Call for the South African Health Products Regulatory Authority to revisit regulations relating to single-use medical devices

To the Editor: African countries face a well-recognised shortage of essential medical equipment and surgical devices. To meet this challenge, we will need context-specific solutions.

On 29 November 2019, the acting chief executive officer of the South African Health Products Regulatory Authority (SAHPRA) issued a directive that contained the following instruction: 'Medical devices intended by the original manufacturer for single use may only be used once, may not be reprocessed and must be disposed of after use.'[1]

A letter from the first author (JL) to SAHPRA (4 February 2020) appealing this mandate was unacknowledged, and later, after multiple attempts to engage, SAHPRA said that the matter was non-negotiable. Following this new rule, Groote Schuur Hospital has banned any reprocessing of medical devices.

The practice of reprocessing single-use devices (SUDs) is widespread across the globe. Many countries have specific regulations in this regard. The widely recognised draft US Food and Drug Administration (FDA) statement (2000) on reprocessing[2] describes a risk-prioritisation scheme that addresses the combined risks of infection and device performance. The FDA states that many SUDs 'are low risk when used for the first time and remain low risk after reprocessing, provided that the reprocessor conducts cleaning and sterilization/disinfection of the SUD in an appropriate manner'.[2] A review of FDA oversight reiterated the safety of reprocessing in a 2008 article that stated: 'available information indicates that their use does not present an elevated health risk'.[3] Over 8 800 hospitals use reprocessed devices in the USA, Canada, Israel, Europe and Japan alone.[4] Yet the practice is outlawed by SAHPRA in South Africa (SA), when the cost/risk benefit may be far more advantageous in less developed economies, and especially in the cost-constrained public sector in SA.

A recent editorial in the *Annals of the Royal College of Surgeons of England* recognises that 'the amount of single use equipment in the operating theatre can be phenomenal … a simple tonsillectomy can generate over 100 pieces of disposable plastic'.[5] Estimates suggest that as much as 7 000 kg of landfill waste could be reduced annually by reprocessing at a 200-bed hospital.[4]

Reprocessing SUDs is also a way to reduce the carbon footprint of healthcare, which is 4.4% of global emissions or equivalent to the annual greenhouse gas emissions from 514 coal-fired power stations.[6] Operating theatres have a particularly huge environmental impact. For example, 'a typical cataract operation in the UK generates 182 $kgCO_2$, but in India the same operation generates only 6 $kgCO_2$ … [while] a robotic hysterectomy [generates] over 800 $kgCO_2$.'[5]

A Commonwealth Fund report has looked at the cost savings inherent in reprocessing of SUDs. It is estimated that in the USA alone, reprocessing would reduce healthcare costs by USD540 million annually.[7]

We call on SAHPRA to engage with stakeholders and to reconsider its 2019 directive. Our hope is that this process would result in the drafting of guidelines to allow quality-controlled reprocessing of selected SUDs to ensure patient safety by mandating strict cleaning, functionality and sterility specifications. Such guidelines would lead to substantial financial and environmental savings for SA, without compromising patient safety.

John Lazarus
Professor and Head, Division of Urology, Faculty of Health Sciences, University of Cape Town, South Africa
j.lazarus@uct.ac.za

Salome Maswime
Head and Associate Professor, Global Surgery Division, Department of Surgery, Faculty of Health Sciences, University of Cape Town, South Africa

Graham Fieggen
Professor and Chair, Division of Neurosurgery, and Head, Department of Surgery, Faculty of Health Sciences, University of Cape Town, South Africa

Lydia L Cairncross
Chair and Head, Division of General Surgery, Faculty of Health Sciences, University of Cape Town, South Africa

James Irlam
Division of Environmental Health, School of Public Health and Family Medicine, University of Cape Town; Chair, Climate Energy and Health Special Interest Group, Public Health Association of South Africa

Anthony Reed
Level 2 Head: Anaesthetics, Metro West and New Somerset Hospital, Cape Town, South Africa; Senior Lecturer, Department of Anaesthesia and Perioperative Care, University of Cape Town, South Africa

Shrikant Peters
Executive Management, Manager Medical Services, Peri-operative and Critical Care Services, Groote Schuur Hospital, Cape Town, South Africa; Honorary Senior Lecturer and Public Health Medicine Specialist, Division of Public Health Medicine, Faculty of Health Sciences, University of Cape Town, South Africa

Johannes J Fagan
Professor and Chair, Division of Otolaryngology, Faculty of Health Sciences, University of Cape Town, South Africa

1. South African Health Products Regulatory Authority (SAHPRA). Reprocessing of single-use medical devices: Communication to stakeholders. 29 November 2019. https://www.sahpra.org.za/wp-content/uploads/2020/01/Reprocessing-of-Single-Use-Medical-Devices_Communication-to-Stakeholders_Nov2019.pdf (accessed 8 February 2022).
2. Food and Drug Administration, USA. Reprocessing and reuse of single-use devices: Review prioritization scheme. Draft released for comment on 8 February 2000. https://p2infohouse.org/ref/06/05561.pdf (accessed 6 February 2022).
3. US Government Accountability Office. Reprocessed single-use medical devices: FDA oversight has increased, and available information does not indicate that use presents an elevated health risk. 31 January 2008. https://www.gao.gov/products/gao-08-147 (accessed 6 February 2022).
4. Wikipedia. Single use medical device reprocessing. Last edited 23 November 2021. https://en.wikipedia.org/wiki/Single_use_medical_device_reprocessing (accessed 6 February 2022).
5. Bhutta MF. Our over-reliance on single-use equipment in the operating theatre is misguided, irrational and harming our planet. Ann R Coll Surg Engl 2021;103(10):709-712. https://doi.org/10.1308/rcsann.2021.0297
6. Health Care Without Harm. Health care's climate footprint: How the health sector contributes to the global climate crisis and opportunities for action. September 2019. https://noharm-global.org/sites/default/files/documents-files/5961/HealthCaresClimateFootprint_092319.pdf (accessed 6 February 2022).
7. Kaplan S, Sadler B, Little K, Franz C, Orris P. Can sustainable hospitals help bend the health care cost curve? Issue Brief (Commonw Fund) 2012;29:1-14.

S Afr Med J 2022;112(4):248. https://doi.org/10.7196/SAMJ.2022.v112i4.16448