



Zambia Medicines Regulatory Authority

GUIDELINES FOR THE MANAGEMENT OF CONTROLLED SUBSTANCES

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1. INTRODUCTION

1.1 Background

Narcotic drugs, psychotropic substances, and precursor chemicals are essential components of modern healthcare systems. They are widely used in the diagnosis, treatment, and management of various medical conditions, including severe pain, mental health disorders, anaesthesia, and palliative care. However, due to their psychoactive properties and potential for dependence, these substances carry a significant risk of misuse, abuse, and diversion if not adequately controlled.

In recognition of these risks, Zambia, as a State Party to international drug control conventions administered by the International Narcotics Control Board (INCB), is obligated to establish and maintain an effective regulatory framework that ensures strict control of these substances. At the same time, Zambia must guarantee their availability for legitimate medical and scientific purposes, particularly in critical areas such as pain management, surgery, and end-of-life care.

These guidelines have therefore been developed to provide a comprehensive framework for the regulation, control, and monitoring of narcotics, psychotropic substances, and precursor chemicals within Zambia. Specifically, the guidelines aim to ensure:

- i. Protection of public health and safety by minimizing risks associated with misuse and abuse
- ii. Prevention of diversion of controlled substances into illegal markets
- iii. Strengthening of regulatory oversight across the entire supply chain
- iv. Compliance with national laws and international obligations

1.2 Legal Mandate

The control and management of narcotics, psychotropic substances, and precursor chemicals in Zambia are governed by a combination of national legislation and international obligations. These guidelines are implemented in accordance with the following legal instruments:

- i. The Medicines and Allied Substances Act No. 3 of 2013
- ii. Controlled Substances Act No. 2 of 2023.
- iii. The Cannabis Act No. 33 of 2021
- iv. The Industrial Hemp Act No. 34 of 2021



The Zambia Medicines Regulatory Authority is designated as the National Competent Authority responsible for regulating the licit use of these controlled substances. In fulfilling this mandate, ZAMRA undertakes the following key functions:

- i. Licensing of facilities, and entities involved in handling-controlled substances
- ii. Regulation and authorization of importation and exportation
- iii. Monitoring, inspection, and enforcement of compliance with regulatory requirements
- iv. Collection and submission of national data and estimates to the INCB

Through these functions, ZAMRA ensures that controlled substances are handled strictly within legal frameworks and used only for legitimate medical and scientific purposes.

2. PURPOSE

These guidelines are intended to be the reference document for management of controlled substances by providing general guidance.

3. SCOPE

These guidelines apply to all authorized persons involved in the handling of narcotic drugs, psychotropic substances, and precursor chemicals within Zambia.

4. DEFINITION

In these guidelines, unless the context otherwise requires -

“Authority” means Zambia Medicines Regulatory Authority;

“Controlled substances” means narcotic drugs, psychotropic substances and precursors in Part I and II of the Narcotic Drugs and Psychotropic Substances Act No. 35 of 2021, of the laws of Zambia;

“Donation” means the act of supplying and acceptance of a medicine or allied substance to recipients by donors for which the recipient does not pay;

“Exporter” means a person authorised by the Authority to export medicines or allied substances;

“Export licence/authorisation” means a licence/authorisation issued by the Authority, authorizing a person to export medicines, allied substances or precursor chemicals;



“Importer” means a person authorised by the Authority to import medicines, allied substances and precursor chemicals;

“Import licence/authorisation” means a **licence/authorisation** issued by the Authority, authority, authorising a person to import medicines, allied substances and precursor chemicals; and

“Medicine” means human medicine, veterinary medicine, medicinal product, herbal medicine or any substance or mixture of substances for human or veterinary use intended to be used or manufactured for use for its therapeutic efficacy or for its pharmacological purpose in the diagnosis, treatment, alleviation, modification or prevention of disease or abnormal physical or mental state or the symptoms of disease in a person or animal;

“Precursor chemical” means a substance that is a requisite in the manufacture of a medicine or allied substance; and

“Quota” means the maximum quantity of narcotic drugs or psychotropic substances a country may produce, manufacture, or import during a calendar year (1 January - 31 December).

5. ABBREVIATIONS

HS Code	Harmonized System (HS) Codes
I2ES	International Import and Export Authorization System
INCB	International Narcotic Control Board
ZAMRA	Zambia Medicines Regulatory Authority



6. IMPORT AND EXPORT REQUIREMENTS

6.1 General Provisions

The importation and exportation of narcotics, psychotropic substances, and precursor chemicals are strictly controlled activities in Zambia. The following provisions shall apply:

- i. No person shall import or export controlled substances without a valid licence or authorisation issued by ZAMRA.
- ii. Only persons that are duly licensed and authorized by ZAMRA shall be permitted to handle these substances.
- iii. Donations of controlled substances must receive prior written approval from ZAMRA before shipment.
- iv. All transactions must be consistent with Zambia's annual national estimates and quotas as submitted to the INCB.

Failure to comply with these provisions may result in regulatory sanctions, including suspension or revocation of licenses.

6.2 Travelers Carrying Controlled Medicines

Travelers entering Zambia while carrying medicines containing narcotic or psychotropic substances are required to declare such medicines to ZAMRA or any other relevant authorities at the port of entry.

The following conditions shall apply:

- i. The traveler must present a valid prescription issued by a licensed medical practitioner
- ii. The quantity of medicine carried must not exceed a 30-day supply or as may be determined by the Authority
- iii. Full details of the patient, including name, prescribed medicine, dosage, and total quantity, must be provided

It should be noted that substances prohibited under international drug control conventions shall not be permitted entry into Zambia, even if they are legally prescribed in the country of origin.



6.3 Personal Importation (Courier Services)

Individuals seeking to import controlled substances for personal medical use through courier services must comply with the following requirements:

- i. Submission of a valid prescription from a registered Zambian practitioner
- ii. Provision of a supporting medical report where necessary
- iii. Submission of a formal justification letter explaining the need for importation

7. PROCEDURE FOR OBTAINING IMPORT/EXPORT LICENCE/AUTHORISATION

7.1 Application Process

Application for an import or export licence/authorisation for controlled substances shall be submitted online available on the ZAMRA website portal, e-services section. Applicants, Applicants without login credentials will be required to register online by clicking the section indicated create account so as to obtain login credentials.

The applicant will be expected to fill all the mandatory sections in the application. Such sections are highlighted in asterisks for mandatory information required during the application of controlled substances.

7.2 Calculation of Pure Anhydrous Base

Most of the products are produced with their salts during manufacture. Their calculation into their pure anhydrous base must be done since it's an international requirement for each product to be on its original status. Conversion factors are provided for by INCB for each specific product and its corresponding salt as indicated in the corresponding links below:

- a. In case of Narcotics, confirmation can be done in table 1 of part 4 of the yellow list. Kindly see part 4 of the yellow list in the link below:
https://www.incb.org/incb/uploads/documents/Narcotic-Drugs/Yellow_List/64th_edition/YL_64th_E.pdf
- b. For Psychotropic Substances, the substance and conversion factor of pure drug content of bases and salts is in the green list. Kindly see part 2 of the green list in the link below:



<https://www.incb.org/incb/uploads/documents/Psychotropics/forms/greenlist/2026/2510307E.pdf>

- c. With Precursor Chemical Substances, table 1 and 2 showing the pure anhydrous base content of some scheduled substances in their salt form is indicated in part 3 of the red list. Kindly see the link below:

https://www.incb.org/incb/uploads/documents/PRECURSORS/RED_LIST/RED_LIST_E.pdf

Note-The conversions are indicated in percentage. The conversion factor for substances in their pure form (without salt), is considered to be one (1) or 100%.

Formula for calculating the anhydrous base (should be in grams)

Unit pack X strength of active ingredient X total quantity imported X conversion factor (%)

Example

Importation/exportation of Pethidine HCl 100mg, 20 packets, each 10 vials

Calculation;

$$100\text{mg} \times 20 \times 10 = 20000\text{mg}$$

Covert to the pure Pethidine

$$20000\text{mg} \times 87/100 = 17,400\text{mg}$$

convert to grams $17,400/1000 = 17.400\text{grams}$

7.3 Supporting Documents

- The documents that shall be considered for issuance of a controlled substance licence/authorisation are as outlined in Annex 1.
- This notwithstanding, importation of substances listed in part 3 of the red list of the precursor chemical substances of 1988, will require a manufacturer's license from the Authority.

7.4 Making payment for controlled substances applications

- The applicant will be expected to proceed after paying the prescribed fees.



8. EVALUATION OF DDA APPLICATION

8.1 The Authority shall:

- a) Upon receipt of the applications for import/export of controlled substances, the Authority shall evaluate the application for adequacy, correctness and compliance to the requirements above.
- b) In making this evaluation, the Authority shall take into consideration the Country Quota allocations.

8.2 Evaluation Outcomes

8.2.1 During evaluation, the below evaluation out-comes may result in:

- **Query** – additional information or clarification required
- **Recommended** – application meets minimum requirements and proceeds for approval
- **Approved** – application fully complies and is authorized
- **Rejected** – application fails to meet requirements

8.2.2 In cases where the application meets the requirements, the application will be recommended for the final approval.

8.2.3 When the application does not meet the requirements above, an online query will be issued to the applicant for rectification before further processing is considered.

8.2.4 Upon answering the raised query and resubmitting the application, it will be re-evaluated, and if satisfactory, the application will be recommended and finally approved. In cases where the application does not meet the requirements, a rejection will be granted, and there shall be no further redress to that application.

8.2.5 All applicants shall be able to print the approved controlled substances licence/authorisation online and share relevant copies with their respective trading country counterparts.

8.2.6 This shall mark the start of the import/export process as outlined in the import/export guideline reference number: xxxxxxxx and subsequent port activities.



9. VALIDITY OF LICENCE/AUTHORISATION

- i. Approved licence/authorisation shall be valid for a period of twelve (12) months from the date of issuance
- ii. Each licence/authorisation shall be valid for a single consignment and shall not be transferable

10. TURN-AROUND TIMES

The turnaround times for the controlled substances applications shall be as outlined in the service charter of the Authority.

11. PORT CLEARANCE AND TRANSPORTATION

All consignments of controlled substances shall be subject to inspection at designated ports of entry or exit.

- i. Documentation must correspond exactly with approved licence/authorisation
- ii. Any discrepancies may result in detention or rejection of the consignment
- iii. Transportation within Zambia must be conducted securely, with measures in place to prevent loss, theft, or diversion

12. STORAGE AND HANDLING

All authorized facilities must ensure that controlled substances are stored and handled in a secure and compliant manner.

This includes:

- i. Storage in lockable cabinets and/or safe rooms
- ii. Restriction of access to authorized personnel only
- iii. Maintenance of appropriate environmental conditions as specified by manufacturers

12.1 Authorized Establishments

The following entities may be authorized to handle controlled substances:

- i. Licensed pharmacies and pharmaceutical wholesalers
- ii. Public and private hospitals and clinics



- iii. Research and academic institutions
- iv. Government institutions and agencies
- v. Faith-based and non-governmental health facilities

12.2 Personnel

Handling of controlled substances shall be restricted to qualified and authorized personnel, including:

- i. Registered pharmacists
- ii. Registered pharmacy technologists
- iii. Other authorized healthcare professionals

All personnel must be duly registered with relevant professional and regulatory bodies and must demonstrate competency in handling controlled substances.

13. DISPENSING REQUIREMENTS

Dispensing of narcotic and psychotropic substances shall be conducted strictly in accordance with national prescribing and dispensing guidelines. Healthcare providers must ensure that dispensing is based on valid prescriptions and that proper documentation is maintained.

14. RECORD KEEPING

Each establishment stocking Controlled substances shall keep complete and accurate records of the receipt and distribution of all Controlled substances. Such records shall be maintained electronically or manually or both for a period not less than five (5) years. These records shall include: -

- a) Complete and accurate records of receipt of all Controlled substances;
- b) Complete and accurate consumption/distribution/sale records of all Controlled substances;
- c) Complete and accurate records of disposal of all Controlled substances;
- d) Complete and accurate records of quarantined Controlled substances as a result of various regulatory decisions such as recalls, PMS query, damaged and expired products.
- e) All records relating to Controlled substances shall be made available for inspection to the Authority inspectors or any other relevant authority.



- f) These records shall be maintained in such a manner that they are readily retrievable from other documents.
- g) In case of a facility closure, the in-charge shall notify the Authority in writing within ninety days (90) and provide detailed information to whom the Controlled substances were transferred or disposed of.
- h) Controlled substances received and issued shall be recorded in a ledger book whose template is attached as Annex II.
- i) Quantity received shall be recorded in red ink and amount issued shall be recorded in blue or black ink to differentiate the two processes on manually managed records.
- j) Errors in record entry in ledger books shall be canceled once with a single strike-through and signed by the author.

15. DISPOSAL

Destruction of unfit/expired/poor quality Controlled substances will be under the direct supervision of the Authority and other relevant authorities. The procedure for disposal shall be as per regulations and guidelines on the disposal of pharmaceutical waste.

16. LOSS OR THEFT

In the event of loss of controlled substances, a complete inventory of the remaining Controlled substances shall be made within forty-eight (48) hours of discovery of loss. The affected establishment shall report the matter to the nearest Police station as soon as practicable and to the Authority for further action.

17. REPORTING REQUIREMENTS

Establishments shall ensure that Controlled substances consumption and estimate reports are filed with the Authority on a quarterly and annual basis. This shall entail submission of quarterly consumption reports by every 2nd week of April, July, October and January in the prescribed form as shown in Annex IV and annual consumption and estimate reports by the end of January of the subsequent year as shown in annex V and VI



All establishments authorized to procure and use controlled and precursor chemical substances shall be required to furnish to the Board the following reports:

- (a) Quarterly consumption reports by every 2nd week of April, July, October and January in a prescribed form (ANNEX III and IV)
- (b) Annual consumption reports by the end of January of the next calendar year.
- (c) Consumption estimates for the coming year by January of the next calendar year.

18. ALIGNMENT WITH INTERNATIONAL FRAMEWORKS

i. Zambia adheres to the following international conventions:

- a) 1961 Single Convention on Narcotic Drugs
- b) 1971 Convention on Psychotropic Substances
- c) 1988 Convention against Illicit Traffic

ii. Data reporting is conducted through INCB systems such as:

- a) International Import and Export Authorization System (I2ES)



19. ANNEXURES

Annex 1: Documents to be Attached

Requirement	Importation of controlled substances	Exportation of controlled substances	Importation of Precursor Chemicals	Donations
1	Proforma/commercial invoice	Proforma invoice	Proforma invoice	Invoice
2	Valid Pharmaceutical Licence , Valid Practicing Licence of the responsible person	Valid Pharmaceutical Licence, Valid Practicing Licence of the responsible person	Valid Pharmceutical Licence, Valid Practicing Licence of the responsible person	Certificate of registration of the recipient organization
3	Certificate of analysis, cGMP certificate	Certificate of analysis, cGMP certificate	Certificate of analysis, cGMP certificate	Certificate of analysis, cGMP certificate
4	Any other documents as required by the Authority	Import permit from the importing country Authority	—	Donation certificate
5	—	—	—	Quality statement or COPP
6	—	—	—	Donation authorization certificate
7	—	—	—	Import authorization (for



donations from
Zambia)

Annex II: Ledger Book Template

Controlled substances Ledger Book (LSE/CS/001/F1)

Name of Establishment _____

Address (P.O. Box) _____ Tel: _____

Controlled Substance Name & Strength _____

Date Received	Received From	Quantity Received	Invoice No.	Issued To	Quantity Issued	Requisition No.	Balance	Receiving Officer (Name & Signature)	Remarks

Annex III: Quarterly Import Returns Template (LSE/CS/001/F2)

Company Name _____

Address _____

Contact _____



Period _____

Drug Name & Strength	Import licence/authorisation No.	Date of Issue	Country of Origin	Total Quantity Imported	Date of Import	Port of Entry	Trade Name	Generic Name

Superintendent Name: _____

Registration Number: _____

Annex IV: Quarterly Export Returns Template (LSE/CS/001/F3)

Company Name _____

Version No. 1



Address _____

Contact _____

Period _____

Drug Name & Strength	Export licence/authorisation No.	Date of issue	Country of Destination	Total Quantity Exported	Date of Export	Port of Exit	Trade Name	Generic Name

Superintendent Name: _____

Registration Number: _____

Signature: _____

Company Seal/Stamp: _____

Annex V: Annual Import Returns Template (LSE/CS/001/F4)

Company Name _____

Version No. 1



Address _____

Contact _____

Period _____

Drug Name & Strength	Balance B/F	Import licence/authorisation No.	Date of issue	Country of Origin	Total Purchased	Quantity Received	Date Received	Port of Entry

Superintendent Name: _____

Registration Number: _____

Signature: _____

Company Seal/Stamp: _____

Annex VI: Annual Export Returns Template (LSE/CS/001/F5)

Company Name _____

Version No. 1



Address _____

Contact _____

Period _____

Drug Name & Strength	Export licence/authorisation No.	Date of issue	Country of Destination	Total Quantity Exported	Date of Export	Port of Exit	Trade Name	Generic Name

Superintendent Name: _____

Registration Number: _____

Signature: _____

Company Seal/Stamp: _____