Medicines Control Authority of Zimbabwe

DRAFT GUIDELINES ON THE PRODUCTION OF CANNABIS FOR MEDICINAL AND SCIENTIFIC USE

1.0 INTRODUCTION

1.1. PREAMBLE

The Medicines Control Authority of Zimbabwe (MCAZ) is a regulatory body established by the Medicines and Allied Substances Control Act (MASCA) [*Chapter 15:03*] and its Regulations, S.I 150 of 1991. The Authority`s mandate is set out in this Act and its accompanying regulations. It is also responsible for administering the Dangerous Drugs Act (Chapter 15:02) and its regulations, Dangerous Drugs Regulations (RGN 1111 of 1975) on behalf of the Ministry of Health and Child Care.

The Dangerous Drugs Act [Chapter 15:02] is an Act that provides for the control of the importation, exportation, production, possession, sale, distribution and use of dangerous drugs; and to provide for matters incidental thereto. In terms of Section 6 of the Dangerous Drugs Act [Chapter 15:02], the Minister of Health and Child Care published the Dangerous Drugs (Production of Cannabis for Medicinal and Scientific Use) Regulations, 2018 [*S.I 62 of 2018*]

These guidelines have been prepared with particular reference to the Dangerous Drugs (Production of Cannabis for Medicinal and Scientific Use) Regulations, 2018 [*S.I 62 of 2018*]

These guidelines seek to explain the processes involved in applying for licences and the conditions for production of cannabis for medical and scientific use.

1.2. DEFINITIONS

1.2.1 **"Act"** refers to the Dangerous Drugs Act [*Chapter 15:02*];

1.2.2 **"Authority"** as defined by the Act refers to the Medicines Control Authority of Zimbabwe;

1.2.3 **"cannabis"** includes fresh or dried cannabis, cannabis oil, cannabis plants or cannabis seeds;

1.2.4 **"Director-General"** means the Director-General of the Authority appointed in terms of section twenty-six of the Act;

1.2.5 "**licensed producer**" means the holder of a licence issued by the Minister of Health for production of cannabis

1.2.6 **"Minister"** means the Minister of Health and Child Care

1.2.7 ***"production"*** means cultivation, drying, extraction, packaging, labelling, storage, and processing of cannabis;

1.2.8 **"Regulations"** refers to the Dangerous Drugs (Production of Cannabis for Medicinal and Scientific Use) Regulations, 2018 [S.I 62 of 2018]

1.2.9 **"Secretary"** means the Secretary for Health in the Ministry of Health and Child Care

1.2.10 **"should** and **shall"** are used interchangeably to define a condition that has to be satisfied

1.2.11 **"site"** means —

(a) a building or a place in a building used by a licensed producer; or

(b) an area occupied exclusively by buildings used by a licensed producer

1.2.12 **"VAT"** refers to a Value Added Tax of 15%.

2.0 SCOPE

These guidelines are meant to outline the following:

2.1 Requirements for a complete application for a licence

2.2 Security requirements

2.3 Personnel

2.4 Conditions for production

2.5 Import and Export

2.6 Record Keeping

2.7 Advertisement

2.8 Inspections

3.0 APPLICATION FOR A PRODUCERS` LICENCE

3.1. Application for a producers` licence may be done by:

3.1.1 A company duly registered by the Registrar of Companies, with the majority of the directors with proof of citizenship or being ordinarily resident in Zimbabwe or with proof of exemption by the Minister;

3.1.2 An individual with proof of citizenship or residence in Zimbabwe or proof of exemption by the Minister.

3.2. Issue of a producers` licence

3.2.1 Application forms and accompanying documents are submitted to the Authority at No. 106 Baines Avenue, Harare.

3.2.2 An application for a producers` licence shall be made in the Form DDPC1 and should be accompanied by:

3.2.2.1 Three copies of a site plan (where the cannabis will be grown) proposed to be licensed.

3.2.2.2 Proof of citizenship or residence for the individual or company directors (if company)

3.2.2.3 Memorandum and Articles of Association and CR 14 (for a company)

3.2.2.4 Appropriate fee

3.2.2.5 Completed security clearance forms accompanied by the following:

i) Certified copy of National Identity Document

ii) The stated persons/ fingerprints taken by the Zimbabwe Republic Police

3.2.2.6 Proof of access to land i.e. title deeds, land permit or offer for A1 and A2. For those in communal areas, a stamped recommendation letter from producer`s local council or headman/chief is required. Stamped recommendation letter from Ministry of Agriculture.

3.2.3 Upon approval of the documentation submitted for the application, the proposed site shall be subjected to a pre-licence inspection by the Authority to verify compliance with the Regulations.

3.3 Amendments to Licences

3.3.1 Should the applicant, for justifiable cause, wish to amend their licence, the request shall be submitted to the Minister in writing. These should be submitted to the Authority at No. 106 Baines Avenue, Harare.

3.3.2 The request for amendment should be submitted together with the following:

(a) A description of the proposed amendment, including information or documents mentioned in section 3.2.2 that are relevant to the proposed amendment.

(b) If applicable, a declaration signed and dated by the authorised person in charge stating that the notices to local authorities have been provided and specifying the names, titles and addresses of the senior officials to whom they were addressed and the dates on which they were provided, together with a copy of each notice

(c) Copy of the original licence and

(d) Appropriate fee + 15% VAT

Note: An expired licence shall not be amended. If the applicant is unable to submit the original copy, they will be required to reapply for the issuance of another licence.

3.4 Validity of Licence

3.4.1 Upon successful application a licence shall be issued in terms of section 6 of the Dangerous Drugs (Production of Cannabis for Medicinal and Scientific Use) Regulations, 2018 [S.I 62 of 2018]

3.4.2 The licence shall be valid for a period of five (5) years from date of issue and may be renewed thereafter before its expiry.

3.4.3 A licence is valid if it has a stamp and signature of the Secretary of the Minister of Health and Child Care or designate.

4.0 REQUIREMENTS FOR SECURITY

A. SITE

4.1. Security measures

The licensed producer shall ensure that the following security measures are in place for the perimeter of the site and for the areas where cannabis is handled:

4.1.1 Perimeter of Site

(a) The licensed producer`s site shall be designed in a manner that prevents unauthorized access to the site.

(b) The perimeter of the site shall be visually monitored at all times by visual recording devices to detect any attempted or actual unauthorized access.

(c) The perimeter shall be secured by means of an intrusion detection system that operates at all times and allows detection of any attempted or actual unauthorized access to or movement in the site or tempering with the system

(d) The intrusion detection system shall be monitored at all times by personnel

4.1.2 Areas where cannabis is handled

(a) There should be restricted access to these areas. This shall be done through the following ways:

(i) Access to areas within the site where cannabis is present shall be restricted to persons whose presence in those areas is required by their work duties

(ii) The responsible person in charge or alternate responsible person in charge shall be physically present while other personnel are in those areas

(iii) A record shall be made of the identity of every person who would be entering and exiting those areas

(b) There shall be physical barriers provided that prevent unauthorised access within a site where cannabis is present.

(c) There shall be visually monitored at all times by visual recording devices to detect illicit conduct.

(d) There shall be an intrusion detection system that operates at all times and allows detection of any attempted or actual unauthorized access to or movement in the site or tempering with the system

(e) The areas where cannabis is present should be equipped with a system that filters air to prevent the escape of odours and if present, pollen.

(f) The intrusion detection system shall be monitored at all times by personnel

B. PERSONS

4.2 The security requirement for persons is security clearance. Security clearance should be provided for the following persons:

(a) the authorised person in charge

(b) the responsible person in charge;

(c) if applicable, the alternate responsible person in charge;

(d) if a producer`s licence is applied for by an individual, that individual and

(e) if a producer`s licence is applied for by a company, each officer and director of the company

** For all the workers, local police clearance should be obtained before recruitment.*

5.0 PERSONNEL

5.1 Authorised person in charge and responsible person in charge

A licensed producer shall designate:

5.1.1 One authorised person in charge. This person shall have the overall responsibility for the management of the activities conducted by the licensed producer under their licence at their site.

5.1.2 One responsible person in charge to work at the licensed producers' site. This person shall be responsible for

(a) supervising the activities pertaining to cannabis conducted by the licensed producer under the licence at that site;

(b) ensuring that the activities at that site comply with the Act and its regulations.

A licensed producer may designate one or more alternate responsible persons in charge to work at the licensed producer's site and can replace the responsible person in charge when that person is absent.

5.2 Quality assurance personnel

The licensed producer shall employ a quality assurance person who has the training, experience and technical knowledge relating to the activity conducted and the requirements for Quality assurance of the product. The personnel shall be responsible for:

(a) Assuring the quality of the fresh or dried cannabis, cannabis oil or cannabis plants or seeds before they are made available for sale, and

(b) Investigating every complaint received in respect of the quality of those substances and, if necessary, takes corrective and preventative measures.

(c) Approval of methods and procedures for production, packaging, labelling and storage prior to their implementation,

(d) Approval of very batch of the substances before it is made available for sell.

5.3 Change of personnel

5.3.1 The licensed producer shall;

(a) Apply for and obtain approval from the Minister before making any changes involving the replacement or addition of :

(i) the authorised person in charge

(ii) the responsible person in charge or the alternative responsible person in charge

(iii) if applicable, an officer or director of the company

(iv) An individual authorised to place an order for cannabis on behalf of the licensed producer

(b) Except in the case of change of the responsible person, the licensed producer shall notify the Minister, not later than five days after the person ceases to carry out their duties; and when a director of the company ceases to be a director.

(c) The licensed producer shall notify the Minister not later than the next business day if the responsible person in charge ceases to carry out their duties and there is no person designated as an alternate responsible person in charge.

5.3.2 The licensed producer with the application for approval of change of personnel shall submit the following information and documents with respect to the new person:

(a) in the case of the replacement of the senior person in charge or the responsible person in charge or the replacement or addition of an alternate responsible person in charge—

(i) they shall complete form DDPC1 and form DDPC2, and submit the relevant accompanying documents

(b) in the case of the replacement or addition of an officer or director, they shall complete form DDPC1 and DDPC2 and submit the relevant accompanying documents

6.0 GENERAL CONDITIONS OF PRODUCTION

6.1. The following conditions should be adhered to during production:

a) All handling of product including ordering, receiving, sampling, storage, labelling, processing, packaging and dispatch should be done in line with written procedures or instructions and should be recorded. The procedures shall be in accordance with the Good Agricultural Practices, Good Manufacturing Practices and Good Laboratory Practices.

b) Whenever there is a deviation from the instructions or procedures, authorization of the deviation should be approved in writing by a designated person, with the involvement of the QA personnel when appropriate.

c) Checks on yields and reconciliation of quantities of cannabis should be carried out as necessary to ensure that there are no discrepancies.

d) There should be appropriate labelling of materials during production. This should be done at all times to indicate the description of a product or material being processed, its strength (where applicable) and the batch number.

e) During packaging operations particular attention should be given to minimise the risk of contamination, mix ups or substitutions.

f) Equipment and instruments for measuring, weighing, analysis and recording should be serviced and calibrated at pre-specified intervals and records should be maintained.

g) To ensure satisfactory functioning, of instruments should be checked daily or prior to use for performing analytical tests. The date of calibration and servicing and the date when recalibration is due should be clearly indicated on a label attached to the instrument

h) There should be a Sanitation Program established by the licensed producer.

i) Personal hygiene procedures, including the wearing of protective clothing, should apply to all persons entering production areas.

j) The licensed producer should ensure training of all personnel is conducted in accordance with a written program.

k) There should be electrical supply, lighting, temperature, humidity and ventilation to ensure that the product is not adversely affect, directly or indirectly, during production, storage and transportation.

l) The site should be carefully maintained, and it should be ensured that repair and maintenance operations do not present any hazard to the quality of products

m) QC laboratories should be designed to suit the processes to be carried out in them. There should be sufficient space to avoid mix ups and contamination. Adequate storage space should be provided for samples, reference standards (if necessary, with cooling), solvents, reagents and records.

n) A recall and adverse reporting system should be available for reporting recalls and adverse drug reactions to fresh or dried cannabis or cannabis oil. This system should be in line with the Regulations.

o) There should be an effective transportation system for fresh or dried cannabis oil which ensures safekeeping of the package. The package containing cannabis to be transported, should be prepared in a manner that ensures that :

- The package is secure, cannot be opened without seal being broken.
- The cannabis odour does not escape.
- The contents of the package cannot be identified without being opened.

7.0 IMPORT AND EXPORT

A licensed producer who wishes to import or export cannabis shall submit:

i) Form DD4 to import cannabis or;

ii) Form DD5 to export cannabis which shall be accompanied by the original copy of the certificate from the country of importation officially approving the importation of that product.

iii) Appropriate fee plus 15% VAT.

The licensed producer is required to submit a notification of importation to the Authority within seven days of the import or export of any product imported or exported by him.

The application forms may be obtained from the Authority website or at the offices located at 106 Baines Avenue, Harare.

8.0 RECORD KEEPING

8.1 Type of records

The following records are required to be present on site:

i) Stock Records
ii) Visual Recording
iii) Batch reconciliation
iv) Import and Export records
v) Transportation Records
vi) Destruction Records
vii) Methods and Standard Operating Procedures
viii) Equipment maintenance records
ix) Analysis records
x) Legislation

The following should be available at the site:

(a) Medicines and Allied Substances Control Act [Chapter 15:03] as amended and up to date regulations made thereunder
(b) Dangerous Drugs Act [Chapter 15:02] as amended and up to date regulations made thereunder

8.2 Preservation of records

Every licensed producer shall keep or cause to be kept a record of such production for a period of five years and shall preserve such record on the premises in which the production takes place, provided that where the premises cease to be used or licensed such person shall make arrangements, acceptable to the Minister, for the preservation or destruction of such records.

9.0 INSPECTIONS

All licensed producers are subject to inspections by the Authority to verify compliance with the Regulations. The Authority can inspect the operations of a licensed producer at any reasonable time to confirm that the legislative and regulatory requirements are being met.

9.1 Inspection Types

There are four types of inspections that will be conducted to assess and monitor compliance with the Regulations.

i). Pre-licence inspection

- This inspection is conducted to assess whether the information submitted to the Authority in a licence application or amendment is accurate.

ii) Initial inspection

-.This is inspection is conducted when the processing begins, to assess whether the facilities, activities, and products are in compliance with the good production practices and record keeping requirements.

iii) Targeted/ Investigative inspection

-. This inspection is conducted to verify compliance with particular areas of the Regulations and in response to a regulatory complaint.

iv) Routine inspection

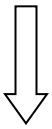
-. This inspection is conducted to monitor and verify compliance with all the requirements of the Regulations prior to licence renewal. These will be conducted every three years.

10. ADVERTISEMENTS

No person shall publish, distribute or in any other manner whatsoever bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any advertisement concerning cannabis without the authority of the Minister.

PROCESS FLOW

SUBMISSION OF APPLICATION DOCUMENTS + APPLICATION FEE



PRE- APPROVAL INSPECTION

APPLICATION + INSPECTION REPORTS SUBMISSION FOR CONSIDERATION BY CANNABIS TECHNICAL COMMITTEE

PAYMENT OF LICENCE ISSUANCE FEE

ISSUANCE OF LICENCE

***** The whole process from beginning to end should not take more than 6 months

* If a company submits incomplete application, it fails the documentation review process or the security clearance process, the application fee is forfeited and the applicant has to reapply.

*.A re-inspection would be conducted after payment of inspection fee when the applicant's initial inspection report is not satisfactory

ANNEXURE 1: APPLICATION FORMS

FORM DDPC1

DANGEROUS DRUGS ACT [*CHAPTER 15:02*]

APPLICATION FOR ISSUE OF A LICENCE FOR PRODUCTION OF CANNABIS

This form is submitted in terms of Section 5 (1) of the Dangerous Drugs (Production of Cannabis for Medicinal and Scientific Use) Regulations, 2017.

(*To be submitted in* duplicate)

PART A (*To be completed by individuals and sole traders*)

1. Full name…….

2. Date and place of birth……

3. Gender……..

4. Address (Home)……..

5. Email address……

6. Mobile phone number……..

7. Present place of employment……..

8. Position of applicant at place of employment (e.g. owner, manager, etc.)

PART B *(To be completed by companies)*

9. If a company: Name of company …….

(a) Physical address……..

(b) Registered Office…….

(c) Email Address……

(d) State shareholders or distribution of shares ……

10.PARTICULARS OF DIRECTORS:

(a) Full names……

(b) Address……

(c) Citizenship……..

(d) Date of Birth……

(e) Gender……

PART C (*To be completed by all applicants*)

11. Name under which business is conducted…….

12. Physical address of premises to be licensed……...

……

13. Postal address of business…….

……..

14. Telephone/Mobile number of proposedsite……

14A. Email address……

15.PARTICULARS OF AUTHORISED PERSON

(a) Full name…….

(b) Date and place of birth……

(c) Gender……..

16.PARTICULARS OF RESPONSIBLE PERSON

(a) Full name…….

(b) Date and place of birth……

(c) Gender ……..

17. State the proposed activities……

18. The substances in respect of which each activity is to be conducted……

19. State the building/s within the site where the proposed activities are to be conducted (*if applicable)*

……
……

20. Have you previously held a licence to produce cannabis? YES / NO*……

If YES, give details……

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

If YES, give details……..

22. Name and address of nearest police station……

23. Name and approximate distance of nearest residence from premises to be licensed……

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

25. If an individual:-

(*a*) are you a citizen of, or ordinarily resident in Zimbabwe? YES/NO*;

(b) if YES supply proof thereof;

(e) Have you within the preceding ten years of this application been convicted inside or outside Zimbabwe of an offence involving the wrongful dealing in or supply or possession of cannabis, or of an offence involving dishonesty? YES/NO* (Attach affidavit)

(f) If YES state details…….

26. If a company:-

(*a*) Are the directors of the company or a majority thereof citizens or ordinarily resident in Zimbabwe? YES/NO*.....

(b) If YES supply proof thereof;

(c) If NO supply proof of exemption by the Minister;

(d) Has the company or any of the directors of the company within the preceding ten years of this application been convicted inside or outside Zimbabwe of an offence involving the wrongful dealing in or supply or possession of cannabis, or of an offence involving dishonesty? YES/NO*****(Attach Affidavit)……

(e) If YES state details……

**Delete the inapplicable*

NOTE:

1. Plans of the premises, the appropriate fee, proof of citizenship, residency or an exemption by the Minister, etc, are required to be attached to the application.
2. Copies of original documents must be properly certified.
3. If any plan document or fee required to be attached is not attached, the application cannot be accepted.
4. If insufficient space is provided in the application, attach a sheet of paper with the additional information.

I enclose **the proof of payment of the** fee of
…….

I do hereby declare that the facts herein are fully within my knowledge and to the best of my knowledge are true and correct.

Signature of applicant …… Date……

…….
Name and position of person in the company

ANNEXURE II

Medicines Control Authority of Zimbabwe

SECURITY CLEARANCE APPLICATION FORM

1. Name: …….
2. Surname: ……
3. Date of birth: .....
4. Place of birth ……..
5. Gender: (*Tick appropriate box)* M ☐ F ☐
6. National I.D. number: …….
7. Height (in metres): ……..
8. Address (Home) ……..

   …….

   …….
9. Any other addresses of all locations resided during the ten years preceding the application:

   …….

   …….

   ……....

   ……
10. Activities conducted during the five years preceding the application:

    EMPLOYMENT DETAILS

    Name of employer: …….

    Address: ……..

    …….

    Name of employer: …….

    Address: ……..

    …….

    Name of employer: …….

    Address: ……..

    …….

…….

…….

EDUCATION DETAILS

Name of school: …….

Address: ……..

Certificate Attained ……

Name of school: …….

Address: ……..

Certificate Attained ……

Name of school: ……

Address: ……..

Certificate Attained …….

11. Full Names of spouse/s……...

…….

…….

…….

Comments (for any additional information)

……

……

…….

…….

…….

…….

ENDORSEMENT BY INTERPOL

……

……

……

NAME SIGNATURE DATE

N.B ***Please ensure that the application form is accompanied by the following***

(a) Certified copy of National Identity Documents

(b) Police Clearance from country of origin and any other country resided in the past 10years

(c) Fingerprints taken by the Zimbabwe Republic Police.

(d) Criminal Background check for the company

ANNEXURE III

Form DD4
For Official Use Only
Licence No……
File No……

DANGEROUS DRUGS ACT [CHAPTER 15:02]
APPLICATION FOR LICENCE TO IMPORT DANGEROUS DRUGS AND CORRESPONDING IMPORT CERTIFICATE
(Dangerous Drugs Regulations, 1975, section 44)

Attention is drawn to the instructions appearing overleaf.
Delay will be caused if these instructions are not followed, or if any of the questions below are not answered, or if the declaration is not signed. (see Instruction 7)

SEPARATE APPLICATIONS MUST BE SUBMITTED IN RESPECT OF EACH CONSIGNMENT TO BE IMPORTED

(a) Full name and address of importer (see Instruction 1)
……..……
……..……
……..
(b) Full name and address of Consignor in exporting country
……..……
……..
(c) The drugs are to be imported *by sea and/or rail via …….
by parcel post via ……
*by air freight via……..and will be imported through……Customs office (State port of entry)

*Delete the inapplicable words

(d) Approximate date of arrival
……..
(e) State the purpose for which the drugs are required (if vague reasons only are given, further inquiries may be necessary, see Instruction 5.)
……..
(f) Particulars of each item (see Instructions 6) to be imported.

Item No	Quantity	Full description of each item	Active principal content (in grammes)	Stocks on hand

I hereby declare that to the best of my knowledge and belief all the particulars in this application are correctly stated, and in particular that the drugs, if their importation is allowed, will not be used for any purpose other than that stated in paragraph (e)

Signed (see Instruction 7)……
Status……..
If on behalf of a company, state position in company……
Date ……..

N.B. This form must be signed in accordance with Instruction 7 and your attention is particularly drawn to section 19 (1)(c) of the Dangerous Drugs Act [Chapter 15:02]

ON REVERSE SIDE OF FORM
Instructions for completing this form
NON-COMPLIANCE WITH THESE INSTRUCTIONS WILL INVOLVE DELAY

Note : An Import Licence is an authority solely for the importation of a particular consignment, and must be produced to the Customs Officer at the time of importation.
An Importation Certificate is for transmission to the consignor in the exporting country, for submission to his Government in support of his application for authority to export the consignment. It is not authority for the admission of the consignment into Zimbabwe

1. Application will, in ordinary circumstances, be entertained only if made by a person or company resident in Zimbabwe. They must always be made by the actual importer and not by a forwarding agent. (i.e. shipping agent or other such person) on his behalf.
2. Import Licences under the Dangerous Drugs Act [Chapter 15:02], are required for all drugs to which the Act applies Copies of the Act and orders made thereunder may be obtained from the Publications Office, Department of Printing and Stationery, Cecil House, Jason Moyo Avenue, Harare, P O Box CY 341, Causeway, Harare Zimbabwe.
3. A separate licence is required in respect of each consignment
4. The application fee for an import licence is two hundred dollars ($ 200.00), and must be forwarded with the application. Cheques, postal orders and money orders must be made payable to the Secretary for Health and Child Welfare.
5. Paragraph (e) The applicants should state the exact use for which the importation is required. e.g. for medical, dental or veterinary use, or for the purpose of being sold or supplied to some other person in accordance with the provisions of the Act.

6. Paragraph (f The following should be carefully observed:
   (a) Not more than one item should appear on each line provided in this space. Preparations of the same drug should be grouped together. Where the details of the items exceed ten lines of typing, six copies of a schedule giving the requisite particulars should be furnished instead of including them in table.

   (b) Each item should be described fully. In the case of ampoules, the total quantity of drug and volume of liquid in each ampoule, and not the quantity intended to be administered, must be stated.
   (c) The official conversion factors must be used in determining the active principal content, the name of which must be stated.
7. Signature of form. The declaration on the front page must be signed by the actual importer, or in the case of a company, by a person authorized under the Act to procure drugs. In either case, the person signing must insert under “status” the class of authorized person to which he belongs.

All applications must be addressed to:-

The Secretary for Health and Child Welfare,
P O Box CY 1122
Causeway

ANNEXURE IV

Form DD5
For Official Use Only
Licence No…….
File No……

DANGEROUS DRUGS ACT [CHAPTER 15:02]
APPLICATION FOR EXPORT LICENCE OR MOVEMENT LICENCE
(Dangerous Drugs Regulations, 1975, section 44 and 46)

Attention is drawn to the Instructions appearing overleaf. It is requested that the form be filled in legibly, preferably typewritten

(a) Full name and address of supplier
……..……
……..……
……..
(b) State method by which drugs are to be exported:
Rail ……
Airfreight……
Road……
(c) State Port or Customs office through which the goods are to be exported
……..

(d) Full name and address of person to whom the drugs are to be supplied (as stated on Import Certificate, if any)
……..……
……..……
……..
(e) State whether the drugs are to be dispatched alone, or form part of a miscellaneous order.
……..……
……..
(f) Particulars of each item to be supplied (see Instruction 3)

Item No	Quantity	Full description of each item	Active principal content (in grammes)	Stocks on hand	

I hereby declare that to the best of my knowledge and belief all the particulars in this application are correctly stated, and I undertake that if this licence is granted to me, it shall be used solely for the supply of goods being my own property or the property of a person or company for whom I am authorized to act in this transaction as the sole responsible representative.

Signed (see Instruction 7) ……
Status……..
Date ……..
If on behalf of a company, state position in company……

N B This form must be signed in accordance with Instruction 4 and your attention is particularly drawn to section 19 (1) (c) of the Dangerous Drugs Act [Chapter 15:02]

ON REVERSE SIDE OF FORM

Instructions for completing this form

NON-COMPLIANCE WITH THESE INSTRUCTIONS WILL INVOLVE DELAY

1. Export Licences and Movement Licences under the Dangerous Drugs Act [Chapter 15:02], are required for all drugs to which the act applies.
2. The application fee for an Export Licence is two hundred dollars ($200,00), which must accompany each application. Cheques, postal orders and money orders must be made payable to the Secretary for Health and Child Welfare. No fee is charged for Movement Licences.
3. Paragraph (f) The following should be carefully observed:
   (i) Not more than one item should appear on each line provided in this space. Preparations of the same drug should be grouped together. Where the details of the items exceed ten lines of typing, six copies of a Schedule giving the requisite particulars should be furnished instead of including them in the table.
   (ii) Each item should be described fully. In the case of ampoules the total quantity of drug and volume of liquid in each ampoule, and not the quantity intended to be administered, shall be stated.
   (iii) The official conversion factors must be used in determining the active principal content, the name of which must be stated.
4. Signing of form. The declaration on the front page must be signed by a person authorized under the Act to supply drugs and domiciled in Zimbabwe, otherwise the application cannot be accepted. The person signing must insert under “status” the class of authorized person to which he belongs.
5. The consignment must be addressed exactly as stated in the licence.

All applications must be addressed to:-

The Secretary for Health and Child Welfare,
P O Box CY 1122
Causeway
Harare
Zimbabwe