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Minister of Health Dr. M.J. Phaahla, MP
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Submitted Electronically

Regarding: Proposed Medical Device Regulations and Reprocessing **27 October 2023**

Dear Minister Phaahla:

The Association of Medical Device Reprocessors (AMDR) – the global non-profit trade association for regulated commercial single-use medical device reprocessors and remanufacturers – submits the following comments in response to the South African Health Products Regulatory Authority's (SAPHRA's)1 August 2023 notice on General Regulations Made in Terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965): Amendment.

Overview: AMDR encourages SAPHRA to modify section 16 on single-use devices (SUDs) as outlined below (see additions in bold-face type). AMDR represents the thriving industry of *regulated* medical device reprocessing and remanufacturing companies. As costs and demands have risen, and particularly since COVID, policymakers, academics, and healthcare providers have intensified their efforts to find safe, cost-effective, sustainable medical devices and stable supply chains for which regulated medical device reprocessors and remanufactures have stood out as the solution.

Without accepting the suggested changes outlined below, SAPHRA will deny South African hospitals access to competitively priced, regulated, safe and effective reprocessed devices that lower costs, strengthen supply chains, and reduce environmental impact. The Authority will also contradict the well-regulated and long-established policies on SUD reprocessing followed in the United States, United Kingdom, European Union, Canada, and Japan.

Definitions from Proposed Regulation

SAPHRA proposes to maintain medical device *reprocessing* in its definition of "**manufacture**." The proposed ban on reprocessing of SUDs in Section 16, therefore, is incongruent with the Authority's definition in section 1 of "manufacture" that includes "reprocessing." Furthermore, Section 15 seems to acknowledge there are instances in which single-use devices can be placed back on the market, in this case, after "refurbishment" (referring to the "substantial rebuilding.")

In section 1, the Authority defines **reprocessing** "as the activity carried out on a used medical device to allow its safe re-use…" Commercial medical device reprocessors meet the same standards, requirements, and regulations of safety and efficacy as those met by the original equipment manufacturers (OEMs). I have attached a list of globally recognized standards, as they are applicable to commercial reprocessors. Interestingly, several AMDR members are OEMs, including Arjo, Cardinal, Medline and Stryker. When devices are reprocessed by commercial reprocessors under these regulatory schemes and in compliance with these standards, the reprocessors become the legal manufacturer and take responsibility and liability for these devices.

Circular business models in healthcare, which recover and extend the life of spent medical device assets, are essential to combat supply chain shortages, and growing waste, emissions and cost concerns. Reprocessed devices are circular, because they keep devices out of the trash or incinerator as long as possible: Hospitals learn to treat reprocessable medical devices as assets, not waste. SAPHRA would be better served to ensure that circular business model products are safe and effective rather than banning them without evaluation. SAPHRA would also be in alignment with leading global regulatory authorities. See historic AMDR understanding of SAPHRA's regulation of SUD reprocessing. We urge SAPHRA to keep this definition, as proposed, but we also urge the amendment of Section 16 as shown below.

Amendments to Section 16 of the Proposed Regulation

AMDR urges SAPHRA to amend section 16 as shown in bold-face type.

Single Use Medical Device
16. (1) A medical device designated by the original manufacturer or as determined by the Authority for single use only –

(a) must be disposed of after use**, unless sent to a registered, regulated reprocessor**; and

(b) may not be reprocessed**, unless the reprocessed device meets all the requirements of this Regulation.**

(2) If the sterility of a medical device designated by the original manufacturer or as determined by the Authority for single use only, is compromised it-

(a) must be disposed of after use, **unless sent to a registered, regulated reprocessor;** and

(b) may not be reprocessed**, unless the reprocessed device meets all the requirements of this Regulation.**

Rationale

A medical device, including a reprocessed device, which has demonstrated compliance with the regulatory requirements governing medical device manufacturers, including a quality management system, has--by definition--demonstrated that the product is safe and effective and, therefore, is legally marketable.

It would be anticompetitive for SAPHRA to prohibit a company from using as raw material a recovered, previously used device and reprocessing it to be safe and effective while also meeting all requirements of the regulation. This prohibition is also bad public/economic policy, because it puts in place a barrier to circular business models that provide less expensive and less pollution-emitting products and stimulate a more resilient supply chain. Rather than deciding which manufacturers can and cannot do business in the South African market, SAPHRA should focus its concern, as do other medical device oversight agencies, on ensuring that all devices placed on the market meet the regulations, ensuring safety and effectiveness.

By adding the suggested amendments, SAPHRA can usher in a proper policy of forbidding hospitals from engaging in unregulated, unvalidated reuse of SUDs and usher in an era of safe, regulated commercial reprocessing subject to manufacturer/regulatory standards and oversight.

COVID-19 and climate change have shone light on the vulnerability and wastefulness of the healthcare supply chain. Major medical journals are filled with articles expressing the growing, global need to convert hospitals from massive carbon sinks into less greenhouse gas emitting, circular business models. Commercial reprocessing is frequently cited as "low hanging fruit," because switching to more reprocessed SUDs is an immediately available solution (examples: British Medical Journal, Health Affairs, The Lancet, JAMA).

Cost savings from the use of reprocessed SUDs are substantial. In 2021 alone, our members saved hospitals worldwide the equivalent of approximately ZAR R 8 037 520,00.

As the proposed regulation is written, we also caution against SAPHRA policing usage of the single use label. SAPHRA would be the first and only medical device competent authority, of which we know, to empower itself to require a single-use label. In all other markets, the manufacturer, not the regulator, makes the decision on how to market a device. The regulatory agency will clear or approve the product based on the manufacturer's designation and the agency's own regulations for that designation. If designated for *single use,* the original manufacturer need only provide data demonstrating the product can be safely used once. If the manufacturer designates the device as *reusable*, it is expected to validate cleaning instructions and demonstrate the device is safe and effective after that cleaning regimen. No other medical device competent authority has claimed the governance to declare a product anything other than what the manufacturer intends. The single-use label is often times used only as a marketing designation for the OEM to sell more devices. In other instances, it is rightly intended to ensure that a device is not used on more than one patient. It does not mean, however, that the product, subject to all medical device manufacturer requirements, cannot be reprocessed.

Instead, regulatory authorities in other jurisdictions have cleared or approved hundreds of models of SUDs to be reprocessed when done so by regulated, commercial firms that have met the regulatory requirements. Once reprocessed, liability for the device shifts from the OEM to the commercial reprocessor. Commercial reprocessors must produce evidence to demonstrate substantial equivalence to OEM devices.

Decades of Successful Regulation

Regulation of commercial reprocessors as manufacturers began in the United States in1998 (Food and Drug Administration) and Canada (Health Canada) and expanded in 2017 to the European Union (EU Medical Device Regulation) as well as Japan (Ministry of Health, Labor and Welfare) and the United Kingdom (Medicines and Healthcare Products Regulatory Agency).

More than 300 kinds of reprocessed devices first labelled for single use by their original manufacturer have been evaluated as safe and effective by FDA and now also by European Notified Bodies. The issue of safety and regulated reprocessed SUDs was put to bed in 2008, when, after nearly a decade of use in thousands of U.S. hospitals, the U.S. General Accounting Office conducted a comprehensive, independent analysis and

found no increased risk to patient safety from reprocessed devices. In 2021 alone, AMDR's members reported that more than 10,500 hospitals used more than 32 million reprocessed single-use medical devices. *No increased risk to patient safety has ever been found.*

Reprocessed devices range from non-invasive EKG leads, tourniquet cuffs and pulse oximeter sensors, to invasive devices used in laparoscopic surgery and cardiac imaging procedures. AMDR members are subsidiaries of global MedTech companies such as Arjo, Cardinal, Medline and Stryker and also independent, third-party companies such as Innovative Health, Northeast Scientific, and Vanguard AGH.

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

A growing body of academic research points to medical device reprocessing as a well-established, proven circular solution that can ensure immediate, measurable benefits. Greater emphasis on SUD reprocessing 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 healthcare facilities 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 SAPHRA to now join other regulatory agencies and play an active role.

Healthcare delivery plays an outsized role in the generation of greenhouse gases that cause climate change and adverse health effects in humans. Consumption of goods in the health sector accounts for almost 5% of all worldwide greenhouse gas emissions. A closer look reveals that more than 80% of greenhouse gas emissions generated by the health sector comes from its supply chain alone (known as "Scope 3 emissions"), a source directly impacted by the reuse and repair of medical devices.

Using reprocessed devices significantly reduces greenhouse gas emissions. Researchers from the Fraunhofer Institute for Environmental, Safety, and Energy Technology UMSICHT published a life cycle assessment of one reprocessed device (an electrophysiology catheter) and found that it reduced ozone depleting emissions by nearly 90%, and climate change-specific emissions by more than 50% compared to using an original device. This is only one example of the positive impacts of reprocessing. A regularly updated list of peer reviewed, published life cycle assessments indicating greenhouse gas emission reductions from regulated, commercially reprocessed single use devices is maintained at our website.

In a field committed 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 reprocessing provides new opportunities to pursue resilient and less wasteful supply chain practices. Now is the time for SAPHRA 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.

Action is needed now, and governments are taking notice. More than forty countries have committed to reducing greenhouse gas emissions from the health sector. Given the extent of the sector's impact on global health, governments and healthcare providers have a responsibility to not only identify sources of greenhouse gas emissions in the supply chain but find lower emission alternatives.

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Conclusion

Regulated, commercially reprocessed SUDs are safe, effective, and legally marketable. Hundreds of millions reprocessed SUDs have been used with no increased risk to patient safety. Preventing a company from using a compliant, previously used device as raw material is anticompetitive and obstructs green, cost-effective, and resilient business models. SAPHRA should ensure that all marketed devices meet regulations for safety and effectiveness rather than choosing which manufacturers can operate in the South African market. We also warn against SAPHRA regulating the "single use" label, a decision typically made by the manufacturer.

We urge SAPHRA to remove the proposed restriction on reprocessing, as it would impede more resilient, sustainable medical device manufacturing. SUD reprocessing is a vital circular solution that SAPHRA can support and use to fulfill the three pillars of its ethos: safety, efficacy and quality. Regulated, safe, reprocessed products offer the immediate benefits of reduced greenhouse gas emissions, waste, and cost-savings, while simultaneously keeping more devices local, which strengthens the supply chain. We urge SAPHRA to reconsider section 16 regarding SUDs with our proposed amendments. Further, with our amendments to Section 16, SAPHRA can prevent hospitals from inappropriate reuse of SUDs (unregulated reprocessing) and at the same time promote safe, regulated commercial reprocessing that adheres to manufacturer and international standards.

In doing so, the Authority will more quickly achieve "its vision of being an agile and responsive African health products regulator that is globally recognized as an enabler of access to safe, effective and quality health products in South Africa."

AMDR remains at your service for discussions on reprocessing. Please reach out if we can assist further.

Thank you.

Sincerely,

Daniel J. Vukelich, Esq., President
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