GOVERNMENT NOTICE NO. 9

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT
(NO. 9 OF 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS, 2022

IN EXERCISE of powers conferred by section 129 of the Pharmacy and Medicines Regulatory Authority Act, I, KHUMBIZE KANDODO CHIPONDA, Minister of Health, make the following Regulations—

Citation

1. These Regulations may be cited as the Pharmacy and Medicines Regulatory Authority (Fees and Forms) Regulations, 2022.

Fees

2. The Authority shall charge the fees specified in the *First Schedule*, in respect of the matters correspondingly specified herein.

Surcharge

3.—(1) The Authority shall charge a surcharge to any person who fails to pay retention fees as specified in the *First Schedule*.

(2) A person who fails to pay retention fees—

(*a*) within three months of the commencement of the Authority's financial year, shall pay a surcharge of fifty percent of the retention fees payable; and

(*b*) after three months of the commencement of the Authority's financial year, shall pay a surcharge of one hundred percent of the retention fees payable.

Forms

4. The forms set out in the *Second Schedule* shall be used for the purposes of the Act.

FIRST SCHEDULE

reg. 2

PRESCRIBED FEES

Matter	*Fees*
1. Registration fees for pharmacy personnel: on application for registration including issuance of a certificate—	
(*a*) pharmacist—	
(i) Malawian pharmacist, including internship	K50,000 00
(ii) non-Malawian pharmacist including vetting . .	US$1,000 00
(iii) Malawian pharmacist re-examination fees, per subject	K25,000 00
(iv) non-Malawian pharmacist re-examination fees, per subject	US$215 00
(v) non- Malawian volunteer pharmacist	US$250 00

Matter	*Fees*
(*b*) pharmacy technologist—	
(i) Malawian technologist	K30,000 00
(ii) non-Malawian technologist, including vetting . .	US$700 00
(iii) Malawian technologist re-examination fees, per subject	K10, 000 00
(iv) non-Malawian technologist re-examination fees, per subject	US$175 00
(*c*) pharmacy assistant—	
(i) Malawian pharmacy assistant.	K20,000 00
(ii) non-Malawian pharmacy assistant, including vetting. .	US$400 00
(iii) Malawian pharmacy assistant re-examination fees, per subject	K8,000 00
(iv) non-Malawian pharmacy assistant re-examination fees, per subject	US$100 00
(*d*) medical representative—	
(i) Malawian medical representative	K150,000 00
(ii) non-Malawian medical representative	US$700 00
2. Retention fees for pharmacy personnel—	
(*a*) pharmacist—	
(i) Malawian pharmacist	K30,000 00
(ii) non-Malawian pharmacist	US$550 00
(iii) non- Malawian volunteer pharmacist	US$250 00
(*b*) pharmacy technologist—	
(i) Malawian technologist	K20,000 00
(ii) non-Malawian technologist	US$300 00
(*c*) pharmacy assistant—	
(i) Malawian pharmacy assistant	K15,000 00
(ii) non-Malawian pharmacy assistant.	US$300 00
(*d*) medical representatives—	
(i) Malawian medical representative	K75,000 00
(ii) non-Malawian medical representative	US$300 00
3. Licencing of premises—	
(*a*) manufacturing licence—	
(i) inspection and processing for oral dosage forms (solids and liquids)	K1,500,000 00
(ii) inspection and processing for external preparations	K1,300,000 00
(iii) inspection and processing for sterile preparations . .	K1,700,000 00
(iv) inspection and processing for primary and secondary packaging	K1,000,000 00
(v) re-inspection of premises, if previously failed . .	*cost of travel

Matter	*Fees*
(*b*) wholesale pharmacy licence—	
(i) inspection and processing	K760,000 00
(ii) re-inspection fees of premises, if previously failed	*cost of travel
(*c*) retail pharmacy licence—	
(i) inspection and processing	K385,000 00
(ii) re-inspection fees of premises, if previously failed . .	*cost of travel
(*d*) medicine store licence or veterinary shop licence—	
(i) inspection and processing	K200,000 00
(ii) re-inspection fees of premises if previously failed . .	*cost of travel
(*e*) dispensing licence—	
(i) inspection and processing of licence for a facility with an admission service	K335,000 00
(ii) inspection and processing of licence for a facility without an admission service	K200,000.00
(iii) re-inspection fees of premises, if previously failed	*cost of travel
(*f*) medical device: wholesale, retail and cosmetic shop—	
(i) inspection and processing	K710,000 00
(ii) re-inspection fees of premises, if previously failed	*cost of travel

*Cost of travel shall be determined by agreement between the Authority and the applicant.

4. Retention fees for premises—

(*a*) manufacturing licence—	
(i) premises with oral dosage forms (solids and liquids)	K350,000 00
(ii) premises with external preparations	K260,000 00
(iii) premises with sterile preparations	K400,000 00
(iv) primary packaging only	K200,000 00
(v) secondary packaging only	K120,000 00
(*b*) wholesale pharmacy licence—	
(i) retention fees	K320,000 00
(ii) inspection and relocation processing	K520,000 00
(*c*) retail pharmacy licence—	
(i) retention fees	K160,000 00
(ii) inspection and relocation processing	K235,000 00
(*d*) medicine store and veterinary shop licence—	
(i) retention fees	K60,000 00
(ii) inspection and relocation processing	K160,000 00
(*e*) medical device: wholesale, retail and cosmetic shop—	
(i) retention fees	K320,000 00
(ii) inspection and relocation processing	K560,000 00

Matter	*Fees*
(*f*) dispensing licence—	
(i) retention for a facility with an admission service . .	K160,000 00
(ii) inspection and relocation processing	K235,000 00
(iii) retention for a facility without and admission service	K55,000 00
(iv) inspection and relocation processing	K155,000 00
5. Registration of medicinal products—	
(*a*) human, veterinary and herbal medicinal products—	
(i) human or veterinary product manufactured in Malawi	K300,000 00
(ii) human or veterinary product manufactured in Malawi (expedited processing of application)	K600,000 00
(iii) human or veterinary product manufactured outside Malawi	US$1500 00
(iv) human or veterinary product manufactured outside Malawi (expedited processing of application).	US$3000 00
(v) herbal product manufactured in Malawi	K80,000 00
(vi) herbal product manufactured outside Malawi . .	US$1,100 00
(vii) human or veterinary product packed in Malawi but manufactured outside Malawi	US$450 00
6. *Retention fees for medicinal products—	
(*a*) human or veterinary and herbal medicinal products—	
(i) human or veterinary product manufactured in Malawi	K150,000 00
(ii) human or veterinary product manufactured outside Malawi	US$700 00
(iii) herbal product manufactured in Malawi	K50,000 00
(iv) herbal product manufactured outside Malawi . .	US$450 00

*Products not retained for one year without submission of withdrawal notice, shall attract payment of the retention fees in arrears first, before re-instatement on the Register.

7. Registration of allied substances—	
(*a*) medical devices, condoms, surgical sundries—	
(i) class I	US$500 00
(ii) class II	US$750 00
(iii) class III	US$1500 00
(*b*) traditional medicines and nutritional supplements—	
(i) nutritional and traditional medicinal product manufactured in Malawi	K80,000 00
(ii) nutritional and traditional medicinal product manufactured outside Malawi	US$500 00
(*c*) cosmetic products—	
(i) cosmetic products manufactured in Malawi . .	K80,000 00
(ii) cosmetic products manufactured outside Malawi . .	US$500 00

Matter	*Fees*
(*d*) disinfectants and reagents—	
(i) disinfectants and reagents manufactured in Malawi. .	K80,000 00
(ii) disinfectants and reagents manufactured outside Malawi	US$400 00
(*e*) feed additives and supplements—	
(i) feed additives and supplements manufactured in Malawi	K100,000 00
(ii) feed additives and supplements manufactured outside Malawi	US$500 00
8. Retention fees for allied substances—	
(*a*) medical devices, condoms and surgical sundries—	
(i) class I	US$200 00
(ii) class II	US$ 300 00
(iii) class III	US$700 00
(*b*) traditional medicines and nutritional supplements—	
(i) nutritional and traditional medicinal product manufactured in Malawi	K50,000 00
(ii) nutritional and traditional medicinal product manufactured outside Malawi	US$200 00
(*c*) cosmetic products—	
(i) cosmetic products manufactured in Malawi . .	K50,000 00
(ii) cosmetic products manufactured outside Malawi . .	US$500 00
(*d*) disinfectants and reagents—	
(i) disinfectants and reagents manufactured in Malawi	K50,000 00
(ii) disinfectants and reagents manufactured outside Malawi	US$150 00
(*e*) feed additives and supplements—	
(i) feed additives and supplements manufactured in Malawi	K80,000 00
(ii) feed additives and supplements manufactured outside Malawi	US$250 00
9. Analysis of samples by the quality control laboratory—	
(*a*) routine drug analysis per batch—	
(i) sample originating from a Malawian . .	*K5,700 – K615,000
(ii) sample originating from a non-Malawian . .	*US$36 00 – US$300 00
(*b*) male latex condoms per batch—	
(i) sample originating from a Malawian	K560,000 00
(ii) sample originating from a non-Malawian	US$700 00
(*c*) samples analysis at laboratories outside the Authority . .	cost of analysis plus 12% service charge

Matter	*Fees*
(*d*) re-analysis of samples at owner's or importer's request—	
(i) sample originating from a Malawian	K700,000 00
(ii) sample originating from a non-Malawian	US$880 00
(*e*) detailed certificate of analysis at the owner of sample's request—	
(i) sample originating from a Malawian	K300,000 00
(ii) sample originating from a non-Malawian	US$380 00
(*f*) analysis of sample under investigation—	
(i) sample originating from a Malawian	K160,000 00
(ii) sample originating from a non-Malawian	US$200 00

*The fees for routine drug analysis shall depend on the type of test and dosage form as shall be indicated on a tabulated chart published by the Authority from time to time.

10. Applications, registration, renewal and amendment of clinical trials—	
(*a*) application, review and registration of a clinical trial . .	5% of total budget
(*b*) annual renewal of a clinical trial	US$2,200 00
(*c*) amendments to a clinical trial	US$300 00
(*d*) veterinary clinical trial	5% of total budget
(*e*) annual renewal of veterinary clinical trial	US$750 00
11. Assessment and issuance of permit for importation, exportation and waivers on importation for medicines and allied substances—	
(*a*) import or export permit for registered medicines (per batch)	1.5% of total invoice value
(*b*) verification fees for commercial consignments and donations to commercial organizations	1.0% of total invoice value
(*c*) importation of unregistered medicines or allied substances from authorized sources	6.0% of total invoice value
(*d*) verification and approval fees for a consignment of medicines and/ or allied substances for disasters, outbreak and raw materials	exempted
(*e*) verification fees for donations to non-profit making organizations	K30,000 00
(*f*) narcotic drugs or psychotropic substances permit . .	K30,000 00
12. Vetting of health products promotional materials, per language—	
(*a*) written materials—	
(i) originating within Malawian	K40,000 00
(ii) originating outside Malawi	US$100 00

Matter	*Fees*
(*b*) audio, video and written scripts—	
(i) originating within Malawi	K80,000 00
(ii) originating outside Malawi	US$100 00
(*c*) posters or billboards on any medium including the internet—	
(i) originating within Malawi	K80,000 00
(ii) originating outside Malawi	US$100 00
(*d*) posters on vehicles—	
(i) originating within Malawi	K40,000 00
(ii) originating outside Malawi	US$100 00
(*e*) t-shirts—	
(i) originating within Malawi	K20,000 00
(ii) originating outside Malawi	US$100 00
(*f*) other materials such as caps, wall clocks, watches, umbrellas or bags—	
(i) originating within Malawi	K20,000 00
(ii) originating outside Malawi	US$100 00
13. Fees for the Authority's publications—	
(*a*) set of Statutes and Statutory Instruments	K21,000 00
(*b*) Code of Ethics	K3,000 00
(*c*) Dangerous drugs register	K10,000 00
(*d*) pharmacist register book	K3,000 00
14. Miscellaneous—	
(*a*) inspection on demand	K200,000 00
(*b*) supervision of medicine destruction	K60,000 00
(c) medicine disposal certificate	K30,000 00
(*d*) licence re-print	K50,000 00
(*e*) licence re-issue following revocation	K200,000 00
15. Licencing of pharmacy colleges and curriculum review—	
(*a*) inspection and processing fees for pharmacy colleges ..	K400,000 00
(*b*) curriculum review of diploma and certificate courses ..	K2,000,000 00
(*c*) curriculum review of degree courses	K3,000,000 00
16. Upon inspection of foreign manufacturing sites to assess current good manufacturing practice (cGMP) inspection & certificate—	
(*a*) manufacturer within the Southern Africa Development Community	US$ 3500 00
(*b*) manufacturer from the rest of Africa	US$ 5,000 00
(*c*) manufacturer from outside Africa	US$6,500 00

SECOND SCHEDULE reg. 4

FORMS

Form No. 1

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(NO. 9 OF 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR REGISTRATION AS A PHARMACIST, PHARMACY TECHNOLOGIST, PHARMACY ASSISTANT OR MEDICAL REPRESENTATIVE*

(*Sections 25 and 39*)

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

(**Delete whichever is not applicable*)

1. Name and address of applicant (in block letters)—

   (*a*) Surname.....

   (*b*) First names .....

   (*c*) Postal address.....

   (*d*) Telephone number.....

2. Date of birth .....

3. Sex (male/female) .....

4. Nationality .....

5. Application for registration in the register of .....

6. Academic qualifications (certificates, diplomas, degrees) and institutions attended (school, university, college)—

Qualification	*Year*	*Institution and Country*
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....

7. Professional qualifications (with dates and institutions attended)—

Qualification	*Year*	*Institution/Body*
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....

8. Present employer and address—

.....

.....

9. I, the above-mentioned applicant, hereby apply for registration on the aforementioned register and submit herewith—

*(*a*) the prescribed application fee of K.....

*(*b*) the prescribed registration fee of K....., and

*(*c*) the following documents in support of my application:.....

.....

10. Declaration—

I, the above-mentioned applicant, hereby solemnly and sincerely declare that the information I have given above is true in every respect to the best of my knowledge and belief and that I have read the Act and the Regulations made under the Act and understand that, if registered, I shall be bound thereby and by any amendments thereto, for as long as my name shall remain on the aforementioned register.

Declared at ..... by.....

Signature of applicant

before me ..... at .....

on this ..... day of ....., 20 .....

.....

Commissioner for Oaths

11. FOR OFFICE USE ONLY—

(*a*) Date of approval of application .....

(*b*) Registration number ..... Certificate number.....

(*c*) Receipt Numbers of application and registration fees.....

(*d*) Remarks

.....

.....

.....

Date ..... Signature .....

Director General
Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2 Application fee is not refundable.]

Form No. 2

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(No. 9 of 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

REGISTER OF PHARMACIST TECHNOLOGIST, PHARMACY ASSISTANT OR MEDICAL REPRESENTATIVE

(Sections 25(3) and 39)

Name of registered person	*Date of regist-ration*	*Regist-ration number*	*Expiry date*	*Address*	*Nationality*	*Date of birth*	*Qualifications*		*University College School or other institution*	*Date of cancella tion of registration, if any*	*Remarks, if any*
							Upon registr-ation	*Subseq-uent to registr ation*			

*(*Delete whichever is not applicable)*

Form No. 3

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(No. 9 of 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

CERTIFICATE OF REGISTRATION OF A PHARMACIST, PHARMACY TECHNOLOGIST, PHARMACY ASSISTANT OR MEDICAL REPRESENTATIVE*

(*Sections 26 and 39*)

Registration number ..... Certificate number .....

This is to certify that .....

is this ..... day of .....,20..... registered on the register of

.....

kept and maintained by the Pharmacy and Medicines Regulatory Authority in accordance with the provisions of the Pharmacy and Medicines Regulatory Authority Act and the Regulations made thereunder.

Valid until ....., 20 .....

Dated .....

....

Director General *Chairperson*

Common Seal

(**Delete whichever is not applicable*)

Form No. 4

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(No. 9 of 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR RETENTION OF NAME OF REGISTERED PHARMACIST, REGISTERED PHARMACY TECHNOLOGIST, REGISTERED PHARMACY ASSISTANT OR REGISTERED MEDICAL REPRESENTATIVE*

(*Sections 27 and 39*)

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

(**Delete whichever is not applicable*)

1. Surname .....
2. First names .....
3. Postal address .....
4. Date of Birth .....
5. Sex (male/female) .....
6. Nationality .....
7. Registration number ..... dated ....., 20.....
8. Certificate number..... dated ....., 20 .....
9. Application for retention of name on the .....

   In respect of .....

   .....

   (*name of registered Pharmacist, registered Pharmacy Technologist, registered Pharmacy Assistant or registered medical representative*)

10. I, the above-mentioned applicant, hereby apply for retention of my name on the aforementioned register and submit therefor—

    *(*a*) application fee of K ..... and

    *(*b*) retention fee of K.....

    Dated this ..... day of ....., 20 .....

    .....

    Signature of applicant

11. FOR OFFICE USE ONLY—

    (*a*) Date of approval of application .....

    (*b*) Registration number .....Certificate number .....

    (*c*) Receipt numbers of application and retention fees .....

    (*d*) Remarks .....

    Date ....

    Director General
    Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2. Application fee is not refundable.]

Form No. 5

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(No. 9 of 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR LICENCING OF PREMISES WHERE A RETAIL PHARMACY BUSINESS IS TO BE CARRIED ON

(*Section 41*)

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

1. Name of business .....

2. Name of applicant .....

3. Email address .....Telephone number.....

4. Postal address.....

5. Location of premises on which a retail pharmacy business it to be carried (Town, Street, Plot No.) (Include a sketch map).....

.....

.....

.....

6. Where the applicant is a company—

(*a*) state registration number of company under the Act.....

(*b*) state name and certificate number of registered pharmacist under whose personal management and control the affairs of the company would be subject to .....

.....

(*c*) attach a copy of the certificate of incorporation of the company

.....

.....

7. Name and number of certificate of registration of a registered pharmacist having control of the premises referred to in paragraph 5 .....

.....

8. I, the above-mentioned applicant, submit herewith the licencing application fee of K .....

Date ....

Signature of applicant

9. FOR OFFICE USE ONLY—

(*a*) Date of inspection of premises .....

(*b*) Remarks .....

(*c*) Date of approval of application .....

(*d*) Licence number .....

(*e*) Receipt number of licencing application fees .....

Date ....

Director General
Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2. Application fee is not refundable.]

Form No. 6

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(No. 9 of 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR LICENCING OF NEW PREMISES WHERE A RETAIL-PHARMACY BUSINESS IS TO BE CARRIED ON

(*Section 41*)

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

1. Name of business .....

2. Name of applicant.....

3. Postal address.....

4. Email address.....Telephone number.....

5. Previous location of the retail pharmacy.....

6. Location of premises to which the retail pharmacy is re-located (city/town, street, plot no.) (include a sketch map).....

.....

.....

7. Where the applicant is a company—

(*a*) state registration number of company under the Act .....

(*b*) state name and certificate number of registered pharmacist under whose personal management and control the affairs of the company would be subject to

.....

(*c*) attach a copy of the certificate of incorporation of the company

.....

8. Name and number of certificate of registration of a registered pharmacist having control of the premises referred to in paragraph 6.....

.....

9. I, the above-mentioned applicant, submit herewith an application fee of K .....

Date ....

Signature of applicant

10. FOR OFFICE USE ONLY—

(*a*) Application fee of K.....

(*b*) Date of inspection of premises .....

(*c*) Remarks .....

(*d*) Date of approval of application .....

(*e*) Licence number .....

(*f*) Receipt number of application .....

Date ....

Director General
Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2. Application fee is not refundable.]

Form No. 7

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(NO. 9 OF 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR LICENCING OF PREMISES WHERE WHOLESALE PHARMACY BUSINESS IS TO BE CARRIED ON

(*Section 41*)

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

1. Name of business.....

2. Name of applicant.....

3. Postal address.....

4. Email address..... Telephone number .....

5. Location of premises on which wholesale pharmacy business is to be carried out (city/town, street, plot no.) include a sketch map)

.....

.....

6. Where the applicant is a company—

(*a*) state the registration number of company under the Act:,.....

(*b*) state the name and registration number of the person under whose personal management and control affairs of the company would be subject to

.....

.....

(*c*) attach a copy of certificate of incorporation of the company

.....

.....

7. Name and registration number of supervising pharmacist having control of the premises referred to in paragraph 5.....

.....

.....

8. I, the abovementioned applicant, submit herewith a licence application fee of K .....

Date ....

Signature of applicant

9. FOR OFFICE USE ONLY—

(*a*) Licence application fee of K .....

(*b*) Remarks .....

(*c*) Date of inspection of premises.....

(*d*) Date of approval of application.....

(*e*) Licence number .....

(*f*) Receipt number of application .....

Date ....

Director General

Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2. Application fee is not refundable.]

Form No. 8

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(NO. 19 OF 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR LICENCING OF NEW PREMISES WHERE WHOLESALE PHARMACY BUSINESS IS TO BE CARRIED ON

(*Section 41*)

To: The Director General

Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

1. Name of business.....

2. Name of applicant.....

3. Postal address.....

4. Email address..... Telephone number .....

5. Previous location of the wholesale pharmacy.....

.....

6. Location of premises on which wholesale pharmacy business is re-located (city/town, street, plot no.) (include a sketch map)

.....

.....

7. Where the applicant is a company—

(*a*) state the registration number of company under the Act:.....

(*b*) state the name and registration number of the person under whose personal management and control affairs of the company would be subject to

.....

.....

(*c*) attach a copy of certificate of incorporation of the company

.....

.....

8. Name and registration number of supervising pharmacist having control of the premises referred to in paragraph 6.....

.....

.....

9. I, the abovementioned applicant, submit herewith an application fee of K .....

Date ....

Signature of applicant

10. FOR OFFICE USE ONLY—

(*a*) Application fee of K .....

(*b*) Remarks .....

(*c*) Date of inspection of premises.....

(*d*) Date of approval of application.....

(*e*) Licence number .....

(*f*) Receipt number of application .....

Date ....

Director General
Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2. The Application fee is not refundable.]

Form No. 9

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(NO. 9 OF 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR LICENCING OF MEDICINE DEVICE WHOLESALER

(*Section 41*)

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
LILONGWE 3

A. Business details

Name of business/company		
Name of applicant		
Postal address		
Physical address (Attach sketch map)		
Contact person		
Telephone number		
Email address		
Name and registration number of person in the pharmacy, nursing or medical field under whose personal management and control affairs of the business/company would be subject.		
Malawi Revenue Authority TPIN (for new business)		
Tax Clearance Certificate No. (for business registered with Malawi Revenue Authority for more than one year)		
Names of public facilities the business/company has supplied medical devices to		

B. Categories of medical supplies

No.	*Description of Category*	*Sources(s) and or Manufacturer(s) and Country of Origin*
1	Reagents	
2	Surgicals e.g. sutures, canulae, catheters, blades etc	
3	Gloves	
4	Dressing materials e.g. bandages	
5	X-ray films and other radiography materials	
6	Dental materials	
7	Syringes	
8	Blankets, linen and mattresses	
9	Medical equipment	
10	General category of consumables e.g. pill bags, aprons,	disposable containers,
11	Others	

C. Competencies and capacity

No	*Description*	*Applicant to fill in the space provided below*
1	Competencies: (i) provide the number, qualifications of employees; and (ii) Is there any employee with experience in handling health products?	
2	Capacity: (i) describe the storage facilities including ventilation, size, and security; and (ii) describe installation, and maintenance arrangements for medical equipment.	

D. General instructions

1. A medical device wholesaler shall provide details of the sources or manufacturers of medical supplies to be stocked.
2. A medical device wholesaler shall have premises which shall be inspected.
3. A medical device wholesaler shall declare "Manufacturer not known" if at this stage the manufacturer(s) is indeed not known.
4. A medical device wholesaler shall be required to have manufacturers' authorizations from their sources when goods are in stock or being supplied.
5. A medical device wholesaler should have a physical location where goods will be kept. The goods in storage shall require supporting transaction documents such as invoices, sales register, receipts, order or import documents etc that will be verified by the Pharmacy and Medicines Regulatory Authority upon demand at any time.
6. A medical device wholesaler should declare the category or categories of medical supplies intended for supply that will be matched with competency levels and capacity declared.

I, the abovementioned applicant, submit herewith a licence application fee of K.....

Date .....

.....
Signature of applicant

FOR OFFICE USE ONLY—

(*a*) Licence application fee of K .....

(*b*) Remarks .....

(*c*) Date of inspection of pre mises.....

(*d*) Date of approval of application.....

(*e*) Licence number .....

(*f*) Receipt number of application .....

Date ....

Director General
Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2. Application fee is not refundable.]

Form No. 10

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(NO. 9 OF 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR LICENCING OF PREMISES WHERE DISPENSING BUSINESS IS TO BE CARRIED ON

(*Section 52*)

To: The Director General

Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

1. Name of clinic/ hospital.....

2. Registration status (attach copy of registration certificate of the clinic/hospital)

.....

3. Postal address.....

4. Email address: ..... Telephone number:.....

5. Location of premises on which a medicine store business is to be carried out (city/town, street, plot no.) (include a sketch map) .....

.....

6. Name and registration number of the clinician (attach copy of valid registration certificate) .....

.....

7. Name, qualifications, experience and registration status of dispenser (attach copy of valid registration certificate).....

8. I, the abovementioned applicant, submit herewith a licence application fee of K.....

Date ....

Signature of applicant

9. FOR OFFICE USE ONLY—

(*a*) Licence application fee of K.....

(*b*) Date of inspection: .....

(*c*) Remarks:.....

(*d*) Receipt number of licence fees: .....

(*e*) Date of approval.....

(*f*) Licence number.....

Date ....

Director General
Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2 Application fee is not refundable.]

Form No. 11

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(NO. 9 OF 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR LICENCING OF NEW PREMISES WHERE DISPENSING BUSINESS IS TO BE CARRIED ON

(*Section 52*)

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

1. Name of clinic/ hospital.....

2. Registration status (attach copy of registration certificate of the clinic/hospital)

.....

3. Postal address.....

4. Email address: ..... Telephone number:.....

5. Previous location of the premises.....

6. Location of premises on which a medicine store business is to be carried out (city/town, street, plot no.) (include a sketch map) .....

.....

7. Name and registration number of the clinician (attach copy of valid registration certificate).....

.....

8. Name, qualifications, experience and registration status of dispenser (attach copy of valid registration certificate).....

9. I, the abovementioned applicant, submit herewith an application fee of K.....

Date ....

Signature of applicant

10. FOR OFFICE USE ONLY—

(*a*) Application fee of K.....

(*b*) Date of inspection: .....

(*c*) Remarks:.....

(*d*) Receipt number of licencing fees: .....

(*e*) Date of approval.....

(*f*) Licence number.....

Date ....

Director General
Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2 Application fee is not refundable.]

Form No. 12

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(No. 9 of 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR LICENCING OF PREMISES WHERE VETERINARY SHOP BUSINESS IS TO BE CARRIED ON

(*Section 53*)

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

1. Name of applicant.....

2. Postal address.....

3. Email address: ..... Telephone number:.....

4. Location of premises on which the veterinary shop business is to be carried out (city/town, street, plot no.) (include a sketch map) .....

.....

5. Name and registration number of the veterinary personnel having control of the premises referred to in paragraph 4 (attach copy of valid registration certificate) .....

.....

6. I, the abovementioned applicant, submit herewith a licence application fee of K.....

Date ....

Signature of applicant

7. FOR OFFICE USE ONLY—

(*a*) Licence application fee of K.....

(*b*) Date of inspection: .....

(*c*) Remarks:.....

(*d*) Receipt number of licence fees: .....

(*e*) Date of approval.....

(*f*) Licence number.....

Date ....

Director General
Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2. Application fee is not refundable.]

Form No. 13

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(No. 9 of 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR LICENCING OF NEW PREMISES WHERE VETERINARY SHOP BUSINESS IS TO BE CARRIED ON

(*Section 53*)

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

1. Name of applicant.....

2. Postal address.....

3. Email address ..... Telephone number.....

4. Previous location of the wholesale pharmacy.....

.....

5. Location of premises on which the veterinary shop business is to be carried out (city/town, street, plot no.) (include a sketch map) .....

.....

6. Name and registration number of the veterinary personnel having control of the premises referred to in paragraph 5 (attach copy of valid registration certificate)

.....

.....

7. I, the abovementioned applicant, submit herewith an application fee of K.....

Date ....

Signature of applicant

8. FOR OFFICE USE ONLY—

(*a*) Application fee of K.....

(*b*) Date of inspection: .....

(*c*) Remarks:.....

(*d*) Receipt number of licence fees: .....

(*e*) Date of approval.....

(*f*) Licence number.....

Date ....

Director General
Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2 Application fee is not refundable.]

Form No. 14

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(NO. 9 OF 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR LICENCING OF PREMISES WHERE A MEDICINE STORE BUSINESS IS TO BE CARRIED ON

(*Section 41*)

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

1. Name of applicant.....

2. Email address..... Telephone number.....

3. Postal address.....

4. Location of premises on which a medicine store business is to be carried out (city/town, street, plot no.) (include a sketch map).....

5. Where the applicant is a company—

   (*a*) state the registration number of company under the Act: .....

   (*b*) state the name and registration number of the person under whose personal management and control affairs of the company would be subject to

   .....

   .....

   (*c*) attach a copy of the certificate of incorporation of the company

   .....

   .....

6. Name and registration number of a full-time pharmacy personnel having control of the premises referred to in paragraph 4

   .....

   .....

7. I, the abovementioned applicant, submit herewith licencing application fee of K.....

   Date ....
   Signature of applicant

8. FOR OFFICE USE ONLY—

   (*a*) Licence application fee of K .....

   (*b*) Remarks .....

   (*c*) Date of inspection of premises.....

   (*d*) Date of approval of application.....

   (*e*) Licence number .....

   (*f*) Receipt number of application .....

   Date ....
   Director General
   Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2. Application fee is not refundable.]

Form No. 15

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(NO. 9 OF 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR LICENCING OF NEW PREMISES WHERE A MEDICINE STORE BUSINESS IS TO BE CARRIED ON

(*Section 41*)

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

1. Name of applicant.....

2. Email address.....Telephone number.....

3. Previous location of medicine store.....

4. Postal address.....

5. Location of premises on which a medicine store business is to be carried out (city/town, street, plot no.) (include a sketch map).....

6. Where the applicant is a company—

   (*a*) state the registration number of company under the Act: .....

   (*b*) state the name and registration number of the person under whose personal management and control affairs of the company would be subject to

   .....

   .....

   (*c*) attach a copy of the certificate of incorporation of the company

   .....

   .....

7. Name and registration number of a full-time pharmacy personnel having control of the premises referred to in paragraph 5.....

   .....

8. I, the abovementioned applicant, submit herewith an application fee of K.....

   Date ....

   Signature of applicant

9. FOR OFFICE USE ONLY—

(*a*) Application fee of K .....

(*b*) Remarks .....

(*c*) Date of inspection of premises.....

(*d*) Date of approval of application.....

(*e*) Licence number .....

(*f*) Receipt number of application .....

Date ....

Director General
Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2 Application fee is not refundable.]

Form No. 16

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(No. 9 of 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR LICENCING OF PREMISES WHERE CURRENT GOOD MANUFACTURING PRACTICE INSPECTION BUSINESS IS TO BE CARRIED ON

(*Section 41*)

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

1. Particulars of applicant—

(*a*) Name of applicant.....

(*b*) Physical address.....

(*c*) Country.....

(*d*) Phone number.....Telefax.....

Email address.....

2. Particulars of site to be inspected—

(*a*) Name of site.....

(*b*) Physical address.....

(*c*) Country.....

(*d*) Telephone number.....Telefax.....

Email address.....

(*Separate application to be filled in for each individual site.)

3. Contact person on site—

(*a*) Name of contact person.....

(*b*) Telephone number.....Telefax.....

Email address.....

4. Authorised Representative/Agent in Malawi—

(*a*) Name of Local Technical Representative.....

(*b*) Telephone number.....Telefax.....

E-mail address.....

5. Type of Drugs Manufactured — (Tick where applicable)

(*a*) human only (*b*) veterinary only (*c*) human and veterinary

6. Inspection Type— (*Please tick where applicable*)

first inspection

routine re- inspection (Previous inspection date_____)

re – inspection after failure

other (please specify).....

7. Lines to be inspected

Dosage form	*Tick where applicable*	**Category*	**activities*
(*a*) Tablets			
(*b*) Capsules			
(*c*) Injections (SVP)			
(*d*) Injections (LVP)			
(*e*) Oral liquids			
(*f*) Creams/Ointments/lotions			
(*g*) Others (specify)			

[*1. Category means any of the following: Beta lactam, Non-beta lactam, Biologicals, Vaccines, Hormones, Cytotoxic products.

2. Activity means any steps in manufacturing that are conducted at this site, e.g complete manufacture of dosage form, primary or secondary packaging, Quality control, warehousing e.t.c.]

8. Registration of Products—

(*a*) Have you submitted dossier for registration? Yes No

(*b*) If Yes, list the products applicable. (Attach a separate sheet)

.....

9. Site Master File

Please attach copy of the Site Master File (not more than 25 pages).

Enclosed - Yes No

I hereby certify that the above information is correct and apply for Good Manufacturing Practice inspection of the above-named site.

Date ....

Signature of applicant

FOR OFFICE USE ONLY—

(*a*) Date of inspection.....

(*b*) Remarks.....

(*c*) Receipt of cGMP fees.....

(*d*) Date of approval.....

(*e*) Licence number.....

Date ....

Director General
Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2 Application fee is not refundable.]

Form No. 17

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(NO. 9 OF 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR LICENCING OF PREMISES WHERE PHARMACEUTICAL MANUFACTURING BUSINESS IS TO BE CARRIED ON

(*Section 57*)

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

1. Name of business.....

2. Name of applicant.....

3. Postal address.....

4. Email address..... Phone number .....

5. Location of premises on which wholesale pharmacy business is re-located (city/town, street, plot no.) (include a sketch map)

.....

.....

6. Where the applicant is a company—

(*a*) state the registration number of company under the Act.....

(*b*) state the name and registration number of the person under whose personal management and control affairs of the company would be subject to

.....

.....

(*c*) attach a copy of certificate of incorporation of the company

.....

.....

7. Name and registration number of supervising pharmacist having control of the premises referred to in paragraph 5

.....

.....

8. Competent technical staff—

(*a*) Production pharmacist.....

(*b*) Quality control analyst.....

9. I, the abovementioned applicant, submit herewith an licencing application fee of K.....

Date ....

Signature of applicant

10. FOR OFFICE USE ONLY—

(*a*) Licence application fee of K.....

(*b*) Remarks .....

(*c*) Date of inspection of premises.....

(*d*) Date of approval of application.....

(*e*) Registration number .....

(*f*) Receipt number of application .....

Date ....

Director General
Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2 Application fee is not refundable.]

Form No. 18

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(NO. 9 OF 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR LICENCING OF NEW PREMISES WHERE PHARMACEUTICAL MANUFACTURING BUSINESS IS TO BE CARRIED ON

(*Section 57*)

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

1. Name of business.....

2. Name of applicant.....

3. Postal address.....

4. Email address..... Phone number .....

5. Previous location of the manufacturer.....

6. Location of premises on which wholesale pharmacy business is re-located (city/town, street, plot no.) (include a sketch map)

.....

.....

7. Where the applicant is a company—

(*a*) state the registration number of company under the Act.....

(*b*) state the name and registration number of the person under whose personal management and control affairs of the company would be subject to

.....

.....

(*c*) attach a copy of certificate of incorporation of the company

.....

.....

8. Name and registration number of supervising pharmacist having control of the premises referred to in paragraph 6.....

.....

.....

9. Competent technical staff—

(*a*) Production pharmacist.....

(*b*) Quality control analyst.....

10. I, the abovementioned applicant, submit herewith an application fee of K .....

Date ....

Signature of applicant

11. FOR OFFICE USE ONLY—

(*a*) Application fee of K .....

(*b*) Remarks .....

(*c*) Date of inspection of premises.....

(*d*) Date of approval of application.....

(*e*) Registration number .....

(*f*) Receipt number of application .....

Date ....

Director General
Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2 Application fee is not refundable.]

Form No. 19

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT
(NO. 9 OF 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

CERTIFICATE OF LICENCING OF PREMISES WHERE A *RETAIL PHARMACY OR WHOLESALE PHARMACY BUSINESS OR MEDICINE STORE OR DISPENSING OR VETERINARY OR PHARMACEUTICAL MANUFACTURING BUSINESS IS TO BE CARRIED ON

(*Sections 42, 52, 53 and 57*)

Registration number ..... Certificate number .....

This is to certify that the premises situated at.....
(*state location of premises, namely town, street and plot no.*)

where ..... is authorized to carry out a
(Name of business owner)

*retail pharmacy business or wholesale pharmacy business or dispensing facility or veterinary shop business or medicine store or pharmaceutical manufacturer, on this ..... day of ....., 20 ..... registered on the register of premises where the business is to be carried on, kept and maintained by the Pharmacy and Medicines Regulatory Authority in accordance with the provisions of the Pharmacy and Medicines Regulatory Authority Act and the Regulations made thereunder.

Date .....

....
Director General *Chairperson*

Common Seal

(**Delete whichever is not applicable*)

Form No. 20

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(No. 9 of 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

REGISTER OF PHARMACY PRACTICE PREMISES

(Section 54)

Location of registered premises			*Date of registration*	*Registration*	*Name, registration and certificate number of registration pharmacist in control of business*	*Remarks, if any*
Town	Street	Plot No.				

Form No. 21

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(No. 9 of 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR AUTHORIZATION FOR THE MARKETING, ADVERTISING OF MEDICINES OR ALLIED SUBSTANCES

(*Section 62*)

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

1. Particulars of applicant—

(*a*) Name of applicant .....

(*b*) Physical address/location.....

(*c*) Postal address.....

(*d*) Email address.....

2. Description of Advertisement—

(*a*) Type of activity for which application is made

.....

(*b*) Type of material (s) to be used (Attach two samples)

.....

(*c*) Medicine or allied substance name.....

(*d*) Language of the publication or advert.....

(*e*) Intended target group.....

Date ....

Signature of applicant

3. FOR OFFICIAL USE ONLY—

(*a*) Application fee of K.....

(*b*) Receipt number.....

(*c*) Date of approval of application.....

(*d*) Authority's entry Number.....

(*e*) Application and samples received.....

Date ....

Director General
Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2 Application fee is not refundable.]

Form No. 22

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(No. 9 of 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR AUTHORIZATION FOR DISPOSAL OF UNFIT PRODUCTS

(*Sections 69 and 129*)

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O. Box 30241
Lilongwe 3

1. I/We.....

of .....
(*postal address*)

undertaking the business of ..... hereby apply for disposal of unfit .....
(*type of products*)

2. Location of business (include a sketch map) .....

3. Name of supervising pharmacist of the premises.....

4. Registration number (if applicable).....

5. Reason for disposal.....

.....

6. Estimated value of unfit products, K.....

7. Attached herewith is the list of products to be disposed of (Attach Health Products Disposal Log)

.....

8. Declaration:

I certify that the information provided in the application form is true and correct.

Date ....
Signature of applicant

9. FOR OFFICE USE ONLY—

(*a*) Application fee of K .....

(*b*) Remarks .....

(*c*) Date of inspection of premises.....

(*d*) Date of approval of application.....

(*e*) Receipt number of application .....

Date ....

Director General
Pharmacy and Medicines Regulatory Authority

[*1. Fee is payable only by cash or cheque.

2 Application fees are not refundable.]

Form No. 23

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(No. 9 of 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

APPLICATION FOR PRODUCT LICENCE (SUMMARY SHEET)

(*Sections 62(1)*)

A. Product Identification

1. PMRA Ref No. (*for office use only*)	2. Proprietary name	3. Non-proprietary name (INN)
4.Dosage form and colour	5. Strength	6. Route of administration
7. Suggested Price (Optional)		

B. Applicant details

1. Name of applicant			
2. Address of Applicant (including contact person)		3. City/town	4. County
5. Telephone No.	6. Fax No.	7. Telex	8. Email address

C. Manufacturer details

1. Name of manufacturer		2. Address	
3. City/town	4. Country	9. Manufacturing Licence No. (attach copies of certificates)	10. Licence date
5. Telephone No.	6. Fax No.	11. Name and address of licensing authority	
7. Telex No.	8. Email address	12. Date of Last GMP inspection. Attach copies of certificates issued by both local NRA and PMRA	

D. Product details

1. Therapeutic category	2. Main indication(s)
3. Dosage details and method of use	4. Stability data (on three consecutive production batches. Provide detailed studies and results (attach validation reports for analytical tests methods used). The stability studies should be conducted in line with Zone IVA or IVB for products meant for storage under prevailing environmental conditions.)
5. Shelf life	6. Storage conditions (supported by the stability data)

7. Complete quantitative formula (per dose form)

(*a*) Substance	(*b*) Function	(*c*) Amount	(*d*) QC specifications
(i)			
(ii)			

(a) Substance	*(b) Function*	*(c) Amount*	*(d) QC specifications*
(iii)			
(iv)			
(v)			
(vi)			
(vii)			
(viii)			
		8. Total weight or volume of dose form	

1. Therapeutic category	2. Main indication(s)
3. Dosage details and method of use	4. Stability data (on first three batches)
5. Shelf life	6. Storage conditions.

E. Active ingredient details

9. Active ingredients

(a) Active ingredient name	*(b) Source of active ingredient*	*(c)Standard e.g. USP, BPcontrols*	*(d) In- process (optional)*
(i)			
(ii)			
(iii)			
(iv)			

F. Chemistry, Manufacturing and Control of Active Pharmaceutical Ingredient

Active pharmaceutical ingredient	*Detailed validated method of synthesis of active pharmaceutical ingredient*	*In process controls for critical quality attributes including particle size distribution: (d10, d50, d90), polymorphism and isomerism*	*Solubility at pH 1.2, 4.5 or 6.8*

G. Manufacturing and Quality Control information

1. Method of manufacture of dosage form (attach flow diagrams and validation reports for manufacturing processes)

2. In process control details (sampling stages and validated test methods used, attach validation reports for analytical tests used)

3. Quality control specifications of the final product (attach as annex)

4. Details of the validated method of analysis for the final product (attach analytical validation reports)

5. Batch No.	6. Date of Manufacture	7. Expiry date

8. Executed and Blank Batch Manufacturing Records. Results of batch testing (Certificate of Analysis including that for biobatch or batch used for dissolution profile). Validation reports for analytical tests should be provided as an annex.

9. Certificate of Pharmaceutical Product in line with WHO format

10. Free Sale Certificate

H. Bio-equivalence Data

Detailed study of comparative bioavailability, with pharmacokinetics data; include study protocols, results and conclusions of study demonstrating bio-equivalence for BCS class II and IV active pharmaceutical ingredients. Attach copies of ethical approval, curriculum vitae of PI, certificate of accreditation of Contract Clinical Research Organization, reports of validated analytical test methods used for QC analysis of pharmacokinetic data. Submit comparative dissolution data for BSC class I and III active pharmaceutical ingredients.

I. Container information

(*a*) Size of container (number of unit doses)	(*b*) Description of container closure system including nature of materials and art work.
(i)	
(ii)	
(iii)	

J. Distribution and Promotional information

1. What is the intended scheduling status of the product? (tick appropriate box)

(a) CD Controlled drug	*(b) POM Prescription only medicine*	*(c) PIM Pharmacist initiated medicine*	*(d) P Pharmacy only medicine*	*(e) GSL General Sales List medicine*	*(f) Veterinary use only medicine*

2. How is it proposed to promote the medicinal product? (tick appropriate box)
   (*a*) to the medical and pharmacy professions only
   (*b*) to the general public by point of sale displays in pharmacies
   (*c*) to the general public
   (*d*) other (please specify)

K. Current Regulatory status of product in other countries (attach relevant supporting documents)

(*a*) Country	(*b*) Product Licence Number.	(*c*) Date of First Registration
(i)		
(ii)		
(iii)		
(iv)		
(v)		

L. Date and Signature of authorised person (s)

(*a*) Date of application	(*b*) Signature of Authorized person e.g. Pharmacist
(*c*) Applicant's official seal	

M. Registration Information (for office use only)

(*a*) Application fee	(*b*) Application fee receipt number.	(*c*) Registration fee	(*d*) Registration fee receipt number.
(*e*) Registration date	(*f*) Registration expiry date	(*g*) Registration number	

(*h*) Full name and signature

Director General
Pharmacy and Medicines Regulatory Authority

Form No. 24

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(NO. 9 OF 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

PRODUCT LICENCE

(*Section 62(8)*)

Product Licence Number ..... issued at .....
under section 62 of the Pharmacy and Medicines Regulatory Authority Act to

.....

(*name of person or firm to whom licence is issued*)

of .....

(*state city, street, plot number and postal address*)

who is hereby licensed to engage in any or all of the business activities outlined under section 41 of, and subject to, the Act in regard to the following medicinal product(s) in accordance with the special conditions specified hereunder—

(*a*) Medicinal product identity—

(i) name .....

(ii) generic form .....

(iii) dosage form .....

(iv) strength .....

(v) manufacturing .....

(vi) manufacturing country .....

(*b*) Year and therapeutic category of the medicinal product

(*c*) Scheduling status

(*d*) Declaration of content—

(i) active ingredient .....

(ii) content per unit dose .....

(*e*) Package—

(i) type of package .....

(ii) size of package .....

(iii) initial retail price per package .....

Further conditions of this Product Licence are—

Valid until ....., 20 .....

Date .....

....

Director General *Chairperson*

Common Seal

Form No. 25

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(No. 9 of 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (FEES AND FORMS) REGULATIONS

REGISTER OF PRODUCT LICENCES

(section 71)

Product licence		*Description of medical products to which licence relates*	*Name and address of licence holder*
No.	Date issued		

Made this 8th day of April, 2022.

K. K. CHIPONDA
Minister of Health

(FILE NO. HTSS-PHARM/1)

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