SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Str
Arcadia
0083

COMMUNICATION TO STAKEHOLDERS

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REPROCESSING OF SINGLE USE MEDICAL DEVICES

1. INTRODUCTION

This document is intended to communicate the position of the South African Health Products Regulatory Authority (SAHPRA) on reprocessing of single use medical devices to stakeholders.

2. BACKGROUND

On 1 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 amended the Medicines and Related Substances Act, 1965 (Act 101 of 1965; the "Act"), including regulation of medical devices and in vitro diagnostic tests (IVDs).

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, packaging, repackaging, labelling, releasing, installation, maintaining, sterilisation, reprocessing or refurbishing of a medical device, and includes the assembly of a collection of medical devices;*

b) ***"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 devices; and*

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c) ***"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 procedure and then the medical device or IVD is disposed of and is not reprocessed and is not used again.*

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.

3. POSITION TAKEN BY SAHPRA

The position taken by SAHPRA is as per the regulations relating to medical devices including IVDs, which was communicated in a position paper published by SAHPRA in 2019 has not changed.

3.1 Each medical device intended by the original manufacturer for single use must be labelled as such.

3.2 A medical device intended by the original manufacturer for single use may only be used once, may not be reprocessed and must be disposed of, after use.

3.3 If the sterility of a medical device intended by the original manufacturer for single use has been compromised and the device has not been used, the compromised medical device intended by the original manufacturer for single use may not be reprocessed and must be disposed.

3.4 Medical devices intended by the original manufacturer to be reprocessed, using predetermined 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.

3.5 The user of a medical device that is legally permitted to be reprocessed is responsible for adhering to the predetermined limitations regarding the number of times that the medical device is reprocessed and reused, as stipulated by the original equipment manufacturer.

3.6 The importation of a reprocessed single use medical device that has been reprocessed in another country and is intended for sale in the Republic of South Africa is prohibited.

3.7 The importation of a reprocessed single use medical device that has been reprocessed in another country and is intended for sale in the Republic of South Africa is prohibited.

3.8 The importation of a single use medical device that has been used in another country with the intention to be reprocessed in the Republic of South Africa is prohibited.

Boitumelo Semete-Makokotlela

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Dr Boitumelo Semete-Makokotlela

SAHPRA Chief Executive Officer (CEO)

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