

MEDICINES CONTROL COUNCIL



SECTION 21 AUTHORISATION OF SALE OF UNREGISTERED MEDICAL DEVICES

To all Applicants

The Medicines and Related Substances Act, 1965 (Act 101 of 1965) read with the General Regulations on Medical Devices, *Government Gazette Notice 40480, No.1515 of 09 December 2016*, provides for the regulatory oversight of Medical Devices and IVDs.

Section 22C(1)(b) of the Act requires all Medical Device establishments doing business in South Africa to obtain a licence from the MCC to manufacture, distribute and wholesale medical devices.

Section 21 of the Act provides for MCC to authorize the sale of a medical device or IVD requiring registration but not yet registered.

At the MCC meeting of 28-29 September 2017 Council confirmed the following:

In view of the fact that Council has not yet called up any medical devices for registration, Medical Device establishments licensed by Council to manufacture or distribute medical devices are not required to submit an application to sell a device according to the provisions of Section 21 of the Act, irrespective of whether the device contains a scheduled substance or not.

DR JC GOUWS
REGISTRAR OF MEDICINES