



REPROCESSING OF SINGLE USE MEDICAL DEVICES

Communication to Stakeholders

1 BACKGROUND

- 1.1 On 01 June 2017, the President of the Republic of South Africa signed into effect Amendment Act 72 of 2008 (and effectively therefore also Amendment Act 14 of 2015), which broadened the regulatory scope of the Medicines and Related Substances Act, 1965 (Act 101 of 1965; the "Act"), to include the regulation of medical devices.
- 1.2 The regulations relating to medical devices (Regulation No 1515 published in Government Gazette No 40480 on 9 December 2016), published by the Minister of Health in terms of section 35(1)(xxvii) of the Act, make provision for the following definitions:
- (a) **"manufacture"** means operations that include the design, purchasing of material, specification development, production, fabrication, assembly, processing, reprocessing, releasing, packaging, repackaging, labelling, and refurbishing of a medical device or IVD, as the case may be, and includes putting a collection of medical devices or IVDs, and possibly other products, together for a medical purpose in accordance with quality assurance and related controls;
 - (b) **"manufacturer"** means -
 - (i) a natural or legal person with the responsibility for the design, manufacture, packaging and labelling of a medical device or IVD before it is placed on the market under the natural or legal person's own name, or in the name of a firm or company, regardless of whether these operations are carried out by that person by himself or on his or her behalf by a third party; or
 - (ii) any other person who assembles, packages, reprocesses, refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a medical device or IVD, with a view to their being placed on the market under the natural or legal person's own name, except a person who assembles or adapts medical devices or IVDs already on the market to their intended purpose for patients;
 - (c) **"reprocess"** means the activity carried out on a used medical device in order to allow its safe re-use including cleaning, disinfection, sterilisation and related procedures, as

well as testing and restoration of the technical and functional safety of the used medical device;

- (d) **"single use"** in terms of a medical device means one use of a medical device on an individual or IVD on a sample during a single procedure and then the medical device or IVD is disposed of and is not reprocessed and not used again.

- 1.3 Regulation 22 (1) identifies the particulars which must appear on the label of each medical device or IVD and sub-section (p)(i) specifically notes that "*where appropriate an indication that the medical device is intended for single use*" must be present.

2 POSITION TAKEN BY SAHPRA

- 2.1 Medical devices intended by the original manufacturer for single use must be labelled as such.
- 2.2 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.
- 2.3 In the event that the sterility of a sterile medical device intended by the original manufacturer for single use has been compromised and the sterile medical device intended by the original manufacturer for single use, has not been used, the compromised medical device intended by the original manufacturer for single use may not be reprocessed and must be disposed of.
- 2.4 Medical devices which are intended by the original manufacturer to be reprocessed, using pre-determined and validated procedures to ensure the safe re-use including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoration of the technical and functional safety of the used medical device, may be legally reprocessed. The user of a medical device that is legally permitted to be reprocessed is responsible for adhering to the pre-determined limitations on the number of times that the medical device is reprocessed and reused as stipulated by the original equipment manufacturer.
- 2.5 Reprocessing of any medical device which is intended by the original manufacturer for "single use" is in contravention of the Act.
- 2.6 The importation of reprocessed single use medical devices, that have been reprocessed in another country and are intended for sale in the Republic of South Africa as a single use medical device is not permitted.

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