

GUIDELINE TO CONTROL NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES AND TO REGULATE THEIR USE AND TRADE THEREIN

WHERE AS, recognizing the significant role of health in proper life and productivity of the people, and so is realized that narcotic drugs and psychotropic substances share a vital role in the health service;

WHERE AS, it is found necessary to deter the illicit production, distribution and use of narcotic drugs and psychotropic substances;

WHERE AS, it is found necessary to maintain the proper production, import, export, distribution, prescribe, dispense and use of narcotic drugs and psychotropic substances;

WHERE AS, to achieve these ends it is essential to lay down a secured narcotic drugs and psychotropic substances control system;

NOW THEREFORE in accordance with the Drug Administration and Control Proclamation No. 176/1999 and the International Narcotic Drugs and Psychotropic Substances Conventions, a Guideline is hereby issued as follows.

PART ONE GENERAL

1. Short Title

This Guideline may be cited as “Guideline to Control and promote proper use of Narcotic Drugs and Psychotropic Substances therein 01/2003”.

2. Definitions

In this Guideline, unless the context provides otherwise;

1. **“Narcotic Drug”** shall mean any drug subject to control according to Narcotic Drugs conventions of the United Nations ratified by Ethiopia. This shall also include a drug that is categorized as narcotic drug by the Drug Administration and control Authority.
2. **“Psychotropic Substance”** shall mean any substance subject to control according to psychotropic substances convention of the United Nations ratified by Ethiopia. This shall also include a substance that is categorized as psychotropic substance by the Drug Administration and Control Authority.

3. **“Precursor Chemical”** shall mean any chemical or drug subject to control according to the 1988 convention against illicit trafficking in Narcotic drugs and psychotropic substances of the United Nations ratified by Ethiopia. This shall also include a chemical that is categorized as precursor chemical by the authority.
4. **“Authority”** shall mean Drug Administration and Control Authority of Ethiopia.
5. **“Health Institution”** shall mean an institution which is authorized or issued certificate of competence by MOH, Regional Health Bureau or Regional Agriculture Bureau to render Health Services for human or animal freely and on payment basis, which includes Hospitals, Health centers, Clinics and diagnostic laboratory centers and Drug distributors not established for profit making purpose.
6. **“Drug trading institution”** shall mean an institution authorized or issued certificate of competence and/or trade license by the Authority and/or other concerned body to produce, import, export, whole sale and retail of Narcotic drugs, psychotropic substances or precursor chemicals.
7. **“Prescription paper”** shall mean any order for Narcotic drug or psychotropic substance written or signed by a duly licensed or authorized medical practitioner issued to a patient in order to collect Narcotic drug or psychotropic substance from dispensing unit.

PART TWO

LICENSE AND LICENSING PROCEDURE

3. Requirements for Licensing

1. No institution shall manufacture, import. Export, distribute narcotic drugs, psychotropic substances, or precursor chemicals or perform chemical analysis or research on same unless it is licensed.
2. Any institution which wishes to engage in the aforementioned activities shall apply on a form that may be prescribed by the Authority.

4. Issuance of Special License

A special license to manufacture, import, export or distribute narcotic drugs, psychotropic substances or precursor chemicals or perform chemical analysis or research on same shall be issued only to legalized Governmental, Non-Governmental and private institutions.

5. Exception of Compulsory Licensing

A special license pursuant to Article 3 shall not be required for a person who, may possess narcotic drugs or psychotropic substances for his/her own private use and for strictly medical purposes, provided that the quantity of such substances does not exceed the quantity prescribed by a licensed physician.

6. Prohibition from Licensing

The license under Article 3 shall not be granted to:

1. Any one who has been convicted of any of the offenses specified in the Drug Administration and Control Proclamation, regulation and Directives.
2. Any one who has been convicted of any offence against drug abuse, drug trafficking, or enactment to commit any such offence, or forgery, the use of forged documents, assumption of false identity, or false testimony, or any one convicted of planning to commit any such offence.
3. Any one who has previously been subjected to disciplinary dismissal from public office on grounds of detrimental to honor or trust.
4. Where adequate rooms, facilities and securities for the participation in the trade in narcotic drugs psychotropic substances, or precursor chemicals fail to exist.
5. Where there is no guarantee for the safety and control of the trade in or the manufacture of narcotic drugs or psychotropic substances.

7. Applications for a special License

The application for obtainment of a special license under Article 3 shall be submitted in duplicate to the Authority and shall contain the following information.

- a. Name in full, profession, and nationality of the applicant.
- b. Name of the institution and its address.
- c. The kind of trade in Narcotic Drugs and Psychotropic Substances, or precursor chemicals to be thought.
- d. Name, type and strength of Narcotic Drugs or Psychotropic substances, or precursor chemicals or raw materials to be employed.

8. Decision Taking

1. The Authority shall make its decisions upon granting the special license at most within two working days following application.
2. If the applicant is given the opportunity to remedy any defects of application, the time limit fixed in this Article sub article 1 shall be suspended until the correction of the defects or until the expiry of the time limit fixed for the correction.
3. The holder of the license shall immediately report to the Authority of any modification of the data specified in Article 6.

9. Suspensions and Revocation of a License

1. The license shall be revoked:
 - a. If it has not been made use of within one calendar year.
 - b. If the institution is suspended by concerned body to undertake the trade or service there in.
 - c. If the institution conflicts with the implementation of the provisions of proclamation No. 176/1999 or regulations and directives issued pursuant to this proclamation.
 - d. If the institution fails to comply with standard requirements.
 - e. If the licensee was found guilty of one of the offenses listed under Article 6.
2. The competent authorities shall be immediately informed about any withdrawal or revocation of the license.
3. If it has not been made use of with in the time limit, can be extended if due interest is substantiated.

PART THREE IMPORT, EXPORT AND TRANSIT

10. Prohibition

1. Importing or exporting narcotic drugs or psychotropic substances packing them with other drugs or items..
2. Importing or exporting narcotic drugs or psychotropic substances without tamper proof packs.
3. Importing or exporting narcotic drugs through the post office or by sea.
4. Releasing narcotic drugs or psychotropic substances or precursor chemicals from the port of entry by Customs Authority unless it is authorized by the Drug Administration and Control Authority or branch office of the Authority.

11. Requirement of Special Import or Export Permit

1. No import or export of narcotic drugs or psychotropic substances or precursor chemicals or raw materials shall be allowed, unless it is authorized by a special permit of the Authority.

12. Application for Import or Export Permit

1. An application for a permit to import or export narcotic drugs or psychotropic substances precursor chemical or raw material, shall be made and each application should indicate:
 - * The name and address of the applicant;
 - * The name and address of the importer or exporter;

- * The name, dosage form, strength & quantity of the drug or precursor chemical or raw material;
- 2. The Authority shall have the power to reject an application, reduce the quantity/weight requested, or exclude certain items from the list of requisition.

13. Issuance of Special Import or Export Permit

1. The Authority shall issue a special license for importation of any Narcotic Drug or Psychotropic Substance or precursor chemicals or raw materials if it finds that:
 - a. The substance is included in the National List of Drugs.
 - b. The substance is necessary to provide medical and scientific needs or other legitimate needs of the country.
 - c. The domestic supply of any Narcotic Drug or Psychotropic substance is inadequate for scientific or Medical purposes.
 - d. The precursor chemical or raw material is found to be necessary.
2. The Drug Administration and Control Authority shall issue a special license for exportation of any locally manufactured narcotic drug, psychotropic substance, precursor chemical or raw materials if:-
 - The exporting institution should obtain special import authorization from the regulatory authority of the importing country.
3. A special Import or Export license for Narcotic drug or psychotropic substance or precursor chemicals shall be given at most with in two working days following application.

14. Distribution of Copies of the Special Import Permit

1. The original copy (copy1) of the special permit shall be issued by the Authority to the importer. The importer shall transmit this copy to the foreign exporter. The foreign exporter shall submit the copy to the proper governmental authority in the exporting country, if required, as a prerequisite to the issuance of an export authorization, for Narcotic drugs, psychotropic substances, precursor chemicals or raw materials.
2. The duplicate copy (copy2) shall be forwarded by the Authority to the proper governmental authorities of the exporting country.
3. The triplicate copy (copy 3) shall be forwarded by the Authority to the customs authority at the port of entry for follow up.
4. The quadruplet copy (copy 4) shall be retained by Drug Administration and Control Authority.

15. Cancellation of Special Import or export Permit & Expiration Date

1. Any licensed institution authorized to import or export Narcotic drugs or psychotropic substances, precursor chemicals or raw materials should apply for a special import permit for each transaction. Such special permit shall be valid only for ninety (90) days.
2. An import or export permit being issued by the authority shall be cancelled provided no shipment has been made and returned to the authority or in the event that a permit is lost and proven with evidence, the authority shall issue new import or export permit in replacement to the cancelled or lost one.
3. Nothing in this part shall affect the right, hereby reserved by the Authority, to cancel a permit at any time for proper cause.

16. Import or export Declaration and Clearance from the Port of Entry or exit

1. While Importing or exporting Narcotic drugs, psychotropic substances, precursor chemicals or raw materials the authority's inspector shall inspect and confirm if they are inline with the Import/Export special permit given by the authority and attached export/import documents at the port of entry and report to the authority.
2. After approval of the said report, the authority shall issue import or export permit for Narcotic drugs, psychotropic substances, precursor chemicals or raw materials.
3. The customs authority at the port of entry shall release Narcotic drugs, psychotropic substances, precursor chemicals or raw materials arriving at customs port only on submission of approval of clearance issued by drug administration and control authority and shall keep records.
4. Copies of the said certificate of clearance shall be kept by drug administration and Control Authority, customs authority at the port of entry and the institution effecting the transaction.

PART FOUR PRESCRIPTION AND DISPENSING AGAINST PRESCRIPTION

17. Prohibition

1. Prescribing narcotic drug or psychotropic substance on ordinary prescription other than Narcotic drug or Psychotropic substance prescription papers.
2. Dispensing narcotic drug or psychotropic substance without narcotic drug or psychotropic substance prescription papers.

3. Sells or supplies narcotic drugs or psychotropic substances on presentation of a prescription, where he/she knows that the prescription is forged, unlawfully altered, canceled or expired.
4. Using narcotic drug or psychotropic substance unless they are prescribed for him/her by medical personnel authorized to prescribe.
5. Medical personnel prescribing narcotic drug or psychotropic substance for him/herself.
6. Prescribing narcotic drugs or psychotropic substances without sufficient reason or above the standard dose, even if he/she has a license.

18. Persons Entitled to Issue Prescriptions

1. A prescription for narcotic drug or psychotropic substance may be issued only by an individual practitioner who is authorized to prescribe narcotic drugs or psychotropic substance in which he is licensed to practice his/her profession.
2. A prescription issued by an authorized practitioner and communicated to a pharmacist or druggist by the user or authorized health personnel of the health institution (for in-patient only) shall be acceptable.

19. Manner of Issuance of Prescription

1. Any prescription for narcotic drugs or psychotropic substances shall:
 - a. Be dated as of, and signed on, the day when issued.
 - b. Bear the full name, age, sex, address and card number of the patient; diagnosis (ICDCODE no); and
 - c. It shall bear name, strength, dosage form quantity of the drug; date of prescribing and clear direction for use.
 - d. Bear the name, address, signature, and license number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document.
2. Prescription papers shall be hand written with ink or indelible pencil and shall be manually written and signed by the practitioner.

20. Dispensing of Narcotic Drugs or Psychotropic Substances

1. No narcotic drug or psychotropic substance prescription paper shall be met which does not fulfill the following requirements.
 - a. Be dated as of, and signed on the day when issued.
 - c. It shall bear the name, age, sex, address, card no, of the patient, diagnosis (ICD code No).
 - d. It shall bear name, strength, dosage form quantity of the drug; date of prescribing and clear direction for use.

- e. It shall have been legibly written and signed by a medical practitioner whose name, registration number and address shall also be legibly written on the prescription.
- e. It shall bear the official seal of the Health Institution from which it is prescribed.
2. A prescription containing narcotic drug or psychotropic substance shall not be dispensed after the elapsing of fifteen days as from the date on which it was issued.

PART FIVE RECORDS AND REPORTS

21. General

1. All narcotic drugs, psychotropic substances and precursor chemicals manufactured, imported, exported or distributed by institution shall be registered on the day of the activity accomplished. All other information as may be required by the Authority shall also be recorded in a separate book.
2. The said register book shall be submitted to Drug Administration and Control Authority and Justice on request.
3. An institution licensed to manufacture, import, export or distribute narcotic drugs; psychotropic substances or precursor chemicals shall send a report, about the drugs, and precursor chemicals to the Authority.

22. Records

1. Every Importer/Wholesaler shall keep records of:
 - a. Imported Narcotic Drugs on form NPS/01/A;
 - b. Imported Psychotropic Substances on form NPS/01/B;
 - a. Imported precursor chemicals and drugs on form NPS/01/C;
 - b. Distributed Narcotic Drugs on form NPS/02/A;
 - c. Distributed psychotropic substances on form NPS/02/B;
 - d. Distributed precursor chemicals and drugs on form NPS/02/C.
2. Every pharmaceutical manufacturing factory shall keep records of:
 - a. Imported and used Narcotic and psychotropic raw materials on Form NPS/02/D
 - b. Imported precursor chemicals and drugs on form NPS/01/C
 - c. Consumed/used precursor chemicals and drugs on form NPS/02/C
 - d. Manufactured Narcotic drugs on Form NPS/01/D
 - e. Manufactured Psychotropic substances on Form NPS/01/E
 - f. Manufactured precursor drugs on form NPS/01/F
 - g. Distributed Narcotic drugs on form NPS/02/A
 - h. Distributed psychotropic substances on form NPS/02/B
 - i. Distributed precursor drugs on form NPS/02/C

3. Every health institution shall keep records of:
 - a. Purchased narcotic drugs or psychotropic substances, on Model 19,
 - b. Distributed narcotic drugs or psychotropic substances to dispensary pharmacies, on model 22;
 - c. Dispensed narcotic drugs or psychotropic substances to in-patients, on forms NPS/08/A & NPS/08/B respectively;
 - d. Dispensed narcotic drugs or psychotropic substances to out patients on the grounds of a prescription, on forms NPS/09/A and NPS/09/B respectively;
4. Every Pharmacy/Drug Shop shall keep records of purchased narcotic drugs or psychotropic substances, and all invoices related to them in Form NPS/19 in a chronological file for not less than five years.

23. Reports

1. Every importer, exporter or wholesaler shall send reports of imported, exported, distributed Narcotic drugs, Psychotropic substances and precursor chemicals and drugs:
 - a) At the end of every quarter on respective forms NPS/01/A, NPS/01/B, NPS/01/C, NPS/02/A, NPS/02/B and NPS/02/C
 - b) At the end of every year on respective forms NPS/03A, NPS/03B and NPS/03C
2. Every pharmaceutical manufacturing factory shall send reports of imported, manufactured and distributed Narcotic drugs, psychotropic substances, precursor chemicals, precursor drugs, Narcotic and Psychotropic raw materials:
 - a) At the end of every quarter on respective forms NPS/01/C, NPS/01/D, NPS/01/E, NPS/01/F, NPS/02/A, NPS/02/B, NPS/02/C and NPS/02/D
 - b) At the end of every year on respective forms NPS/03/A, NPS/03/B, NPS/03/C and NPS/03/D.
3. Every Health Institution or Drug retail outlet shall send reports of purchased and dispensed narcotic drugs and psychotropic substances at the end of every year on Forms NPS/15/A and NPS/15/B respectively to Drug Administration and Control Authority.

PART SIX MISCELLANEOUS

24. Storage

Narcotic drugs, psychotropic substances and invoices, registers, prescriptions and the like therefore shall be stored in a strong locked metal cupboard or in a special room the key to which shall at all times remain in the possession of the authorized professional.

25. Disposal

1. Narcotic drugs, psychotropic substances, precursor chemicals or raw materials no longer useful, due to expiry or damage, shall be destroyed if:-
 - e. Governmental, non-governmental or private health institutions and drug retail outlets under the ministry of health and Addis Ababa City shall apply to the Authority and the drugs shall be disposed under the direct supervision of the authority.
 - b. Governmental, non-governmental or private health institutions and drug retail outlets under regional health bureaus shall apply to their respective regional health bureaus or zonal/desk health departments or district health offices and the drugs shall be disposed under the direct supervision of the same.
2. Issuance of Disposal certificate
 - a. The Authority shall issue disposal certificate (form NPS/14) for Governmental, Non-governmental or private health institutions and drug retail outlets under the ministry of health and Addis Ababa city.
 - b. Regional health bureaus, Zonal health departments or District health offices shall issue disposal certificate (Form NPS/14) for their respective Governmental, Non-governmental or private health institutions and drug retail outlets a copy of the certificate given by regional health bureaus or Zonal/Desk health departments or District health offices shall be sent to the Authority.
3. Narcotic Drugs or Psychotropic substances seized in illicit traffic, illicit manufacture (clandestine laboratory) and illicit market shall be disposed, in accordance with the International, Treaty requirement, under the direct supervision of a committee whose members include the Authority, Ministry of Justice, Customs Authority and other relevant Ministries.

26. Theft of Narcotic Drugs or Psychotropic Substances

If any theft of Narcotic Drugs or Psychotropic Substances have under taken in an institution, it shall upon discovery notify the Authority or its representative or the local police Force within the next working day.

Such report shall contain the following information.

- * Name and Address of the institution,
- * License number,
- * Date of theft,
- * Local Police Department notified,
- * Type of theft and
- * List of Narcotic Drugs or Psychotropic Substances missed, strength, dosage form, unit and quantity.

Annex 7

FORM NPS/02/A

**Quarterly Statistics of distributed
Narcotic Drugs**

Name of Reporting Organization _____

Address: Region _____ City/Town _____

P.O. Box _____ Tel _____

These statistics relates to the calendar year _____ Quarter of the calendar of the year

Ser. No.	Narcotic Drugs	Strength	Dosage form	Date of Issue	Issued to	Quantity Issued	Issuing/transfer Voucher No.	Remark

Remark:- Report on the following Narcotic Drugs is required quarterly.

- 1. Codiene Phosphate
- 2. Morphine
- 3. Methadone
- 4. Fentanyl
- 5. Pethidine

Annex 8

FORM NPS/02/B

**Quarterly Statistics of distributed
Psychotropic Substances**

Name of Reporting Organization _____

Address: Region _____ City/Town _____

P.O. Box _____ Tel _____

These statistics relates to the calendar year _____ Quarter of the calendar of the year

Ser. No.	Psychotropic substances	Strength	Dosage form	Date of Issue	Issued to	Quantity Issued	Issuing/transfer Voucher No.	Remark

Remark:- Report on the following Psychotropic Substances is required quarterly

1. Alprazolam
2. Chlordiazepoxide
3. Diazepam
4. Medazepam
5. Oxazepam
6. Midazolam
7. Pentazocine
8. Pentobarbitone
9. Phenobarbitone
10. Temazepam
11. Other combination drugs
Containing controlled
psychotropic

Annex 15

FORM NPS/08/A

Date _____

PSYCHOTROPIC SUBSTANCES ADMINISTRATION RECORD IN
HEALTH INSTITUTION

Name of Health Institution: _____

Serial No. _____

Description of Drug _____ Quantity Issued _____

Ward/Department _____

Chief pharmacist: Name _____ Signature _____

Head Nurse: Name _____ Signature _____

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FORM NPS/08/B

Date _____

Name of Health Institution: _____

Serial No. _____

The following is an accurate record of _____

Total quantity _____ each used in ward Department _____

Please fill the following record clearly and neatly.

Date	Hour	Name of patient	Bed No.	Chart No.	Nurse	Dose

Ward physician: Name _____ Signature _____

Annex 16

FORM NPS/08/B
Date _____

**PSYCHOTROPIC SUBSTANCES ADMINISTRATION RECORD IN
HEALTH INSTITUTION**

Name of Health Institution: _____
Serial No. _____
Description of Drug _____ Quantity Issued _____
Ward/Department _____
Chief pharmacist: Name _____ Signature _____
Head Nurse: Name _____ Signature _____
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FORM NPS/08/B
Date _____

Name of Health Institution: _____
Serial No. _____
The following is an accurate record of _____
Total quantity _____ each used in ward Department _____
Please fill the following record clearly and neatly.

Date	Hour	Name of patient	Bed No.	Chart No.	Nurse	Dose

Ward physician: Name _____ Signature _____
Ward Head Nurse: Name _____ Signature _____

Record of Dispensed Narcotic Drugs in Dispensary Pharmacy of Health Institution

Name of Health Institution _____

Address _____

Serial No. _____

S. N.	Date	Name of Patient	Age	Sex	Address	Description of Drug	Quantity Dispensed	Name of Prescriber	Prescription Serial No.

Remark: Record on the following Psychotropic Drugs is required
A. Morphine HCl D. Fentanyl
B. Codeine Phosphate E. Methadone
C. Pethidine HCl F. Other controlled substances if present

Annex 19

Form NPS/14

Ref. No _____

Date _____

Disposal Certificate of Expired/unfit for use Narcotic drugs, psychotropic substances or precursor chemicals

We here by certify that Narcotic drug(s), psychotropic substance(s) or precursor chemicals enumerated /imported/ stocked in _____ have been destroyed under the direct supervision of inspector(s) of the _____ on _____

Ser. No.	Description	Unit	Quantity	Batch No	Exp. Date	MFD	Manufacturer's name	Country of origin	Remark

Inspectors	Signature	Date	Signature of authorized person
1.	_____	_____	_____
2.	_____	_____	_____
3.	_____	_____	_____

Note:- One copy of this verbal is sent to drug administration and control authority

Original _____
2nd copy _____
3rd copy _____

