AMDR comments to the UK Medicines and Healthcare Products Agency (MHRA):

Consultation on the future regulation of medical devices in the United Kingdom

23 November 2021

Note: comments were submitted via MHRA's portal on Chapters 4 (Registration and UDI), 7 (Clinical Investigation/Performance Studies), 12 (Other Product-Specific Changes) and 13 (Environmental sustainability and public health impacts).

Chapter 4: Registration and UDI:

(Response to question 21:13) AMDR proposes that MHRA not allow SUDs reprocessed in hospital settings to be placed on the market, and, absent a change after this consultation, it does not seem likely MHRA will allow such products anyway.

Chapter 7: Clinical Investigation/Performance Studies:

Q31.1: Do you think the specific requirements, outlined paragraph 31.11 that related to claiming equivalence should be introduced? y/n/don't know.

No.

Q31.2: Please provide any additional information (for example outline what requirements you think should be introduced around claiming equivalence or explain why you do not agree that additional requirements should be introduced.

Summary:

AMDR does not believe the additional specific requirements outlined in paragraph 31.11 are necessary. However, if maintained, AMDR urges MHRA to:

Strike 31.11(b)(i) on contract requirements; and

Include remanufactured SUDs in the future exemption list (31.11(c)(ii)).

We urge that 31.11(b)(i), that a "contract [be] in place with the manufacturer to allow them full access to the technical documentation for the medical device," be stricken. Instead, we urge MHRA simply require that any manufacturer seeking to demonstrate equivalence under this subsection must, "demonstrate with satisfactory data used against industry standards, or by contract with the original manufacture or other

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means, knowledge of the material composition and construction of a device, and proving equivalent functionality with the predicate device, on an ongoing basis."

Contract requirements with original manufacturers are not the only way to obtain technical documentation to underscore a fundamental knowledge of a product. SUD remanufacturers, for instance, have over 20 years' experience reverse-engineering, or employing other mechanisms, to document intimate knowledge of a product's composition. A contractual requirement obligation is anticompetitive, as it allows original manufacturers to dictate which firms can and cannot compete with them for certain products. We think MHRA should instead focus on safety, and not contractual obligations, to ensure, as the paragraph seems to seek, that any manufacturer demonstrating equivalence has a complete knowledge of the product's technical composition.

Further, should MHRA maintain the requirements of 31.11(c), we urge the agency to include remanufactured SUDs in the future exemption list (31.11(c)(ii)), as such devices have already undergone a full conformity assessment. Remanufactured devices are not only equivalent but are almost always identical in their design (the predicate and the remanufactured device are the same device). Remanufacturers, as required elsewhere in the regulation, instead should focus on supplying additional cleaning, sterilization and functional performance data demonstrating the product is equivalent to the predicate device.

Chapter 12: Other Product-Specific Changes:

Q67.1: Do you think that the UK MDR should include the requirements for re-manufacturers for SUDs set out in paragraph 67.5?

Yes.

Q67.2: Please outline any other requirements which should be introduced for the remanufacturing of SUDs.

None.

Q67.3: Do you think the UK MDR should introduce the requirements set out in paragraph 67.6 for remanufacturers of SUDs on behalf of health institutions?

No.

Q67.4: Please outline any other requirements which should be considered or explain why you do not agree that additional requirements should be introduced.

Summary: AMDR proposes to strike 67.6(a) as "closed loop" adds needless confusion.

"Closed loop" can be a confusing term and we believe the intent here could get lost. We urge striking of subsection (a) or, alternatively, ask MHRA to amend, for clarity. We believe the intent of the regulation is to ensure a "closed loop" as between a hospital and remanufacturer, meaning no other third-party should interrupt that loop as MHRA intends to prevent, for instance, another third-party remanufacturer from gaining access to devices and potentially remanufacturing a device that has already been remanufactured by another firm. As written, this subsection could be interpreted to prevent hospitals from working with more than one remanufacturer (a hospital may choose different remanufacturers for different device types, for example). We don't believe, in practice, the concerns here are a real problem. SUD remanufacturers already have systems in place, as they are required to, to identify the number of cycles a device has been remanufactured. Anything arriving with any indicia of reuse NOT done by that remanufacturer, would be rejected. We therefore urge striking of 67.6 as "closed loop" only creates more confusion than clarification.

Alternatively, we urge MHRA to strike the second sentence of subpart (a). Compliance with the first sentence would not result in violation of the second sentence. A contractual obligation between hospital and remanufacturer(s) is sufficient to ensure a "closed loop."

Q67.5: Do you think that the MHRA should allow the re-manufacturing of Class I single-use medical devices?

Yes.

Q67.6: If you have answered yes to question 67.5, please outline what the requirements should be in place for the remanufacturing of Class I single-use medical devices.

Summary: MHRA should lift the prohibition on class I device remanufacturing. The original ban was written at a different time when class I devices were subject to less premarket review.

We believe MHRA's original prohibition on class I remanufactured devices was released at a time when the concept of SUD remanufacturing was new or unproven. This is no longer the case, and class I device controls have increased since 2016 (both in the EU and UK). Therefore, we do not think this restriction is necessary any longer. By definition, a device that meets the requirements of the Regulation has demonstrated meeting safety and efficacy requirements, including remanufactured devices (which must meet all requirements and those outlined in 67.5).

The new EU and UK medical device regulations, for Class I devices, have controls for sterile, measuring and devices intended for reuse or reprocessing. As with any of the products, we believe these additional class I controls suffice for remanufactured products as well. Chapter 5, subpart 22, confirms that manufacturers are required to

undergo conformity assessment UNLESS the medical devices are "class I medical devices without sterile/measuring functions."

Further, Chapter 7, subsection 31.1(b)(iii) requires that class I devices "have post market studies in place to collect their own data for their medical devices." We believe these requirements suffice and there should not be additional class I restriction for remanufactured devices. Remanufactured class I devices that are sold as sterile or have measuring functions, would still be subject to the same controls and conformity assessments as if sold original (new). Further, post market surveillance data will ensure, that these low-risk devices, are indeed low risk, as post market data should confirm such for remanufactured devices just the same as original devices.

Q67.7: Do you think that the MHRA should continue to allow the reprocessing of single-use devices? y/n/don't know

No**.**

Q67.8: If yes above, please outline what requirements should be put in place for reprocessing of SUDs.

Q67.9: Please provide your reasoning (including ay available relevant evidence) to support your answers to questions 67.1-67.8, including any impacts on you or other stakeholder groups.

Summary: We believe MHRA's existing guidance on SUD reprocessing DOES sufficiently make clear that such practices are NOT ALLOWED.

AMDR does not support a change in this policy. MHRA has spent considerable time vetting SUD reuse and has concluded, as per the above provisions, that any reuse of SUDs should comply with the same level of regulatory requirements as any other product placed on the market. To allow SUD reprocessing and introduce a new lower standard for some products for some users, would inject an un-level regulatory playing field, disparate safety standards and is therefore not acceptable for UK patients.

For over 20 years, AMDR has advocated worldwide for harmonized regulatory oversight of SUD reuse as a manufacturing activity (or, remanufacturing), subject to the same controls applicable to all other devices. In the US, Canada, Germany, the UK, Japan and increasingly more EU Member States, SUD reprocessing increasingly has moved out of hospitals to specialized, commercial facilities. The US FDA and European Notified Bodies have cleared or approved remanufactured SUDs from commercial remanufacturers for availability on the US, EU and UK markets, and product offers continue to grow.

Chapter 13: Environmental sustainability and public health impacts.

Hospitals and health systems were environmentally wasteful long 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." 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."

The medical community is increasingly aware that single-use plastic products are part of the problem, as evidenced by a recent editorial in the British Medical Journal online, stating,

"We must not let our reliance on single-use plastic in healthcare become the 'new normal' or set-back the strides taken prior to the covid-19 pandemic to address the primary existential crisis concerning our environment … At a product level, the re-manufacture of [EP] catheters was found to reduce its carbon emissions by a minimum of 50%."

Remanufactured SUDs are regulated to the same safety and efficacy standards as new devices by MHRA, the US FDA, Health Canada, Japan and now the EU. SUD remanufacturing saves money, improves supply chain resiliency and, at the same time significantly reduces waste and greenhouse gas emissions.

Although AMDR member companies remanufactured over 31 million such devices and returned them to over 10,300 hospitals last year, our members are convinced this represents only a tiny fraction of the SUDs that could be remanufactured because they are regulatorily cleared for remanufacturing.

Reducing greenhouse gas emissions to reduce the impact on the environment is of paramount importance. MHRA has the authority, with consideration of this policy, to assure that hospitals will have the ability to use safe and effective remanufactured devices.

MHRA is no doubt aware that the National Health Service (NHS) has committed to a Net Zero emissions program. The initiative sets two targets: For the emissions NHS controls directly, NHS will reach net zero by 2040, with an ambition to reach an 80% reduction by 2028 to 2032. For the emissions NHS can influence, NHS will reach net zero by 2045, with an ambition to reach an 80% reduction by 2036 to 2039.

AMDR and our members are thrilled that NHS is committed to using remanufactured SUDs whenever possible (Please see interview with Alan Wain, Chief Operating Officer for NHS Supply Chain Coordination, National Health System).

Q71.1 To what extent are you or your organisation already implementing, or planning, activities to reduce the impact of medical devices on the environment? Please outline any key activities you have underway or planned.

Summary: Remanufactured SUDs offer a scientifically proven, lower greenhouse gas emitting medical device option.

In 2020, AMDR members remanufactured 31,849,353 SUDs, returning these products to over 10,000 hospitals around the world, including in the United Kingdom.

Researchers from Yale, Northeastern, and the University of British Colombia – among other institutions – took a deep dive (Health Affairs, *Health Care Pollution and Public Health Damage in the United States; an Update,* Eckelman, Huang, Lagasse, Senay, Dubrow and Sherman, December 2020) into the environmental emissions from the U.S. healthcare sector and found that Scope 3 emissions, those largely from the supply chain required to treat patients, accounts for 82% of the problem (updating the previously referenced 71% figure from HCWH). Thus, solutions that specifically address supply chain emissions, such as single-use device remanufacturing, should be given heightened attention.

Further, a number of British academic papers are calling for health care institutions to address needless consumption and generation of plastic waste, and to embrace SUD remanufacturing as a solution, see, Royal College of Surgeons, *Using Surgical Sustainability Principles to Improve Planetary Health and Optimise Surgical Services Following the COVID-19 Pandemic*, Rizan, Reed, Mortimer, Jones, Stancliffe and Bhutta, July 1, 2020. See also, British Journal of Surgery, *Strategy for Net-Zero Carbon Surgery*, Rizan, Bhutta, 8 May 2021. See also, Journal of the Royal Society of *Medicine, Plastics in Healthcare: Time for Re-evaluation*, Rizan, Mortimer, Stancliffe, February 7, 2020. Finally, see Cleaner and Responsible Consumption, *Hierarchical Analysis of Factors Influencing Acceptance of Remanufactured Medical Devices*, Akano, Ijomah and Windmill, June 2021.

A well-designed, peer reviewed, published (Sustainability, *Combining Life Cycle Assessment and Circularity Assessment to Analyze Environmental Impacts of the Medical Remanufacturing of Electrophysiology Catheters,* Schulte, Maga and Thonemann, 13 January 2021) life cycle analysis (LCA) of one type of the devices our members remanufacture, electrophysiology catheters, found that remanufacturing was environmentally preferable to the use of new devices in 13 of 16 environmental inputs measured, including significant (89%) reduction of emissions.

More life cycle analysis studies are planned for other devices cleared or approved for remanufacturing in the US and Europe. We anticipate these will confirm the findings of the initial LCA. We believe SUD remanufacturing is central to creating a circular economy in health care. SUD remanufacturing reduces our reliance on new devices, reduces reliance on a global supply chain, reduces costs, and reduces waste and greenhouse gas emissions.

Therefore, AMDR strongly supports MHRA actions to require manufactures to complete, as part of their conformity assessment for medical devices, an assessment of the device's impact on both the environment and public health, including whether the device can be reused, reprocessed, remanufactured or recycled and of the greenhouse gas emissions associated with its disposal.

Further, AMDR supports MHRA in its efforts to introduce waste management responsibilities into the medical device supply chain with a focus on minimizing needless purchasing of original devices when reused, reprocessed or remanufactured devices could be used. We believe requiring end of life greenhouse gas emissions estimates would help fuel more conscientious medical device procurement.

Lastly, AMDR supports broadened MHRA use of electronic labels. We believe FDA has already instituted such a transition to E-IFUs in the US and, so far as our experience tells us, it has worked positively and reduced paper/paperwork, product shipment weights, etc.

Q71.2 Do you see a need for additional requirements to be placed on economic operators in order to encourage them to consider and/or mitigate the environmental impact of medical devices they place on the UK market?

End of life "costs" should be assessed at the initial design stage, not after the fact. Therefore, AMDR encourages MHRA to assess the environmental and financial costs of disposal of products as these costs fall to the Health Trusts and the emissions associated with their incineration adversely impact local communities.

As it stands with MHRA and most medical device regulatory authorities, manufacturers are incentivized to label devices for single-use. Not only do manufacturers sell more devices, but the premarket regulatory burden is less. Specifically, manufacturers submitting devices marked for single-use need not validate cleaning or sterilization protocols. They need not write cleaning or reprocessing instructions. The end user simply throws the device away.

The reality, however, is there is no "away." Instead, the spent device becomes the Health Trust and the local community's problem. This wasteful mindset contributes to the over 80% of health care emissions that originate from the supply chain.

Disposal of single-use devices contributes to a shocking amount of costly medical waste that is often incinerated, creating greenhouse gas and other toxic emissions that are known to make humans sicker. In a field where care providers commit to "doing no harm," our medical institutions are too frequently burning toxic medical waste. Studies show patients living near incinerators are nine times more likely to suffer from wheezing or coughs, and twice as likely to develop asthma and other respiratory diseases. For this reason, AMDR supports MHRA efforts to have manufacturers address a device's end of life impact at the conformity assessment stage.

Consistent with the hierarchical analysis outlined in the Cleaner and Responsible Consumption Journal article (cited above), MHRA should address end of life product recovery strategies in its product evaluation. Direct reuse and remanufacturing should be prioritized over recycling.

UK Health Trusts should be encouraged to purchase reusable or remanufactured medical devices over SUDs. AMDR supports efforts to require Health Trusts to commit to using remanufactured products, if available.

MHRA should develop guidance for Health Trusts exercising its regulatory authority over the shipment of products to remanufacturers versus shipment for incineration. SUDs intended for remanufacturing should be subject to the same sort of transport restrictions or controls as multiple use devices to be serviced or repaired.

Q71.3 Please explain the rationale for your response to question 71.2 and any expected impacts.

We believe, consistent with MHRA's mission, the safety of a device at its end of life should be contemplated during the review stage. Taxpayers are paying to dispose of or incinerate disposable healthcare devices and products, with their pounds and with their health. NHS and MHRA should therefore, consistent with the overall mission to meeting net zero commitments and to promote circular economies in health care, promote environmental and public health assessments at the conformity assessment stage, with a focus on promoting medical device reuse and remanufacturing options.

Q71.4 What are your views on the options for change outlined in paragraph 71.5? Please state your rationale, key implementation considerations and the expected impact of these options.

AMDR believes this is a good start. Admittedly, the UK is ahead of much of the world in its commitment to making its health care Net Zero. NHS is making measurable improvements to reduce supply chain emissions. Clinicians are engaged. And MHRA as competent authority, the first of its kind, so far as we know, is looking to contemplate environmental sustainability and public health impacts of medical devices at the design stage to be reviewed at the conformity assessment stage.

While MHRA and NHS are among the first to promote these considerations, AMDR believes that environmental and human health impacts of medical products WILL be assessed by procurement and authorizing agencies worldwide. Based on the statistics noted above, there is no alternative. And, in a field committed to doing no harm, the moral imperative is clear.

That said, this is just a start. Major change will encounter opposition, largely from the MedTech sector. But industry will follow, and we believe, as evidenced by the very existence of the SUD remanufacturing industry, it can develop circular, sustainable solutions if demanded to do so by their health care providers customers. We believe MHRA has appropriately identified reasonable options for change. We support the agency in its efforts to begin contemplating consideration of the items outlined in 71.4 and 5 at the conformity assessment level.

Q71.5 What other changes or key considerations do you think are needed to ensure more sustainable medical devices?

We believe government should play a role in eliminating the growing practice of intentionally designing products for single-use, as it contributes to global warming through unnecessary take-make-waste processes. We propose to empower MHRA and Notified Bodies to have the power to question technological changes to iterative generations of medical devices that contain suspected "forced obsolesce." "Kill chips," software "upgrades," the cheapening of materials used in construction, or intentional construction mechanisms aimed at thwarting subsequent device repair or remanufacturing should not be allowed for consumer products like cell phones and most certainly not for devices we use to treat and cure our patients.

If or when reprocessable or remanufactured versions of medical devices have achieved a UKCA or CE marking, subsequent iterations of that device from the original manufacturer should be given a special review to ensure forced obsolescence measures are not being employed to force the NHS to procure more devices when a reusable or remanufactured version exists.

As MHRA and Notified Bodies core competencies are safety and efficacy, only MHRA and Notified Body independent assessment and curtailment of designed obsolescence will be credible. Further, MHRA and Notified Bodies will have access to both the OEM and remanufacturer design files. Market actors, medical device companies and remarketers and refurbishers, need the third-party, vendor neutral arbiter of such oversight authorities. To continue to ignore this "gaming of the system" whereby some manufacturers force needless additional consumption of new medical equipment costs the taxpayers money and pollutes the environments of the patient populations we are seeking to heal.

Q71.6 What are the key implementation considerations for the options outlined in paragraph 71.5 and any further potential changes you consider are required?

MHRA has a role in weeding out "green washing," by some medical device companies to market their products as environmentally preferrable. Recycling less appealing than reuse functions such as remanufacturing because more environmental disruption is required than reuse or remanufacturing. Requiring premarket public health impact assessments and waste management responsibilities will help to counter misinformation and make health care purchasers more informed about the full health and environmental impact of their medical device choices.

Q71.7 Please set out which options could be introduced quickly (within 1-2 years) and which could be introduced within a longer timeframe?

Fundamentally, AMDR's view is that the options presented in 71.5 a through d are listed in the priority of their impact. We note environmental and public health impact assessments during the conformity assessment would shine a spotlight on devices that are NOT in some way reusable and contribute to the growing waste problem.

We also suggest highlighting alternatives to wasteful practices -- medical devices that are reusable/reprocessable or remanufacturable. Stronger regulatory oversight of "chipping," or other forced obsolescence efforts with single-use devices would reduce the launch of devices with no added clinical benefit that cost more and/or produce more waste. Public reporting of such information to MHRA would provide health care consumers more information to move away from the "take-make-waste" mindset to one of circular economy solutions.

Secondly, a focus on waste management responsibilities would highlight that throwing a device "away," simply shifts disposal responsibility to the Health Trusts. It further forces the needless generation of harmful emissions IN the UK, putting patient populations at risk. Disposal at the end of life is not a waste management solution; it's shifting the problem from producer to consumer.

Third, asking manufacturers to account for the substances used in the manufacture of devices could reveal harmful materials ending up in the atmosphere.

About AMDR

The 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 reprocessing 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.