Ministry of Health and Quality of Life

Procedures for the registration, renewal, change in characteristics and extension in range of both imported and locally manufactured registered pharmaceutical product.

1.0 Introduction

1.1 Sections 25 and 36A of the Pharmacy Act 1983, amended under the Economic and Financial Measures (Miscellaneous Provisions) Act No. 27 of 2013, make provision for the registration of both imported and locally manufactured pharmaceutical products and for the payment of fees.

1.2 The Pharmaceutical Product (Fees) Regulations Government Notice No:47 of 2016 makes provision for the payment of:

a) A non-refundable processing fee at the time of submission of an application for the registration for both imported and locally manufactured pharmaceutical products.

b) A registration fee for imported and locally manufactured pharmaceutical products.

c) An annual renewal fee for imported and locally manufactured pharmaceutical products.

d) Fees for change in characteristics and extension in range of both imported and locally manufactured pharmaceutical products.

1.3 These procedures are available for consultation at the Ministry of Health and Quality of Life, 8th Floor, Emmanuel Anquetil Building, Port Louis and will be posted on the website of the Ministry at http://health.govmu.org.

2.0 Procedures for registration, renewal, change in characteristics and extension in range of imported and locally manufactured pharmaceutical product.

2.1 IMPORTED PHARMACEUTICAL PRODUCT

A. Registration of a Pharmaceutical Product

(i) A person who wishes to register an imported pharmaceutical product shall make an application, in duplicate, to the Board in the prescribed form as set out in **First Schedule**.

(ii) The application form will be accompanied by:

a) a non-refundable processing fee of Rs 2,500 as specified in the **Second Schedule**; and

b) the corresponding registration file, in duplicate, containing all the technical information and specifications in the Common Technical Document(CTD) Format.

(iii) Upon submission of the application and the payment of the prescribed fee, a receipt will be delivered to the applicant.

(iv) The Pharmacy Board will refer the application to the Trade and Therapeutics Committee for its recommendations, following which, the Board may approve or reject the application.

(v) Upon approval by the Board, the applicant shall pay the prescribed registration fee of Rs 5,000 as specified in the **Second Schedule** and a receipt will be delivered to the applicant.

(vi) The Board will then register the pharmaceutical product and issue to the applicant a certificate of registration as set out in the **Third Schedule** and on such conditions that it may determine.

(vii) The certificate of registration will be valid for a period of one year as from the date specified on the certificate of registration.

B. Renewal of Registration of a Pharmaceutical Product

(i) The holder of a certificate of registration of a registered pharmaceutical product wishing to renew the registration shall inform the Board 3 months prior to the expiry date of the registration.

(ii) The annual renewal fee of Rs 2,000 payable will be as specified in the **Second Schedule.**

(iii) Upon payment of the annual renewal fee, a receipt will be issued to the holder of the certificate and the registration shall be renewed for a period of one year.

(iv) Non payment of the renewal fee shall entail suspension of the registration of the pharmaceutical product until such time that payment is effected.

(v) Importation of a pharmaceutical product, for which the annual renewal fee has not been paid, shall not be allowed.

C. Change in Characteristics and Extension in Range of an imported pharmaceutical product

(i) The holder of a certificate of registration of a registered pharmaceutical product wishing to modify the product characteristics or to extend the range as specified in the **Fourth Schedule**, of the registered pharmaceutical product:

a) will apply to the Board in the prescribed form as set out in the **Fifth Schedule**; and

b) upon approval of the change in characteristics and extension in range of a pharmaceutical product, shall pay the prescribed fee as specified in the **Fourth Schedule.** A receipt shall be delivered to the applicant.

A certificate of registration for the new presentation as set out in the **Sixth Schedule** shall be delivered to the applicant.

2.2. LOCALLY MANUFACTURED PHARMACEUTICAL PRODUCT

A. Registration of a Pharmaceutical Product

(i) A manufacturer who wishes to sell a manufactured pharmaceutical product shall make an application for the registration of the pharmaceutical product, in duplicate, to the Board in the prescribed form as set out in **Seventh Schedule**.

(ii) The application form shall be accompanied by:

a) a non-refundable processing fee of Rs 2,500 as specified in the **Second Schedule**; and

b) the corresponding registration file, in duplicate, containing all the technical information and specifications in the Common Technical Document(CTD) Format.

(iii) Upon submission of the application and the payment of the prescribed fee, a receipt shall be delivered to the applicant.

(iv) The Pharmacy Board shall refer the application to the Trade and Therapeutics Committee for its recommendations, following which, the Board may approve or reject the application.

(v) Upon approval by the Board, the applicant shall pay the prescribed registration fee of Rs 5,000 as specified in the **Second Schedule** and a receipt will be delivered to the applicant.

(vi) The Board shall then register the pharmaceutical product and issue to the applicant a certificate of registration as set out in the **Eighth Schedule** and on such conditions that it may determine.

(vii) The certificate of registration shall be valid for a period of one year as from the date specified on the certificate of registration.

B. Renewal of Registration of a Pharmaceutical Product

(i) The holder of a certificate of registration of a manufactured pharmaceutical product wishing to renew the registration shall inform the Board 3 months prior to the expiry date of the registration.

(ii) The annual renewal fee of Rs 2,000 payable shall be as specified in the **Second Schedule.**

(iii) Upon payment of the annual renewal fee, a receipt will be issued to the holder of the certificate and the registration shall be renewed for a period of one year.

(iv) Non payment of the renewal fee shall entail suspension of the registration of the pharmaceutical product until such time that payment is effected.

(v) Sale of a manufactured pharmaceutical product, for which the annual renewal fee has not been paid, shall not be allowed.

C. <u>Change in Characteristics and Extension in Range of a locally manufactured pharmaceutical product</u>

(i) The holder of a certificate of registration of a manufactured pharmaceutical product wishing to modify the product characteristics or to extend the range as specified in the **Fourth Schedule**, of the manufactured pharmaceutical product:

a) will apply to the Board in the prescribed form as set out in the **Ninth Schedule**; and

b) upon approval of the change in characteristics and extension in range of a pharmaceutical product, shall pay the prescribed fee as specified in the **Fourth Schedule**. A receipt shall be delivered to the applicant.

(ii) A certificate of registration for the new presentation as set out in the **Tenth Schedule** shall be delivered to the applicant.

3.0 Any person who for the purposes of an application under section 25 willfully –

a) Makes a false statement or a statement which he knows or ought to have known to be false in any material particular;

b) Makes a false representation; or

c) Fails to disclose a material fact,

shall commit an offence under the Pharmacy Act.

1. All applications for registration, renewal of registration, change in characteristics and extension in range of a pharmaceutical product (locally manufactured or imported), should be made on the prescribed forms which may be downloaded from the website of the Ministry of Health and Quality of Life at http://health.govmu.org or obtained from the office of the Registrar of the Pharmacy Board.

2. All applications should be addressed to:

   The Registrar
   Pharmacy Board
   Ministry of Health and Quality of Life
   Level 8, Emmanuel Anquetil Building,
   Port- Louis.

   Tel No. 201 1334 / 201 3608

3. Payment of appropriate fees, supported by the relevant forms, should be made between **08 45 hours to 12 00 hours and 12 30 hours to 15 00 hours during weekdays** at:

   The Cash Office
   Finance Section
   Ministry of Health and Quality of Life
   Level 3, Bacha Building
   Lislet Geoffroy Street
   Port Louis

   Tel No. 211 6630

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