Pharmaceutical Product (Fees) Regulations 2016

GN No. 47 of 2016
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THE PHARMACY ACT

Regulations made by the Minister under section 47 of the Pharmacy Act

1. These regulations may be cited as the **Pharmaceutical Product (Fees) Regulations 2016**.

2. In these regulations -

Act" means the Pharmacy Act;

"pharmaceutical product" -

(a) has the same meaning as in section 2 of the Act; and

(b) includes imported and locally manufactured pharmaceutical product.

3. For the purpose of section 25(2) (a) of the Act, the prescribed form shall be the form set out in the First Schedule.

4. For the purpose of section 25(2) (b) of the Act, the non-refundable processing fee shall be as specified in the Second Schedule.

5. For the purpose of section 25(5) of the Act -

(a) the registration fee shall be as specified in the Second Schedule;

(b) the certificate of registration shall be as set out in the Third Schedule.

6. For the purpose of section 25(6) of the Act, the annual renewal fee shall be as specified in the Second Schedule.

7. For the purpose of section 25(7) of the Act -

(a) any person wishing to extend the range of presentations or modify the product characteristics as specified in the Fourth Schedule, for any imported pharmaceutical product, shall apply to the Board on the prescribed form as set out in the Fifth Schedule;

(b) the fee for any change in characteristics and extension in range of the imported pharmaceutical product shall be as specified in the Fourth Schedule;

(c) the certificate or registration for the new presentation shall be as set out in the Sixth Schedule.

8. For the purpose of section 36A (2)(a) of the Act, the prescribed form shall be as set out in the Seventh Schedule.

9. For the purpose of section 36A (2)(b) of the Act, the non-refundable processing fee shall be as specified in the Second Schedule.

10. For the purpose of section 36A (5) of the Act -

(a) the registration fee shall be as specified in the Second Schedule;

(b) the certificate of registration shall be as set out in the Eighth Schedule.

11. For the purpose of section 36A(6) of the Act, the annual renewal fee shall be as specified in the Second Schedule.

12. For the purpose of section 36A(7) of the Act -

(a) any person wishing to extend the range of presentations or modify the product

characteristics, as specified in the Fourth Schedule, for any locally manufactured

pharmaceutical product shall apply to the Board on the prescribed form as set out in the Ninth Schedule;

(b) the fee for any change in characteristics and extension in range of the locally manufactured pharmaceutical product shall be as specified in the Fourth Schedule;

(c) the certificate or registration for the new presentation shall be as set out in the Tenth Schedule.

13. These regulations shall come into operation on 1 April 2016.

Made by the Minister on 28 March 2016.

FIRST SCHEDULE

[Regulation 3]

APPLICATION FOR REGISTRATION OF IMPORTED PHARMACEUTICAL PRODUCT

(to be filled in duplicate)

I, …….. ,(name) of …….. *(address)* holder of National Identity Card number ……. representative/accredited agent in Mauritius, of …… *(name of person represented)* am applying, on his behalf, to the Pharmacy Board for the registration of ……. containing the following active ingredients —

(a) ……..;

(b) ……;

(c) ……;

manufactured by …….*(name of manufacturer)*
at …….. *(manufacturing site)* with ……. being the channel of distribution from the country of origin to Mauritius.

I certify that the information contained in this application form is true.

…….. ……..
Phone number Email address

…….. ……..
Date Authorised signature

SECOND SCHEDULE

[Regulations 4, 5(a), 6, 9, 10(a) and 11]

PROCESSING, REGISTRATION AND RENEWAL FEES

		(Rs)
1.	Non-refundable processing fee	2,500
2.	Registration fee for imported pharmaceutical product	5,000
3.	Annual renewal fee for imported pharmaceutical product	2,000
4.	Registration fee for locally manufactured pharmaceutical product	5,000
5.	Annual renewal fee for locally manufactured pharmaceutical product	2,000

THIRD SCHEDULE

[Regulation 5(b)]

CERTIFICATE OF REGISTRATION OF IMPORTED PHARMACEUTICAL PRODUCT

(to be filled by the Registrar of the Pharmacy Board)

This is to certify that…….. *(name of product),*

containing the following active ingredients -

(a) …….

(b) …….

(c)…….

manufactured by……..….*(name of manufacturer)*

at……*(manufacturing site)* with……., being the channel of distribution from the country of origin to Mauritius, is registered in Mauritius under the Pharmacy Act under Registration number ……

This certificate shall be valid until……...
This registration number shall appear on all import and export invoices.

……	……..
Registrar	Chairperson
Pharmacy Board	Pharmacy Board
…….	…….
Date	Official Stamp

FOURTH SCHEDULE

[Regulations 7(b) and 12(b)]

FEE FOR CHANGE IN CHARACTERISTICS AND EXTENSION IN RANGE OF IMPORTED AND LOCALLY MANUFACTURED PHARMACEUTICAL PRODUCTS

		(Rs)
1.	Change in shelf life	2,000
2.	Change in manufacturing site/distribution channel	2,000
3.	Extension in line of product	2,000
4.	Change in trade name	2,000
5.	Change in/additional pack size	1,000
6.	Change in pack design (primary pack)	1,000
7.	Change in pack design (secondary pack)	1,000
8.	Change in packing material	1,000
9.	Change in label design	1,000

FIFTH SCHEDULE

[Regulation 7(a)]

APPLICATION FOR CHANGE IN CHARACTERISTICS OF IMPORTED PHARMACEUTICAL PRODUCT

(to be filled in duplicate)

I,…… *(name)* of…… *(address)* holder **of National** Identity Card number representative/accredited agent in Mauritius, of *(name of person represented)* am applying, on his behalf, to the Pharmacy Board for the change in characteristics/extension in range of already registered under the Pharmacy Act with Registration Certificate number — *(state variation/s)*

(a) ……..……;

(b) ……..……;

(c) .....;

I certify that the information contained in this application form is true.

……	……..
Phone number	Email address
…….	…….
Date	Authorised Signature

SIXTH SCHEDULE

[Regulation 7(c)]

(to be filled by the Registrar of the Pharmacy Board)

CERTIFICATE OF REGISTRATION OF IMPORTED PHARMACEUTICAL PRODUCT (Variations)

This is to certify that ……..; containing the following active ingredients —

(a) ……;

(b) ……..;

(c) ……..; manufactured by …… , *(name of manufacturer)* at ……*(manufacturing site)* with ……. , being the channel of distribution from the country of origin to Mauritius with the following variations …… and registered in Mauritius under the Pharmacy Act under Registration number ……

This Registration number shall appear on all import and export invoices.

The previous registration number ……is struck off.

This certificate shall be valid until ……..
This registration number shall have to appear on all import and export invoices.

……	……..
Registrar Pharmacy Board	Chairperson Pharmacy Board

…….
Date of issue

SEVENTH SCHEDULE

[Regulation 8]

APPLICATION FOR REGISTRATION OF LOCALLY MANUFACTURED PHARMACEUTICAL PRODUCT

(to be filled in duplicate)

I, ……..., *(name)* of …… , *(address)* holder of National Identity Card number ……. ,representative/ accredited agent in Mauritius, of …… *(name of person represented),* am applying, on his behalf, to the Pharmacy Board for the registration of ……containing the following active ingredients —

(a) ……..;

(b) ……;

(c) ……;

manufactured by ……*(name of manufacturer)*
at ……*(manufacturing site)* in Mauritius.

I certify that the information contained in this application form is true.

……	……...
Phone number	Email address
…….	…….
Date	Authorised Signature

EIGHTH SCHEDULE

[Regulation 10(b)]

CERTIFICATE OF REGISTRATION OF LOCALLY MANUFACTURED PHARMACEUTICAL PRODUCT

This is to certify that ……....., *(name of locally manufactured pharmaceutical product)* containing the following active ingredients —

(a) ……;

(b) ……;

(c) ……..;
manufactured by …….. *(name of manufacturer)* at …….. *(manufacturing site)* and registered in Mauritius under the Pharmacy Act under Registration number …….

This certificate shall be valid until ……

This registration number shall appear on all import and export invoices.

……	……..
Registrar	Chairperson
Pharmacy Board	Pharmacy Board
…….	…….
Date	Official Stamp

NINTH SCHEDULE

[Regulation 12(a)]

APPLICATION FOR CHANGE IN CHARACTERISTICS OF LOCALLY MANUFACTURED PHARMACEUTICAL PRODUCT

(to be filled in duplicate)

I, ……, *(name)* of …….., *(address)* holder of National Identity Card number ……..., am applying to the Pharmacy Board for the change in characteristics/extension in range of …….. , already registered under the Pharmacy Act with registration number ……..... *(state variation/s)*

(a) ……..;

(b) ……;……;

(c) ……;

I certify that the information contained in this application form is true.

…… ……..

Phone number Email address

…… ……..

Date Authorised Signature

TENTH SCHEDULE

[Regulation 12(c)]

CERTIFICATE OF REGISTRATION OF LOCALLY MANUFACTURED PHARMACEUTICAL PRODUCT

(Variations)

This is to certify that ……..containing the following active ingredients —

(a) ……..;

(b) ……..……;

(c) ……..……;

manufactured by ……*(name of manufacturer)* at ……*(manufacturing site)* with the following variations ……. and registered in Mauritius under the Pharmacy Act under registration number ……

This registration number shall appear on all import and export invoices.

Previous registration number ……...is struck off.

This certificate shall be valid until ……..

……	……..
Registrar	Chairperson
Pharmacy Board	Pharmacy Board
……	……..
Date	Official Stamp