

## DEPARTMENT OF HEALTH

NO. 157

24 FEBRUARY 2017

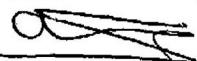
**MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)**

The Medicines Control Council by virtue of the powers vested in it by section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and Regulation 27(2) of the Regulations relating to Medical Devices and *In Vitro* Diagnostics (*IVDs*) has by resolution resolved that, with effect from the date of publication of this notice, all unlicensed manufacturers, distributors and wholesalers of Medical Devices and *IVDs* are required to submit applications, as the case may be, for a licence to manufacture, wholesale or distribute medical devices and *IVDs*.

In terms of the Regulation 5(1) of the Regulations on Medical Devices and *IVDs* a manufacturer, wholesaler or distributor referred to in section 22C(1)(b) of the Act must:

- "(a)...."
- (b) submit to the Registrar an application for a licence, on a form approved and provided by the Council;
- (c) as part of the application, provide acceptable documentary proof of-
  - (i) the particulars of the owner of the business;
  - (ii) the particulars of the authorised representative; and
  - (iii) certification to a Quality Management System for medical devices and *IVDs* as determined by the Council;
- (d) specify, as determined by the Council, the Medical Devices or *IVDs* or group or family of medical devices or *IVDs* to be manufactured, imported, exported or distributed and sold; and
- (e) pay the application fee.

The applications for licensing of a Manufacturer or Distributor should be submitted within six (6) months of the date following the publication of this notice. The application for licensing of a Wholesaler should be submitted within twelve (12) months of the date following the publication of this notice. If no application is made within the required period, the Manufacturer, Distributor or Wholesaler will be considered to be trading in contravention of section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).



DR J GOUWS  
REGISTRAR OF MEDICINES