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MEDICINES CONTROL AUTHORITY

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]

APPLICATION FOR ISSUE OF A LICENCE FOR PREMISES

(To be submitted in triplicate)

(Pharmacy, dispensing medical practitioner, veterinary surgeon, manufacturer, clinic, other)*

Part A *(To be completed by all applicants)*

1. Particulars of proposed licensee

If an individual: Full names .....

Date and place of birth .....

Qualifications .....

Number of Registration with the Health Professions Authority* or the Council of Veterinary Surgeons*

Address (Home) .....

If a company: Name of company .....

Physical address .....

Registered Office .....

State shareholders or distribution of shares or nominees .....

Particulars of Directors:

Full Names	**Physical Address**	**Citizenship**
……	……	……
……	……	……
……	……	……

If any director is registered with the Health Professions Authority* or the Council of Veterinary Surgeons* state the registration number

……

Position of applicant in the company .....

2.Name under which business is conducted .....

Address .....

……

3. Physical address of premises to be licensed .....

4. Postal address of business .....

5. Telephone number .....

6. Purposes for which premises to be licensed (e.g. manufacture of medicines, dispensing, packing, etc.)……..

……

7. Have you previously held a licence to manufacture, pack or sell medicines? YES/NO*

If YES give details ……..

8. Has any application made by you for a licence been refused or cancelled? YES/NO*

If YES give details ……

9. Name and address of nearest police station ……

10. Name and approximate distance of nearest pharmacy from premises to be license……

……

11. Particulars and date of any trading or other licence held by the applicant or business……..

12. State the name of the person under whose personal supervision the premises will be for the purposes of section 34(1)(b) of the Act and the registration number of that person with the Health Professions Authority* or the Council of Veterinary Surgeons* and the practising certificate number thereof.

Name	**Numbers**
…….	……..
…….	……..

13. If an individual
    (a) Are you a citizen of, or ordinarily resident in Zimbabwe? YES/NO*
    If YES supply proof thereof.
    If NO, have you been exempted by the Minister in terms of the proviso to paragraph (a) of subsectio n (2) of section 59 of the Act? YES/NO* If YES supply proof thereof.
    (b) Have you within the preceding three years of this application been convicted inside or outside Zimbabwe of an offence involving the wrongful dealing in or supply or possession of medicines, or of an offence involving dishonesty? YES/No*

    If YES state details ……

14. If a company
    (a) Are the directors of the company or a majority thereof citizens or ordinarily resident in Zimbabwe?

    ……
    If YES supply proof thereof.
    If NO. has the company been exempted by the Minister in terms of the proviso to p aragraph (a) of subsection (1) of section 38 of the Act? YES/NO*
    If YES supply proof thereof.
    (b) Has the company or any of the directors to the company within the preceding three years of this application been convicted inside or outside Zimbabwe of an offence involving the wrongful dealing in or supply or possession of medicines, or of an offence involving dishonesy?.YES/NO* If YES supply proof thereof.

    If YES state details ……

Date …… ……
Signature of applicant

** Delete inapplicable*

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NOTE: 1. Plans of the premises in accordance with the Fourth Schedule, the appropriate fee, proof of citizenship, residency or an exemption by the Minister etc., are required to be attached to the application. Copies of original documents must be properly certified.

If any plan, document or fee required to be attached is not attached, the application cannot be accepted.

2. A person who wishes to obtain a licence for pharmaceutical premises need only complete Part A.

3. If insufficient space is provided in the application, attach a sheet of paper with the additional information

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PartB

This part shall also be completed by persons applying for the issue of a licence for the manufacture of medicines and allied substances.

APPLICATION TO MANUFACTURE DRUGS AND ALLIED SUBSTANCES

I hereby make application for a licence to manufacture the medicines* and allied substances* listed below (attach extra li st if insufficient space provided here).

Indicate by reference to one of the following paragraphs which of the following classes the medicines and allied substances* come within:

(a) antibiotics, or preparations of antibiotics;

(b) vaccines and sera;

(c) sterile preparations;

(d) hormones and steroid preparations;

(e) vitamin preparations;

(f) antineoplastic agents and immunosupressant agents other than steroid preparations;

(g) narcotic medicines;

(h) psychotropic substances;

(i) genetic engineering;

(j) other medicines not included in paragraphs (a) to (i), above;

(k) allied substances (specify type of substance).

Appropriate designation	**Trade mark of drug or allied substance**	**Class**
……..	……	……
……..	……	…….
……..	……	…….
……..	……	…….

Premises where manufacture (including packing and labelling) of the drugs and allied substances* will be carried **out:**

……..

I enclose the fee of…….

Date…… …….

Signature of applicant

**Delete the inapplicable*

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Part C

This part should also be completed by persons applying for the issue of a licence to pack medicines and allied substances.

APPLICATION TO PACK MEDICINES AND ALLIED SUBSTANCES

I hereby make application for a licence to pack the medicines* and allied substances* listed below (attach extra list if insufficient space provided here).

Indicate in the third column the category for distribution as per the Fifth Schedule.

Appropriate designation	**Trade mark of medicine or allied substance**	**Category for distribution**
……	……	……
……	……	……
……	……	……
……	……	……
……	……	……

Premises where packing and labelling will be carried out ……

……

I enclose the fee of ……

Date …… ……..

Signature of applicant

**Delete the inapplicable*