AMENDMENT OF MEDICAL DEVICE ESTABLISHMENT LICENCE

Communication to Stakeholders

1 BACKGROUND

1.1 On 01 June 2017, the President of the Republic of South Africa signed into effect Amendment Act 72 of 2008 (and effectively therefore also Amendment Act 14 of 2015), which broadened the regulatory scope of the Medicines and Related Substances Act, 1965 (Act 101 of 1965; the "Act"), to include the regulation of medical devices.

1.2 In terms of Section 22C(1)(b) of the Act–

the Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a medical device or IVD establishment, manufacturer, wholesaler or distributor of a medicine, Scheduled substance, medical device or IVD a licence to manufacture, import, export, act as a wholesaler of or distribute, as the case may be, such medicine, Scheduled substance, medical device or IVD upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the Authority may determine.

1.3 The regulations relating to medical devices (Regulation No 1515 published in Government Gazette No 40480 on 9 December 2016), published by the Minister of Health in terms of section 35(1)(xxvii) of the Act, make provision for the licensing of medical device establishments.

1.4 Section 5(7) makes provision for the amendment of a medical device establishment licence–

A licensee must notify the Authority in writing of a change to any of the particulars furnished in the application or entered in the register, which occurs after the issue of the licence.

2 POSITION TAKEN BY SAHPRA

2.1 Licensees are required to make application for the amendment of a medical device establishment licence in the event of a change in the following:

a) Name of Licence Holder
b) Address of Licence Holder

c) Class of Medical Device Manufactured / Distributed / Imported / Exported / Wholesaled

d) Particulars of personnel responsible for operation on the premises on behalf of the licence holder including: Authorised Representative / Manufacture /Import / Distribution / Export Control Person / Quality Control Person

e) Particulars of licence holder contact

2.2 Licensees are not required to make application for amendment of a medical device establishment licence in the event of a change in the product listings provided in section 4.1, 4.2, 4.3, 4.4 and 17.3 of the manufacturers and distributors licence application form and section 3 of the wholesaler's application form: Provided that the class of medical device/s for which the licensee has been licensed is not affected and does not change.

2.3 In the event of a change to section 4.1, 4.2, 4.3, 4.4 and 17.3 of the manufacturers (6.21) and distributors (6.22) licence application form and section 3 of the wholesalers (6.26) application form that does not affect the class of medical device/s for which the licensee has been licensed, the licensee is required to notify the Authority in writing.

2.4 A fee will not be levied for the notification to the Authority as noted in 2.3.

2.5 Written notifications to the Authority of changes to Medical Device Establishment Licences as noted in 2.3 must be prepared as follows:

a) The written notification must be prepared on the company letterhead of the licence holder;

b) The subject of the written notification must state: Notification of amendment to section/s [X] of the [Manufacturer/Distributor/Wholesaler] Medical Device Establishment Licence [Licence Number] of [Company Name] [MDF Number];

c) The written notification must include an updated list of the products to be included or removed from the various section/s of the relevant licence/s, in the same format as provided for in the relevant licence application form;

d) A written declaration by the Authorised Representative indicating that the changes made to the product list/s in the various section/s of the relevant licence/s do/does not affect the class of medical device/s for which the licensee has been licensed;

e) The written notification must be dated and singed by the Authorised Representative;

f) Written notifications must be accompanied by the new version of the fully completed medical device establishment licence application form which will include an updated product list in the various section/s of the relevant licence/s as indicated in the written notification;

g) Written notifications and updated copies of the amended licence application form should be submitted as an electronic copy (on a CD) to the SAHPRA Reception.

MS PORTIA NKAMBULE

ACTING CEO OF SAHPRA

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