

AMDR Summary: International Regulation of “Single-Use” Medical Device Reprocessing

Since 2000, the United States Food and Drug Administration (FDA) has regulated reprocessors of so-called “single-use” medical devices (SUDs) as medical device manufacturers, subjecting all reprocessors (third-party, hospital, and original equipment manufacturers (OEMs)) to all of the agency’s medical device manufacturer requirements. Thus, FDA’s regulatory framework for reprocessing is perhaps the longest-standing, most comprehensive in the world. However, the U.S. is not the only nation to address the reprocessing of SUDs. This summary outlines, to the best of AMDR’s knowledge, the legal and regulatory status of SUD reprocessing in a number of jurisdictions, including the European Union (EU), Australia, Canada, Japan, South Korea, Saudi Arabia, and Israel.

The reprocessing of SUDs is commonplace worldwide. Even in developed nations, including those that have reprocessing prohibitions in place, hospitals routinely reuse SUDs. Unless otherwise noted below, the available evidence indicates that the reuse of SUDs in most other nations is unregulated. In many cases (particularly in Africa and Asia), uncontrolled reuse of such devices is relatively common, if not the norm.¹

EUROPEAN UNION

Currently, the European Union (EU) does not have a single policy regarding the reprocessing of SUDs. However, it is in the process of revising its Medical Device Directive. In 1993, at the issuance of the last Medical Device Directive, the issue of medical device reprocessing was identified as in need of additional clarification and the European Commission was instructed to submit a report on the issue by 2010.² In August, 2010, the Commission released its report,³ highlighting the risks of unregulated reprocessing. Ultimately, the European Commission released its proposal⁴ and the European Parliament approved its draft⁵ (9 October 2013). Both legislative

¹ Walter Popp (Hospital Hygiene, University Clinics of Essen, Hufelandstr. 55, 45122 Essen, Germany), Ossama Rasslan (Infectious Diseases Research and Infection Control Unit, Ain Shams Faculty of Medicine, Cairo, Egypt), Akeau Unahalekhaka (Faculty of Nursing, Chiang Mai University, Thailand), Pola Brenner (Universidad de Valparaiso, Valparaiso, Chile), Edith Fischnaller (Institute of Hygiene and Public Health, WHO CC of University Bonn, Germany), Maha Fathy (Infectious Diseases Research and Infection Control Unit, Ain Shams Faculty of Medicine, Cairo, Egypt), Carol Goldman (Consultant, Toronto, Ontario, Canada) and Elizabeth Gillespie (Sterilisation and Infection Control Co-Director, Southern Health, Australia), [What is the Use? An International Look at Reuse of Single-Use Medical Devices, International Journal of Hygiene and Environmental Health, Volume 213, Issue 4](#), (July 2010), Pages 302-307 [hereinafter Journal of Hygiene Report].

² [Council Directive 93/42/EEC](#) (14 June 1993), Article 12a, OJ L 169, 12.7.1993, p. 1.

³ 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](#), European Commission (27 August 2010), [hereinafter Commission Report].

⁴ European Commission, Proposal for a [REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, on medical devices, and amending Directive 2001/83/EC, Regulation \(EC\) No 178/2002 and Regulation \(EC\) No 1223/2009](#) (26 September 2012).

⁵ European Parliament, [Report on the proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation \(EC\) No 178/2002 and Regulation](#)

versions propose to regulate reprocessing as *manufacturing*. The European Council is now set to approve its own version of the legislation. Ultimately, both the Council and Parliament will have to agree, meeting in Trialogue with the European Commission, on the final version of the legislation. It is hoped the final agreement on the regulation will be completed in 2015.

Until then, regulation of reprocessing activities is left to the individual Member States. Since 2001, Germany has had in place a regulatory framework that does not distinguish between the reprocessing of “reusable” and so-called “single-use” medical devices. The guidelines, therefore, allow for SUD reprocessing if conformance with certain standards is achieved. The German Medical Devices Law and the Medical Devices Operator Ordinance regulate the reprocessing of medical devices and in doing so refer to the mutual recommendation by the Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) and the Federal Institute for Drugs and Medical Devices (BfArM) for the reprocessing of medical devices.⁶ As a result, the KRINKO requirements must be observed.

Institutions, which want to reprocess single-use medical devices, must adopt and implement a quality management system according to DIN EN ISO 13485:2007.⁷ Compliance with the quality management requirements is monitored annually by “Notified Bodies” that have been accredited by the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG).

Other Member States, such as the United Kingdom, Spain and France,⁸ discourage or prohibit SUD reprocessing. The majority of Member States in Europe do not have any national regulations regarding reprocessing.⁹

AUSTRALIA / New Zealand

Australia enacted regulations regarding the reprocessing (“remanufacturing” in Australia) of SUDs in 2003.¹⁰ Similar to the U.S., in Australia, all reprocessors (third-party, hospital, and OEM) must conform to medical device manufacturer requirements as regulated by the Therapeutic Goods Administration (TGA). Prior to implementation of these requirements, hospital reprocessing of SUDs was common. Also like in the U.S., AMDR understands that due to the costs and high technical standards required to meet the TGA’s conformity assessment requirements, hospitals

[\(EC\) No 1223/2009 \(COM\(2012\)0542 – C7-0318/2012 – 2012/0266\(COD\)\)](#), Committee on the Environment, Public Health and Food Safety (9 October 2013).

⁶ *Hygienic Requirements for Processing of Medical Devices: Recommendation by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal German Institute for Medical Drugs and Medical Products (BfArM) Concerning the “Hygienic Requirements for Processing of Medical Devices,”* Robert Koch Institute: Recommendation (2001).

⁷ *Id.*

⁸ Commission Report, *supra* note 3, at 6. See also, Circulaire DGS/DH n 51 (29 December 1994) *Relative a l’utilisation des dispositifs médicaux stériles a usage unique dans les établissements de santé publics et privés* (France), Ministerio de sanidad y consume, *Royal Decree 414.1996 Sec. 5*, (9 July 1999) (Spain) and MHRA Device Bulletin: DB 2006(04) *Single-Use Medical Devices: Implications and Consequences of Reuse* (UK).

⁹ Commission Report, *supra* note 3, at 6. See also, [European Association of Medical Device Reprocessors](#).

¹⁰ [Statement by the TGA on regulations for sterilisation of single use devices](#), Australian Government, Therapeutic Goods Administration (21 July 2003).

have ceased reprocessing SUDs in-house. In New Zealand, the Regulator Medsafe requires either compliance with the US 510(k), CE approval or a listing with the Australian TGA for the sale of medical devices within the country. Besides a notification procedure, no further regulatory approval is required.

CANADA

Historically, Health Canada asserted that it did not have the legal authority to regulate the reprocessing of SUDs. The Canadian *Food and Drugs Act* and Canadian *Medical Device Regulations* do not address the way in which healthcare facilities use, maintain or sterilize medical devices *after* sale. However, in 2014, Health Canada changed course. The agency released a letter in July, 2014 to all Provincial and Territorial Ministers of Health indicating that the agency would, henceforth, apply “the existing regulations to all incoming license applications for reprocessed SUDS.” In that same letter, Health Canada announced that it had issued, for the first time, a license to an SUD reprocessor.¹¹

In February, 2015, the agency issued a Notice to all stakeholders confirming that it now concluded that “Health Canada has authority under the existing Food and Drugs Act and Medical Devices Regulations to require commercially reprocessed devices meet appropriate standards for safety, effectiveness and labeling.”¹² Further, the agency gave an anticipated 18 month timeframe by which “companies that reprocess and distribute medical devices originally authorized and labelled for single use to Canadian healthcare facilities will be held to the same requirements as manufacturers of new devices. This means they must meet requirements for licensing, quality system management, labelling, investigating and handling complaints, maintaining distribution records, conducting recalls, reporting incidents and informing Health Canada of any changes to the information in their license application.”¹³ The requirements apply to commercial reproducers in our outside of Canada and the expectation is all such firms are to be compliant by September 1, 2016.¹⁴

SUD reprocessing in Canada had historically been left to the territorial and provincial health ministries and hospital boards, and in-hospital reprocessing will remain a Provincial and Territorial responsibility.¹⁵ The large provinces have adopted similar positions more or less requiring any hospital that wishes to reprocess critical SUDs to do so through an FDA-regulated vendor.

British Columbia

¹¹ Letter from Barbara J. Sabourin, Director General, Health Canada, Therapeutic Products Directorate, to Provincial and Territorial Ministries of Health, “Re: Medical Device License,” (31 July 2014).

¹² Letter from Barbara J. Sabourin, Director General, Health Canada, therapeutic Products Directorate, to all stakeholders, “Health Canada’s Regulatory Approach to Commercial Reprocessing of Medical Devices Originally Labelled for Single Use,” (5 February 2015).

¹³ *Id.*

¹⁴ *Id.*

¹⁵ [Issue Analysis Summary: The Reuse of Single-Use Medical Devices](#) Health Canada; Therapeutic Products Directorate (28 April 2005). See also, [Reprocessing Single-Use Medical Devices: An Update of the Clinical Evidence and An Environmental Scan of Policies in Canada](#), Canadian Agency for Drugs and Technologies in Health (23 June 2010) [hereinafter CADTH Report].

British Columbia issued a policy to its health authorities stating that by January 1, 2008, all health authorities must have eliminated the reprocessing and reuse of critical contact SUDs, unless they have been reprocessed by a licensed third-party reprocessor that is certified by a national regulatory authority such as Health Canada or the U.S. Food and Drug Administration.¹⁶ 2011 policy requires that all “critical and semi-critical medical devices labelled as single-use shall not be reprocessed and re-used unless the reprocessing is done by a licensed reprocessor.”¹⁷

Manitoba

Manitoba does not permit hospitals to reuse SUDs in-house, but does permit hospitals to contract with an FDA regulated vendor, among other requirements.¹⁸

Northwest Territories

Since 2005, the Northwest Territories have prohibited reprocessing. Specifically, the Northwest Territories Department of Health and Social Services revised its *Hospital and Health Care Facility Standards Regulations* to require that “a disposable device intended to be used on a patient during a single procedure shall not be used on a patient for more than one procedure and shall not be used on another patient.”¹⁹

Ontario

In 2013, Public Health Ontario released its third addition document developed by its Provincial Infectious Diseases Advisory Committee (PIDAC) advising that critical and semi-critical SUDs must not be reprocessed and reused, unless the reprocessing is done by a licensed reprocessor.²⁰

Saskatchewan

In 2013, Saskatchewan Health affirmed a policy outlining requirements for hospitals that reprocess SUDs. Consistent with the above policies of other provinces, Saskatchewan requires, among other things, that hospitals outsource to an FDA regulated vendor.²¹

ASIA

The reuse of SUDs in much of Asia is common, particularly for injection needles.²² For the most part, there are no national regulations governing reuse of SUDs and, thus, third-party reproducers

¹⁶ *Id.*

¹⁷ BC Ministry of Health, [Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices In BC Health Authorities](#), at 65 (December 2011).

¹⁸ Manitoba Deputy Health Minister’s Office (21 March 2013).

¹⁹ CADTH Report, *supra* note 9.

²⁰ Public Health Ontario, Provincial Infectious Diseases Advisory Committee (PIDAC), [Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices, In All Health Care Settings, 3rd edition](#) (May 2013).

²¹ Saskatchewan Health, Deputy Minister’s Office (27 June 2013).

²² Journal of Hygiene Report, *supra* note 1, at 304.

do not offer their services in Asia. Rather, most reuse in Asia is conducted in an unregulated-manner at the user-facility level.

Japan

Reprocessing is not currently regulated in Japan, but, available data indicates that the reuse of SUDs is relatively common. A 2003 survey found that 80 to 90 percent of hospitals reused SUDs.²³

South Korea

To the best of our knowledge, South Korea does not regulate reprocessing of medical devices. South Korea’s move toward device regulation in general started with the Medical Devices Act (MDA), which went into effect May 30, 2004, but was not fully implemented until March 30, 2007. Prior to the enactment of the MDA, reprocessing was a topic that was anticipated to be included in that legislation.²⁴ However, it does not appear that provisions concerning reprocessing ultimately were enacted. AMDR has met with South Korean officials twice in the last several years, indicating that governmental interest in enacting a regulatory framework may still exist.

India

There are no known regulations regarding reuse of medical devices in India. According to information obtained by AMDR, hospitals in India do routinely reuse SUDs. While private hospitals may have guidelines regarding SUD reuse, the processes are not regulated by the government.

AFRICA AND THE MIDDLE EAST

The lack of resources, including medical devices and distribution channels, “necessitates the reuse of single-use devices” in much of Africa.²⁵ This includes the reuse of syringes and needles that have not been sterilized, and even rubber gloves. In the Middle East, available data indicates that reuse of SUDs is common throughout Arab countries (particularly for cardiac catheters), despite the absence of a regulatory framework. Reprocessing in both Africa and the Middle East is done at the user-facility level.²⁶

Israel

Israel does not have regulations in place specific to the reprocessing of SUDs, but as a general matter, medical devices must be registered with the Ministry of Health (MOH) before they can be sold in the country. If a product is approved by the U.S. FDA, it will generally be registered by

²³ *Id.*, at 305.

²⁴ [Medical Device Regulatory Requirements for South Korea](#), U.S. International Trade Administration (20 December 2005).

²⁵ Journal of Hygiene Report, *supra* note 1, at 305.

²⁶ Journal of Hygiene Report, *supra* note 1, at 305.

the MOH with no further testing requirements and, therefore, may be lawfully marketed in the country. Consistent with this policy, FDA-cleared reprocessed devices have been registered with MOH and are actively imported into the country.²⁷

Of note, as with many other countries, hospitals in Israel are reusing many types of SUDs without any federal oversight or controls. AMDR understands a “Medical Devices Bill” currently under consideration may recommend regulations for reprocessing.²⁸

Saudi Arabia

The Kingdom of Saudi Arabia (KSA) has recently taken steps to establish a medical device regulatory structure. The Saudi Food and Drug Authority (SFDA) published an Interim Regulation concerning medical devices on December 27, 2008, which went into effect on March 27, 2009.²⁹ The Interim Regulation will apply until a comprehensive medical device law is approved.³⁰

The Interim Regulation provides that devices may be marketed in Saudi Arabia if they:

“Comply with the relevant regulatory requirements applicable in one or more of the jurisdictions of Australia, Canada, Japan, the USA and the EU/EFTA, and additionally with provisions specific to the KSA concerning labeling and conditions of supply and/or use.”³¹

The devices reprocessed by AMDR’s members comply with the regulatory requirements in the United States. Moreover, there does not appear to be a reprocessing-specific provision included in the Interim Regulation. As such, importing reprocessed devices into the KSA appears to be permissible. However, the SFDA website includes an “information page” that describes an SUD as “intended for use once, on an individual patient for a single procedure.”³² This information page goes on to state that an SUD “should not be reprocessed or reused on another patient.”³³ Thus, it appears as though the SFDA has adopted an informal policy that prohibits reprocessing.

Like South Korea, AMDR has had interactions with Saudi Arabian officials, which may indicate a governmental interest in adopting a more comprehensive regulatory framework for SUD reprocessing. To date, AMDR is unaware of either third-party reprocessing taking place in KSA or importation of third-party reprocessed devices into KSA.

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²⁷ [Medical Device Regulatory Requirements for Israel](#), U.S. International Trade Administration (2 May 2005).

²⁸ [Reuse of Single-Use Medical Devices, Annual Report 55B](#), pp. 553-565, Israeli State Comptroller, Ministry of Health.

²⁹ [The Medical Devices Interim Regulation](#), Saudi Food and Drug Authority (April 10, 2010).

³⁰ *Id.*

³¹ [Medical Devices Interim Regulation](#), Report issued by the Saudi Food and Drug Authority Board of Directors, Medical Devices Sector (17 April 2009).

³² [Consumer Information Regarding Single-Use Medical Devices](#), Saudi Food and Drug Authority (visited 07/11/11).

³³ *Id.*