SAHPRA
South African Health Products Regulatory Authority

CSIR Campus
Building 10F
Meiring Naudé Road
Brummeria
Pretoria

Communication to Stakeholders 22 July 2020

MD012: Notice of contravention with provision/s of the Medicines and Related Substances Act, 1965

BACKGROUND

1. It has come to the attention of the South African Health Products Regulatory Authority (SAHPRA) that there are a number of individuals, companies and medical device establishments that have contravened or have failed to comply with the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
2. All individuals, companies and/or medical device establishments that manufacture, distribute and/or wholesale medical devices including in-vitro diagnostics (IVDs) must comply with the requirements of Act 101 of 1965. **Penalties will apply for any contravention of Act 101 of 1965.**

REGULATION OF MEDICAL DEVICES AND IN-VITRO DIAGNOSTICS

3. **Medical devices including in-vitro diagnostics (IVDs) are regulated products. These products are regulated by SAHPRA, the National Regulatory Authority in South Africa. As such these products must comply with the regulatory requirements.**

   The Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended, read in conjunction with the General Regulations on Medical Devices, published in Government Gazette Notice 40480, No.1515 of 09 December 2016, provides for the regulatory oversight of Medical Devices including In-Vitro Diagnostics (IVDs) in South Africa.

LICENCE TO MANUFACTURE, DISTRIBUTE OR WHOLESALE MEDICAL DEVICES AND IVDS

4. **You may not manufacture, distribute (including import and/or export) and/or wholesale a medical device or IVD without a valid SAHPRA licence.**

   In terms of Section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and Regulation 5 of the General Regulations on Medical Devices
   A manufacturer, distributor (including importer and/or exporter) or wholesaler referred to in Section 22C(1)(b) of the Act must—
   a) prior to commencing business, apply to SAHPRA for a licence to manufacture, distribute (including import and/or export) and/or wholesale medical devices or IVDs; and
   b) appoint and designate an authorised representative who must reside in South Africa and be responsible to SAHPRA for compliance with the Act.

ADVERTISING OF MEDICAL DEVICES AND IVDS

5. **You may not advertise Class C and Class D medical devices to the public. For example it is illegal to advertise COVID-19 rapid test kits to the public.**

In terms of the General Regulations for Medical Devices, Regulation 21. Advertising of medical devices or IVDs only Class A and Class B medical devices and IVDs may be advertised to the public or lay person.

SALE OR USE OF MEDICAL DEVICES OR IVDS

6. No medical devices or IVDs have been registered by SAHPRA. Only medical devices and IVDs that have been **listed** on the licence application/s of SAHPRA medical device establishment licence holders may be sold and/or used.

CONTRAVENTION OF ACT 101 OF 1965

7. Any individuals, companies and medical device establishments that have contravened or have failed to comply with the provisions of Act 101 of 1965 will be notified in writing by SAHPRA of such offence/s.

8. A written response to the notification of contravention with Act 101 of 1965 will be required within 20 days from the date of the notice.

9. **Penalties apply for any contravention of Act 101 of 1965.**

DR B SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER OF SAHPRA
22 JULY 2020