FOOD AND DRUGS AUTHORITY

GUIDELINES FOR THE SALE, SUPPLY AND USE OF CONTROLLED SUBSTANCES

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1 INTRODUCTION

In pursuance of Section 126 of the Public Health Act, 2012 (ACT 851), the Food and Drugs Authority (FDA) shall regulate narcotic drugs, psychotropic substances for legal or medical use and precursor chemicals in accordance with the international conventions and any other relevant guidelines and protocols to which Ghana subscribes, including;

a. The Single Convention on Narcotic Drugs of 1961 (1961 Convention), as amended by the 1972 Protocol;
b. The Convention on Psychotropic Substances of 1971 (1971 Convention) and, adopted in 1988,
c. The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988 Convention).

The above mentioned Conventions and other related resolutions of the Economic and Social Council (ECOSOC) and Commission on Narcotic Drugs (CND) provides the framework for international cooperation in preventing the diversion of narcotic drugs, psychotropic substances and precursors. They impose a general obligation on States parties to cooperate in limiting the use of controlled substances to medical and scientific purposes, whilst preventing their diversion to illicit trade and abuse.

1.1 SCOPE

The guideline is aimed at developing good practice for the general management of controlled drugs. The guide is applicable to all avenues of controlled substance usage including but not limited to

- Retail and wholesale settings
- Health professionals providing care for people being treated with controlled substances, for example, doctors, pharmacists and nurses.
- People being treated with controlled substance, their families or carers, and the public.
- Providers of services where controlled drugs are used, for example, substance misuse services, ambulance services, home care providers, community pharmacies, community health providers and doctors.
- Researchers, drug manufacturers and law enforcement agencies.

This guide intends to create robust systems for obtaining, storing, supplying, recording, monitoring and disposing safely of controlled substances, while at the same time ensuring appropriate and convenient access for those patients that require controlled substances.

2 GLOSSARY

In these Guidelines, unless the context otherwise states:

a) **"FDA"** means Food and Drugs Authority.
b) **INCB** means International Narcotic Control Board
c) **"Controlled Substances"** or "Controlled drug" means a Narcotic drug, Psychotropic substance or Precursor chemical.
d) **"Narcotic drugs"** means substances listed in Schedules I and II of the 1961 Convention. The esters and ethers and the salts of esters and ethers of the narcotic drugs in Schedule I are also subject to control.
e) **"Psychotropic substance"** means those natural or synthetic substances or any natural material listed in the four Schedules of the 1971 Convention. The salts of those substances, where they exist, as well as preparations containing those substances, are subject to the same control requirements as the base substance.
f) **"Precursor chemical"** means those substances listed in Tables I and II of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 (1988 Convention) frequently used in the illicit manufacture of narcotic drugs and psychotropic substances under the international control.
g) **"Importer"** means a licensed pharmaceutical company registered with the FDA to import drugs into Ghana.

3 REQUIREMENTS

3.1 General Requirements

This section applies to all controlled drugs, whether held by a doctor, a pharmacist or other healthcare professional (personally or as part of the activities of an institution or organization).

- Controlled drugs should be dispensed only upon receipt of a valid prescription. For the purposes of these guidelines, valid prescription is defined as outlined in the Health Professions Regulatory Bodies Act, 2013 Act 857 Part 4 Section 103.

  HPRA, 2013 Act 857

  (1) a prescription is valid only if it is for the sale or supply of medicine and;
  a) is in indelible writing signed and dated by a medical practitioner, dentist or veterinary surgeon, or approved prescriber
  b) states the name, qualification and address of the person signing it,
  c) states the name and address of the person for whom the treatment is given or the name of the person to whom the medicine is to be delivered if for veterinary purposes,
  d) indicates the total amount of the medicine to be supplied and the dose of the medicine to be taken except in the case of an ointment, and
  e) has not previously been fully dispensed

(2) A valid prescription signed by
a) a dentist shall bear the words "for dental treatment only", or
b) a veterinary surgeon shall bear the words "for animal treatment only".

- Pharmaceutical wholesale facilities are to distribute controlled drugs to only licensed pharmaceutical outlets. Where the authenticity of the buyer is in doubt, it is recommended that a copy of the pharmaceutical licence is inspected prior to the supply of controlled drugs.

- Sale records of controlled drugs and their respective prescriptions must be retained in the facility for at least two years.
- A copy of purchase invoices, stock transfer documents and other details of stock, receipts and supplies of controlled substances must be retained in the facility for at least two years. The invoice must state the supplier of the controlled drug and the respective batch numbers of the products.

4 SCHEDULE SPECIFIC REQUIREMENTS

The following requirements are mandatory for the Schedule 1 drugs of the 1961 convention (as listed in the Appendix), methylphenidate and all other exceptions made by the FDA.

4.1 Prescription Highlights

Apart from meeting the requirements of a valid prescription, the following prerequisites are to be met;

- The prescription should be stamped with the personal stamp of the prescribing officer and thus bear his/her name.

- The authorized prescriber is to state his or her registration number as issued by their respective professional regulatory bodies. For example, a narcotic drug under this part prescribed by a medical doctor should bear the registration number of the doctor as issued by the Medical and Dental Council.

- For prescriptions outside hospitals or clinics and intended for community pharmacies, separate prescriptions are recommended for Schedule 1 controlled drugs since the original prescription is to be retained and not copies.

- Exceptions may be made for hospitals running an e-system provided the prescriptions are retrievable and traceable to the prescriber.

4.2 Storage & Display

Schedule 1 Drugs (1961 Convention) and any other exceptions made by the Authority are subject to safe custody requirements. The safe custody requirements imply that they must be stored in a locked receptacle.

The FDA approved cabinet should;

- be a securely lockable cabinet or safe.
- be made of metal with suitable hinges

The storage should only be accessible by the registered pharmacist authorized to possess controlled drugs or a person authorized by that person.

4.3 Record Keeping

A record of all controlled drugs obtained and supplied must be kept in a register. All records related to those specific substances must be maintained and be available for inspection for a minimum of two years. Any person who purchases or supplies a controlled drug under this part must maintain a Controlled Drugs Register (CDR).

4.3.1 Controlled Drugs Registers (CDR)

- The register must be either a computerized auditable system (FDA approved) or a bound book (which does not include any form of loose-leaf register or card index)

4.3.1.1 Electronic Controlled Drugs Registers

- Where electronic CDRs are adopted, the following features should be incorporated to warrant it's approval by the FDA:
    - computerized entries must be traceable, auditable and compliant with best practice.
    - It must be capable of printing or displaying the name, form and strength of the drug in such a way that the details appear at the top of each display or printout to comply with the prescribed requirements under Appendix 9.4 of this document.
    - The author of each entry should be identifiable.
    - Computerized entries cannot be altered at a later date.
    - Access control systems should be incorporated to minimize the risk of unauthorized access to data.
    - Adequate backups must be made of electronic CDRs to avoid data loss.
    - Adequate arrangements should be made to ensure inspectors have unrestricted access to the electronic CDRs at any time with minimum disruption to the dispensing process.

4.3.1.2 Non-Electronic Controlled Drug Registers

- Where manual entries are to be adopted using a Controlled Drug Register, the register should meet the following specifications:
    - The drug register should contain all the necessary data as prescribed under Appendix 9.4 of this document.
    - The sample template of the CDR included in the appendix of this document can be downloaded via http://fdaghana.gov.gh/img/applicationform/CONTROLLED%20DRUG%20REGISTER%20SHEET.docx
    - The drug register leaflets should be printed using standard A3 paper to ensure adequate spacing for the required information.
    - The CDR pages should be numbered throughout the entire register.
    - The register leaflets should be bound in soft manilla card cover or bound in standard form Art vellum or cloth.
    - The bound book should not include any form of loose-leaf register or card index.

The register must:

- be separated into each class of drug
- have a separate page for each strength and form of that drug, with this recorded at the top of each page
- have the entries in chronological order and made on the day of the transaction or, if not reasonably practical, the next day
- have the entries made in ink
- Not have cancellations or alterations between entries. Corrections must be made with dated marginal notes or footnotes
- ensure any corrections are made by a signed and dated entry in the margin or at the bottom of the page
- be kept at the premises to which it relates (for example separate registers for each set of premises) and be available for inspection at any time
- not be used for any other purpose
- be kept for a minimum of two years after the date of the last entry

The following must be recorded in the register when controlled drugs are received or purchased:

- date supply received
- name and address of supplier (e.g. wholesaler, pharmacy)
- Invoice number of transactional document
- quantity received

The following must be recorded in the register when controlled drugs are supplied or dispensed (which includes by way of administration):

- date supplied
- name and address of recipient that is the person the controlled drug was supplied to (or the company supplied to, if wholesale)
- name of the patient (if the recipient differs from the patient)
- name and address of prescriber that is the giver of the prescription order
- quantity supplied

In addition to the above, a running balance of stock must be kept in the register.

The aim of maintaining a running balance in the register is to ensure irregularities are identified as quickly as possible. The running balance of drugs remaining should be calculated and recorded after each transaction and balances should be checked with the physical amount of stock at regular intervals.

5 SUPPLY

Supply is restricted to licensed wholesalers, hospitals and registered pharmacies. Wholesalers are permitted to supply only to a person authorized to possess. Hospitals (in so far as it represents the business of the hospital) may supply patients, wards and practitioners. Pharmacies may supply **ONLY** on receipt of a valid prescription or signed order.

6 REFILLS

The refilling of a prescription for a controlled substance listed in Schedule I or exceptions defined from other schedules by the Authority is strictly prohibited and the original prescription is to be retained in the facility.

7 SAFE DISPOSAL

The safe disposal of controlled drugs must be appropriately authorized and the person witnessing the disposal must be authorized to do so. For the disposal of controlled drugs under this part, the FDA should be notified in writing or email and approval granted accordingly prior to safe disposal.

The date of disposal and the quantity disposed must be recorded in the register and signed by the witness.

8 BREAKAGE, SPILLAGE AND LOSS OF CONTROLLED SUBSTANCES

In the case of loss, theft or burglary of controlled drugs under this part, the FDA office should be duly notified in writing or via email.

The loss should be equally documented in the drug register with the corresponding explanation provided briefly in footnotes.

9 APPENDIX

9.1 LISTS OF NARCOTICS SUBSTANCES

The compilation developed by the International Narcotic Control Board (INCB) contains the current list of narcotic drugs under international control. In the 1961 Convention, narcotic drugs and their preparations are listed in four schedules according to their dependence potential, abuse liability and therapeutic usefulness.

The list of narcotic substances includes but not limited to the UN Convention's yellow list link quoted below:

https://www.incb.org/documents/Narcotic-Drugs/Yellow_List/58th_Edition/Yellow_List_-ENG.pdf

9.1.1 Drugs Included in Schedule I of the 1961 Convention

Substances listed in Schedule I are highly addictive and highly liable to abuse. This schedule lists all substances in the opiate, cocaine and cannabis groups and subjects them to all specified controls of the convention.

SCHEDULE 1

NARCOTIC DRUGS	DESCRIPTION/CHEMICAL NAME
Cocaine	methyl ester of benzoylecgonine (an alkaloid found in coca leaves or prepared by synthesis from ecgonine)
Fentanyl	1-phenethyl-4-N-propionylanilinopiperidine
Heroin	diacetylmorphine (derivative of morphine)
Methadone	6-dimethylamino-4,4-diphenyl-3-heptanone
Morphine	the principal alkaloid of opium and of opium poppy
Opium	the coagulated juice of the opium poppy (plant species Papaver somniferum L.)
Oxycodone	14-hydroxydihydrocodeinone (derivate of morphine)
Pethidine	1-methyl-4-phenylpiperidine-4-carboxylic acid ethyl ester
Remifentanil	1-(2-methoxycarbonylethyl)-4-(phenylpropionylamino)-piperidine-4carboxylic acid methyl ester
Thebaine	(an alkaloid of opium; also found in Papaver bracteatum)
Cannabis	the flowering or fruiting tops of the cannabis plant (resin not extracted)
Cannabis Resin, extracts and tinctures	the separated resin, crude or purified, obtained from the cannabis plant
***Tramadol	

9.1.2 Drugs Included in Schedule II of the 1961 Convention

In general, this includes the substances more commonly used for medical purposes and needing less strict control because of the smaller risk of abuse. These substances are less and less liable to abuse than Schedule I drugs.

NARCOTIC DRUGS	DESCRIPTION/CHEMICAL NAME
Codeine	3-methylmorphine (derivative of morphine, alkaloid contained in opium & poppy straw)
Dextropropoxyphene	α –(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-butanol propionate (Dextro-rotary isomer of propoxyphene)
Dihydrocodeine	(derivative of morphine)

9.1.3 Drugs Included in Schedule IV of the 1961 Convention

This includes substances characterized as having particularly dangerous properties but very limited therapeutic use. They are drugs equally listed in Schedule 1 and are highly liable to abuse.

NARCOTIC DRUGS	DESCRIPTION/CHEMICAL NAME
Heroin	Diacetylmorphine (derivative of morphine)

9.2 LISTS OF PSYCHOTROPIC SUBSTANCES

In the 1971 Convention, substances are categorized in four schedules, depending on the risk of abuse, the threat to public health and the therapeutic value associated with them.
The list of psychotropic substances includes but not limited to the UN Convention's Green list quoted below:-
https://www.incb.org/documents/Psychotropics/forms/greenlist/Green_list_ENG_08673.pdf

9.2.1 Schedule I (1971 Convention)

Substances presenting a high risk of abuse, posing a particularly serious threat to public health that are of very little or no therapeutic value. This includes the hallucinogen group LSD, DMT, psilocybin etc. Controls over these drugs are of the strictest nature and include special provisions for very firm controls to limit their use chiefly to research.

9.2.2 Substances in Schedule II (1971 Convention)

Schedule II drugs under the psychotropic convention contains stimulant sympathomimetic drugs of the amphetamine type, of very limited therapeutic usefulness. These substances are known to be highly addictive and the controls over them are generally the same as schedule I.

International Non-proprietary name	**Other non-proprietary or trivial names**	**DESCRIPTION/CHEMICAL NAME**
DRONABINOL	Delta-9-tetrahydrocannabinol and its stereochemical variants	(6Ar,10aR)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6Hdibenzo[b,d]pyran-1-ol
METHYLPHENIDATE		Methyl α-phenyl-2-piperidine acetate

9.2.3 Substances in Schedule III (1971 Convention)

Substances outlined within this schedule include fast- and medium-acting barbiturates that present a strong risk of abuse. Despite, the potential threat to public health, are therapeutically useful.

International Non-proprietary name	**Other non-proprietary or trivial names**	**DESCRIPTION/CHEMICAL NAME**
FLUNITRAZEPAM		5-(o-fluorophenyl)-1,3-dihydro-1-methyl-7-nitro-2H-1,4-benzodiazepin-2-one
PENTAZOCINE		(2R*, 6R*, 11R*)-1,2,3,4,5,6-hexahydro-6,11-dimethyl-3-(3-methyl-2-butenyl)-2,6-methano-3-benzazocin-8-ol
PENTOBARBITAL		5-ethyl-5-(1-methylbutyl)barbituric acid

9.2.4 Substances in Schedule IV (1971 Convention)

This includes a variety of hypnotic, tranquilizing and analgesic drugs that have marked addictive properties, but are widely used therapeutically. A relatively lesser degree of control is attached to these drugs.

International Non-proprietary name	Other non-proprietary or trivial names	DESCRIPTION/CHEMICAL NAME
ALPRAZOLAM		8-chloro-1-methyl-6-phenyl-4H-striazolo[4,3-α][1,4]benzodiazepine
BARBITAL		5,5-diethylbarbituric acid
BROMAZEPAM		7-bromo-1,3-dihydro-5-(2-pyridyl)-2H-1,4-benzodiazepin-2-one
CHLORDIAZEPOXIDE		7-chloro-2-(methylamino)-5-phenyl-3H-1,4-benzodiazepine-4-oxide
CLORAZEPATE		7-chloro-2,3-dihydro-2-oxo-5-phenyl-1H-1,4-benzodiazepine-3-carboxylic acid
DIAZEPAM		7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one
ETILAMFETAMINE	N-ethylamphetamine	N-ethyl-α-methylphenethylamine
FLURAZEPAM		7-chloro-1-[2-(diethylamino)ethyl]-5-(o-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one
LORAZEPAM		7-chloro-5-(o-chlorophenyl)-1,3-dihydro-3-hydroxy-2H-1,4-benzodiazepin-2-one
MEPROBAMATE		2-methyl-2-propyl-1,3-propanedioldicarbamate
MIDAZOLAM		8-chloro-6-(o-fluorophenyl)-1-methyl-4H-imidazo[1,5-α][1,4]benzodiazepine
NITRAZEPAM		1,3-dihydro-7-nitro-5-phenyl-2H-1,4-benzodiazepin-2-one
PHENOBARBITAL		5-ethyl-5-phenylbarbituric acid
PHENTERMINE		α,α-dimethylphenethylamine
PINAZEPAM		7-chloro-1,3-dihydro-5-phenyl-1-(2-propynyl)-2H-1,4-benzodiazepin-2-one
TEMAZEPAM		7-chloro-1,3-dihydro-3-hydroxy-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one
TRIAZOLAM		8-chloro-6-(o-chlorophenyl)-1-methyl-4H-s-triazolo][4,3-a][1,4]benzodiazepine
ZOLPIDEM		N,N,6-trimethyl-2-p-tolylimidazo[1,2-a]pyridine-3-acetamide

9.3 LIST OF PRECURSOR CHEMICALS SUBSTANCES

This list is an INCB compilation and used as a tool for the identification of substances scheduled in Tables I and II of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 (1988 Convention). The list includes but is not limited to UN Convention's red list link quoted below:
https://www.incb.org/documents/PRECURSORS/RED_LIST/2020/Red_List_2020_E.pdf

9.3.1 Substances included in Table I (1988 Convention)

International Non-proprietary name	**DESCRIPTION/CHEMICAL NAME**
EPHEDRINE	([R-(R*,S*)]- α-[1-(methylamino)ethyl]-benzenemethanol)
ERGOMETRINE	(ergoline-8-carboxamide,9,10-didehydro-N-(2-hydroxy-1-methylethyl)-6-methyl-,[8β(S)])
NOREPHEDRINE (Phenylpropanolamine HCl)	(R*,S*)- α-(1-aminoethyl)benzenemethanol
POTASSIUM PERMANGANATE	(Permanganic acid (HMnO4), potassium salt)
PSEUDOEPHEDRINE	([S-(R*,R*)]-α-[1-(methylamino)ethyl]-benzenemethanol)

9.4 SAMPLE OF CONTROLLED DRUG REGISTER SHEET

Name of Drug:____________________ Strength__________ Form______________

DATE	RECIEVED			SUPPLIED					Running Balance
	Name/Address of person/firm received	Invoice No.	quantity	Name/Address of person/firm supplied	Details of Supplier	Person collecting controlled drug If HCP, name and address	Name and Identification No. of Prescriber/Wholesale	quantity	