electrodes from “reusable” to “single use,” “our manufacturing processes . . . have not changed. These electrodes are made with the same materials and in the same manner as they have been in the past”). See also, Letter from Geoffrey M. Allen, Boston Scientific Corp., Microvase Division (May 1, 1987), at 2 (informing a hospital that its “BICAP® Hemostatic Probes are recommended for single use only. However, this recommendation does not prohibit reuse under certain specific conditions. . .”).

¹³ U.S. Government Accountability Office, GAO/HEHS-00-123, *Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted* (June 2000), at 11 [hereinafter 2000 GAO Report].

¹⁴ Directive, Annex I section 23.2(n) of Directive 93/42/EEC

¹⁵ AMDR <http://amdr.org/reprocessing-by-the-numbers/>

products in their territories (Article 17.1, 9) as the MDR requires that not only must remanufactured versions of medical devices meet the same requirements as new devices, but they must also be allowed on the individual Member State markets, as permitted by national law. See further discussion below.

Despite this critical analysis of the SUD label and existing regulations, AMDR supports the cornerstone principle of the MDR's Article 17, which concludes that reprocessing of SUDs is manufacturing, and thus subject to the same requirements as any other medical device placed on the market. This regulatory vehicle ensures a path to market for device companies wishing to offer environmentally beneficial remanufactured device options. However, we urge the Commission to include medical products in its evaluation of the Products Sustainability Initiative.

Remanufacturing Certain Medical Devices – The Easy, Sustainable Change

Solutions such as medical device remanufacturing help promote a more resilient, cost-effective, and environmentally sustainable health care supply chain. Medical device remanufacturing also builds a circular health care economy, creating jobs in the EU and keeping financial resources at home, within health institutions, rather than spent on unnecessary supplies from a global supply chain. However, Europe has been slow to adopt this solution.

We urge the Commission to include health care consumers (i.e., hospitals, medical professionals, purchasers, and the like) in the scope of any work concerning the Sustainable Products Initiative or others aimed at promoting the circular economy. Medical device remanufacturing is one immediate, regulated solution that can “facilitate preparing for re-use and recycling of waste in the EU.”¹⁶

Promoting these initiatives will “generate additional economic activities in the sectors of recycling and trade/transport of recycled materials, especially within the EU,”¹⁷ and promote the generation of high-tech, medical technology sector jobs such as biomedical and mechanical engineers, collections technicians, and cleaning and sterilization professionals. This will incentivize development of a larger EU medical device remanufacturing industry or encourage the manufacturers “to become more circular, resource-efficient and reduce their carbon footprint, in line with the climate and energy goals of the EU.”¹⁸

Reliable and Relevant Information at Point of Sale

AMDR encourages the Commission to include medical devices in the revision of any existing policy instruments on products' environmental performance. In health

¹⁶ European Commission, Inception Impact Assessment, *Waste Shipments – Revision of EU Rules*, 2020.

¹⁷ *Id.*

¹⁸ *Id.*

care, as in other sectors, consumers often lack reliable, consistent, or relevant environmental characteristics data. Further, there is a false perception that regulated, remanufactured SUDs may be inferior to new devices, despite both being subject to the same safety and efficacy standards.

Information from the Commission to health care consumers on what it means to be a remanufactured SUD would greatly assist already overwhelmed hospitals as they make medical device purchasing decisions. As the Impact Statement specifically addresses three subcategories of concerns, we provide brief comments below related to medical device consumers:

Product Sustainability

AMDR is unaware of any uniform mechanism by which to identify environmentally preferable options in health care and is not aware of great use of the EcoDesign label for health care products. AMDR is aware of efforts by Health Care Without Harm to promote environmentally preferable options in health care,¹⁹ but no “green certification” exists. The development of a uniform “Green” seal, of course, is no small undertaking, but should the Commission seek to revise existing policy instruments to make products’ environmental performance available, AMDR would greatly support such an initiative. We believe device manufacturers would thereby be appropriately incentivized to make medical devices that allow the consumer to get more value or lifespan from devices, and thereby create less medical waste.

Availability of Repair Services

AMDR supports more information on the availability of repair, reprocess, or remanufacturing options. Broadly speaking, if a remanufactured equivalent of an existing medical device achieves a Conformance Europeene (CE) mark, indicating conformity with health, safety, and environmental protection standards for products sold in the EU, AMDR greatly supports making that information available to all health care 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, disposable options. Such a move would foster the growth of European remanufacturing operations rather than rely on the import of disposables from Asia.

Software Upgrades/Updates

¹⁹ <https://noharm-europe.org/>

One of the biggest threats to a Circular Economy for medical devices is OEM use of software “updates” or “upgrades” that have the intended effect of preventing remanufactured versions of medical devices from working with consoles or generators. OEMs make both the consoles/generators and the instruments 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 by preventing remanufactured versions of medical devices from working. AMDR believes this activity is anticompetitive 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 at [link](#) (and cited below) to address this issue in further detail and to provide instruction for hospitals on how to combat unwanted software upgrades.²⁰ AMDR supports any Commission initiative to strengthen health care consumers’ rights when it comes to software updates or upgrades.

Commercial Practices that Cause Confusion and Misinformation to Dampen the Purchase of Remanufactured Medical Devices

In addition to software upgrades or updates aimed at ensuring hospitals buy more unnecessary equipment, AMDR believes the use of 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.²¹

New iterations of devices are consistently placed on the market, often with little to no evidence of improved performance, cost, or other positive variables necessitating adoption of newer generations. Health care consumers have had little option but to accept the latest model medical equipment, which often means accepting devices that have wasteful, built-in planned obsolescence. This dramatic tilting of the scales in favor of the device companies disfavors health care consumers, patients, and taxpayers, creating additional unnecessary manufacturing of original devices when more environmentally sustainable remanufacturing could be used. The incentives placed on manufacturers are to sell more, not develop better, longer

²⁰ AMDR, [Software “Updates” Aimed to Thwart Reprocessing](#), 19 April 2018.

²¹ [Forced Obsolescence Designed Into Devices](#), AMDR, 19 April 2018.

lasting, and more environmentally sustainable products. Education for health care consumers on forced early failure efforts by device companies would provide a strong counterbalance to the power of the device industry and would encourage such manufacturers to be more holistic in future medical device development and design.

The Opt-In Process Unfairly Discriminates Against a Healthier EU

Finally, as eluded to earlier, the existing EU regulation for Medical devices places an unlevel regulatory burden on medical device remanufacturing, thus discouraging a circular economy in the medical device sector.²² While medical devices must bear a CE mark to be lawfully marketed, indicating conformance with the Regulation or Directive's requirements, EU Member States must also affirmatively "opt in" to allowing remanufactured devices within their territory.

This anti-competitive measure runs counter to sound science and good environmental policy. To allow Member States to supplant their judgement, 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 normal 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 carve out exists in EU regulations whereby Member States are allowed to prospectively reject otherwise CE mark entitled products, absent any existing safety concerns (The Safeguard Clause (Article 8) of the MDD).²³

This additional National law requirement deprives many in the EU of access to safe, lower cost and environmentally preferable medical device options. This "opt in" provision creates an enormous disincentive in Europe for hospitals to be good environmental stewards by remanufacturing their devices, despite Regulations ensuring the safety and efficacy of such products. 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 and efficacy of medical device products, including remanufactured devices, that meet the MDR's requirements.

When it comes to remanufacturing of single-use medical devices, hospitals and patients can reduce environmental impact, reduce costs, build a more resilient supply chain, and encourage a more competitive environment for health care products. But we need the European Commission to play an active role to make it

²² 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.

²³ Article 8, European Council Directive 93/42/EEC 14 June 1993 concerning medical devices.

so. We urge the Commission to consider health care products in its Sustainable Products Initiative and we hope remanufacturing of single-use medical devices will be given special attention due to its immediate potential to transition to sustainable, circular alternatives.

Thank you for your consideration and for this opportunity to comment.

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Vukelich', written in a cursive style.

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