

MEDICINES CONTROL COUNCIL



POSITION STATEMENT: TRANSITIONAL ARRANGEMENTS FOR MEDICAL DEVICES

To all Applicants

Kindly be advised that the Medicines Control Council resolved on the transitional arrangements for medical devices, to allow for the sale and use of medical devices, under the ambit of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended.

1 BACKGROUND

1.1 Following the promulgation of the Medicines and Related Substances Amendment Act, 2008 (Act No. 72 of 2008), read together with (Act No. 14 of 2015):

- (a) Section 13 provides for separate registers which shall be kept for medical devices/IVDs and for medicines; and
- (b) Section 14 regarding the prohibition on the sale of medicines and medical devices or IVDs which are subject to registration and are not registered; and
- (c) Section 21 provides for the authorization for sale of unregistered medicine, medical devices or IVDs for certain purposes; and
- (d) Section 22C(1)(b) that requires the Medicines Control Council (MCC), on the application in the prescribed manner, to issue to a manufacturer, wholesaler and distributor of Medical Devices and *In Vitro* Diagnostics (IVDs) a licence to conduct their respective businesses; and

1.2 The Regulations relating to Medical Devices and IVDs, published in the *Government Gazette* No. 40480, on the 09 December 2016:

- (a) Regulation 3. Importation of medical devices and IVDs into the Republic:
A person may only import a medical device or IVD if that person-
Is licensed in terms of section 22C(1)(b) of the Act to import medical devices or IVDs; and
In the case of unregistered medical devices or IVDs, is authorised by the Council to import the unregistered medical devices or IVDs.

- (b) Regulation 5(1) that prescribes the requirements of the applications and the manner in which the applications will be handled;
- (c) Regulation 11. Classification of Medical devices and IVDs:
Medical devices, except custom made medical devices, and IVDs must be registered with the Council in terms of call up notices before they may be sold or used in the Republic;
- (d) Regulation 27. Transitional arrangements regarding unlicensed manufacturer, distributor and wholesaler:
A manufacturer, distributor or wholesaler who, at the time of the commencement of these Regulations, sells medical devices or IVDs in the Republic is, subject to regulation 5, considered to be trading legally.

2 TRANSITIONAL ARRANGEMENTS FOR MEDICAL DEVICES

- 2.1 As per the call up notice, published in *Government Gazette* No. 40637, on the 24 February 2017, applications for licensing of a Manufacturer or Distributor should be submitted by the 24 August 2017. Applications for licensing of a Wholesaler should be submitted by the 24 February 2018. 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).
- 2.2 Manufacturers and Distributors, who have not submitted a licence application, are deemed to be trading legally until the 24 August 2017, when the required period for applications, for licensing of Manufacturer and Distributor, ends. Wholesalers, who have not submitted a licence application, are deemed to be trading legally until the 24 February 2018, when the required period for applications, for licensing of a Wholesaler, ends.
- 2.3 Medical devices and IVDs that were sold or used in the Republic prior to the publication of the Regulations relating to Medical Devices and IVDs, in the *Government Gazette* No. 40480, on the 09 December 2016, are deemed to be sold or used in the Republic legally, provided that-
 - (a) Applicants, responsible for such medical devices and IVDs, are licensed accordingly as Medical Device Establishments; and
 - (b) Up until such time, the medical devices and IVDs sold or used in the Republic are called up for registration.
- 2.4 Medical devices and IVDs that were sold or used in the Republic following the publication of the Regulations relating to Medical Devices and IVDs, in the *Government Gazette* No. 40480, on the 09 December 2016, are deemed to be sold or used in the Republic legally, provided that-
 - (a) Applicants, responsible for such medical devices and IVDs, are licensed accordingly as Medical Device Establishments; and
 - (b) Up until such time, the medical devices and IVDs sold or used in the Republic are called up for registration, via publication in the *Gazette*.
- 2.5 Applicants wishing to launch new medical devices and IVDs for sale or use in the Republic are deemed to do so legally, provided that-
 - (a) Applicants, responsible for such medical devices and IVDs, are licensed accordingly as Medical Device Establishments; and
 - (b) Up until such time, the medical devices and IVDs sold or used in the Republic are called up for registration, via publication in the *Gazette*.

- 2.6 Medical devices and IVDs, that are imported and/or distributed, for sale or use in the Republic, are deemed to be imported and/or distributed legally, provided that-
- (a) Applicants, responsible for such medical devices and IVDs, are licensed accordingly as Medical Device Establishments; and
 - (b) Up until such time, the medical devices and IVDs sold or used in the Republic are called up for registration, via publication in the *Gazette*.
- 2.7 With the exception of devices containing a scheduled substance, it is not necessary to obtain Section 21 authorisation for medical devices and IVDs, sold or used in the Republic, provided that-
- (a) Applicants, responsible for such medical devices and IVDs, are licensed accordingly as Medical Device Establishments; and
 - (b) Up until such time, the medical devices and IVDs sold or used in the Republic, are called up for registration, via publication in the *Gazette*.
- 2.8 Applicants who are responsible for an unregistered device, containing a scheduled substance, are required to obtain Section 21 authorisation for said devices, prior to sale or use in the Republic.
- (a) Applicants, responsible for such devices, must be licensed accordingly as Medical Device Establishments; and
 - (b) Applicants must continue to obtain section 21 authorisation until such time that said devices, containing a scheduled substance, are registered as a medical device.
- 2.9 Applicants who are responsible for a medical device or IVD that is currently registered as a medicine must use the REQUEST FOR DESIGNATION procedure, in Section 7 of the Guideline on Borderline Products, available on the MCC website (www.mccza.com), to motivate for the transfer of the product currently registered as a medicine to the medical device register.
- 2.10 Applicants who have submitted a dossier for the registration of a medical device or IVD as a medicine, and who have not yet received confirmation of registration of said medical device or IVD as a medicine, must use the REQUEST FOR DESIGNATION procedure, in Section 7 of the Guideline on Borderline Products, available on the MCC website (www.mccza.com), to motivate for the transfer of the product currently registered as a medicine to the medical device register.
- 2.11 With the exception of devices containing a scheduled substance, medical devices and IVDs that have been submitted for registration as medicines and that have not been registered, but are sold or used in the Republic, through Section 21 authorisation, need no longer apply for Section 21 authorisation for the medical device or IVD, provided that-
- (a) Applicants submit the REQUEST FOR DESIGNATION, as described in Section 7 of the Guideline on Borderline Products, to motivate for the transfer of the product currently registered as a medicine to the medical device register; and
 - (b) Applicants, responsible for such medical devices and IVDs, are licensed accordingly as Medical Device Establishments; and
 - (c) Up until such time, the medical devices and IVDs sold or used in the Republic, are called up for registration, via publication in the *Gazette*.
- 2.12 Applicants who have submitted an application for registration, for medical devices and IVDs, that have been called up for registration, via publication in the *Gazette*, and where said registration has not yet been approved, are required to obtain Section 21 authorisation, for such products, intended for sale or use in the Republic.

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REGISTRAR OF MEDICINES