DIRECTORATE: SUPPLY CHAIN GOVERNANCE

REFERENCE: 8/1/3/P

ENQUIRIES: F Barnes/ C Okkers

ALL HEADS OF HEAD OFFICE COMPONENTS
All HEADS STRATEGIC AND OPERATIONAL MESOS
All SUPPLY CHAIN MANAGEMENT UNITS

SUPPLY CHAIN MANAGEMENT INSTRUCTION SCM 04/2021

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY (SAHPRA) LICENSING

1. PURPOSE

1.1 To inform Institutions of the South African Health Products Regulatory Authority (SAHPRA) requirements to be included in the specifications when procuring Medical Devices and In-Vitro Diagnostics (IVDs).

2. DEFINITIONS

2.1 "***Medical Devices***" means any instrument, apparatus, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article –

a) intended by the manufacturer to be used, alone or in combination, for human beings for:
   i. Diagnosis, prevention, monitoring, treatment or alleviation of disease;
   ii. Diagnoses, monitoring, treatment, alleviation of/or compensation of an injury;
   iii. Investigation, replacement, modification or support of anatomy or of a physiological process;
   iv. Supporting or sustaining life;
   v. Control of conception
   vi. Disinfection of medical devices; or
   vii. Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

b) Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function.

2.2 "***IVDs***" means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

3. REGULATORY CONTEXT

3.1 The registration of Medical Devices and IVDs in South Africa is governed by the requirements of the Medicines and Related Substance Amendment Act No. 72 of 2008, as amended in 2017. The Act requires that certain Medical Devices are registered (see par. 4.1 below) and that the manufacturers, wholesalers or distributors of certain Medical Devices are SAHPRA-licensed.

3.2 SAHPRA is mandated, by the Act, to regulate all health products and their use in South Africa. SAHPRA's function is therefore to promote public health and safety by ensuring that all medicines and medical devices that are available and used in the country are safe, effective and of good quality.

4. APPLICATION

4.1 SAHPRA has not yet commenced the registration of Medical Devices and IVDs (i.e. the products themselves). The current requirement is for all companies who manufacture, distribute or wholesale medical devices in the market, to be licensed by SAHPRA.

4.2 Only manufacturers, distributors or wholesalers who are in possession of a SAHPRA license can trade legally under the provisions of the Act.

4.3 The regulatory framework makes provision for a classification system for Medical Devices and IVDs. The classification levels for Medical Devices are depicted in the table below:

Classification	Level of risk
Class A	Low risk
Class B	Low-moderate risk
Class C	Moderate-high risk
Class D	High risk: where risk relates to the patient or public health

4.4 The manufacturer or distributor is responsible for determining the classification of a Medical Device using the classification rules supplied by SAHPRA, which are based on the:

- manufacturer's or distributor's intended use of the device or IVD;
- level of risk to patients, users and other persons (the probability of occurrence of harm and the severity of that harm);
- degree of invasiveness in the human body; and
- duration of use and exposure.

4.5 Identical Medical Devices may be classified differently if they are to be used in different parts of the body. Therefore, the original manufacturer's intended use of the device is critical to determining the appropriate classification. The intended use can be obtained from the:

- instructions for use;
- label;
- original manufacturer's advertising materials; and/or
- technical documentation

4.6 Manufacturers should consider all the Classification Rules when determining the appropriate classification for a device as more than one rule may apply; in such cases, the higher classification applies.

4.7 A high-level summary of the classification rules is noted in Paragraph 2.6 of Annexure A.

4.8 Manufacturers, distributors or wholesalers of **non-sterile, non-measuring Class A Medical Device are exempted** from the requirement to be SAHPRA-licensed. A list of examples of such Class A devices is attached as Annexure B.

4.9 SAHPRA licenses will be valid from June 2017; prior to this, certain manufacturers, wholesalers & distributors were already licensed under the previous requirements of the MRSAA and such licenses were issued by the Medicines Control Council (MCC). SAHPRA has confirmed that MCC licenses will remain applicable until their expiry. Thereafter, a new license will be issued by SAHPRA.

5. REQUEST AND EFFECTIVE DATE

5.1 In order to comply with the requirements of the Medicines and Related Substance Amendment Act No. 72 of 2008, as amended in 2017, Institutions must ensure that the conditions of bid inform the prospective bidders (manufacturers, wholesalers or distributors) to submit a copy of their SAHPRA license in order for their bid to be deemed compliant. Failure to comply with this requirement will result in such offers not being considered.

5.2 The content of this SCM Instruction must be brought to the attention of all relevant officials.

Chief Director: Supply Chain Management
Date: 05.03.2021

ANNEXURES:

Annexure A	**Classification of Medical Devices (Author: SAHPRA)**
Annexure B	**List of Examples of Class A Medical Devices**

Annexure B
List of Examples of Class A Medical Devices:

- urine collection bottles,
- wound drainage collection bottles,
- incontinence pads,
- sanitary towels,
- tampons,
- non-sterile dressings (which do not contain medicines or other active ingredients),
- plaster bandages,
- cervical collars and gravity traction devices or compression hosiery,
- non-sterile surgical masks,
- cloth masks,
- non-sterile gowns,
- overshoes/boot covers,
- mop caps,
- aprons,
- goggles,
- visors/face shields,
- coveralls,
- sanitiser,
- body bags,
- non-sterile gloves.

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