AMDR Comments to the European Commission's Inception Impact Assessment on Waste Shipments- Revision of EU Rules

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

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The Association of Medical Device Reprocessors (AMDR) welcomes the Commission's Inception Impact Assessment on the Waste Shipment Regulation (WSR). AMDR members are professional medical device reprocessing and remanufacturing companies, subject to the European Union's Medical Device Regulation (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 reprocessing and requires commercial firms to meet manufacturer standards, thus adoption of the term, "remanufactured," in Europe.

The Need to Decarbonize the Health Care Supply Chain

Healthcare 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."[1] 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." HCWH calls on Europe to "decarbonize the health care supply chain. Health ministries, hospitals, and health systems should set criteria for low-carbon or zero emissions procurement; while suppliers and manufacturers should decarbonize their operations and products."

A disposable culture has emerged in recent decades, predicated on the false belief that many medical instruments can only be used once, or hospitals are at risk of creating cross infections in their patients. The shift to disposable products has contributed to a mountain of waste generated by hospitals. Additionally, healthcare's contribution to Greenhouse gas emissions (GHG) has been studied and linked to acid rain, photochemical smog, and respiratory disease. These studies suggest healthcare itself is making people sicker.[2]

The COVID crisis has only fueled the healthcare waste crisis. The pandemic is generating tons of additional medical waste as clinicians dispose of single-use Personal Protective Equipment (PPE) and ancillary medical devices used on COVID patients.[3] The strain on the healthcare supply chain has led to shortages of desperately needed PPE and other medical devices. This does not account for the cost associated with the additional demands, supplies, waste, waste disposal costs and adverse environmental "costs."

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

2 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

3 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

Remanufacturing Certain Medical Devices – The Easy, Sustainable Change

AMDR appreciates the Commission's communication on a European Green Deal and efforts to mobilize industry for a clean and circular economy. Solutions like medical device remanufacturing help promote a more resilient, cost-effective, and environmentally sustainable healthcare supply chain. Medical device remanufacturing also builds a circular healthcare 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. But Europe has been slow to adopt this solution.

As it relates to the current Impact Assessment, as written, the WSR and the European Agreement Concerning the International Carriage of Dangerous Goods by Road[4] do not contain any restrictions on the transport of medical devices intended to be remanufactured. However, medical devices, at their end of life, are not traditionally exported out of the EU are most often incinerated here in Europe.

Consistent with the objectives and policy options currently contemplated, we urge the Commission to explore "other possible initiatives or guidance documents, with a view to improving its implementation." Consistent with the Impact Assessment policy options, medical device remanufacturing is one immediate, regulated solution that can "facilitate preparing for re-use and recycling of waste in the EU." We appreciate that the Commission has not limited its potential policy options to only revisions of the WSR itself. AMDR supports flanking measures with soft law guidance or information tools make Ministries of Health, hospitals, and health systems aware of their ability to reduce the impact of waste in healthcare.

Additionally, promoting these initiatives will "generate additional economic activities in the sectors of recycling and trade/transport of recycles materials, especially within the EU," and promote the generation of high tech, medical technology sector jobs such as biomedical and mechanical engineers, collections technicians, cleaning and sterilization professional, etc. This will incentivize development of a larger EU medical device remanufacturing industry or encourage the manufacturers themselves (note, AMDR members are both independent of original equipment manufacturers (OEMs) and also subsidiaries of OEMs) "to become more circular, resource-efficient and reduce its carbon footprint, in line with the climate and energy goals of the EU." Also, consistent with the United Nations *Sustainable Health Procurement Guidance Note,* AMDR believes that guiding healthcare purchasing and disposal decisions "towards more sustainable consumption and production practices (SDG 12) can drive markets toward innovation and sustainability, thereby enabling the transition toward a greener economy, resilient health sector, healthier people and plant."[5]

The Opt-In Process Unfairly Discriminates Against a Healthier EU

The Impact Assessment notes the Commission's intent to implement and enforce regulations "in the same way by all Member States to ensure a level playing field." As noted, there is nothing detrimental to the transport of medical devices intended for remanufacturing, but

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[4] *European Agreement Concerning the International Carriage of Dangerous Goods by Road, ADR*, v. 1 **United Nations**, January 2019: https://www.unece.org/fileadmin/DAM/trans/publications/ADR_2019_vol1_1818953_E.pdf

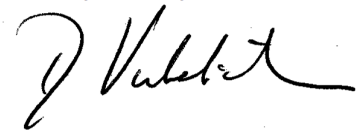
[5] *Sustainable Health Procurement Guidance Note,* **United Nations Development Programme,** March, 2020: https://www.undp.org/content/undp/en/home/librarypage/hiv-aids/guidelines-for-sustainable-procurement-of-healthcare-commodities.html

other existing EU regulations (EU MDR)[6] place an unlevel regulatory burden on medical device remanufacturing. Specifically, 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. AMDR can find no other example where a carve out exists in EU regulations whereby Member States are allowed to reject CE marked products, absent any existing safety concerns (The Safeguard Clause (Article 8) of the MDD).[7] This creates an enormous disincentive in Europe for hospitals to remanufacture their devices, despite Regulations ensuring their safety and efficacy.

AMDR therefore respectfully requests the Commission to:

- Consider inclusion of incentivizing measures aimed at reducing healthcare waste within the context of revisions of the WSR;
- Develop "other possible initiatives or guidance documents" to promote medical device remanufacturing in Europe to help achieve the objectives of the Impact Statement. AMDR supports flanking measures with soft law guidance or information tools make Ministries of Health, hospitals and health systems aware of their ability to reduce the impact of waste in healthcare;
- Work with stakeholders such as the European Remanufacturing Council, Healthcare Without Harm and AMDR to further disseminate information to Member States to encourage opting-in to the EU MDR's Reprocessing and Remanufacturing provisions and/or other measures to reduce healthcare waste; and
- Seek greater harmonization of medical device remanufacturing and regulation across the various Member States to encourage a circular economy and promote a green recovery by guidance, education, or other measures.

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



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[6] *See* Article 17, 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.

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