FOOD AND DRUGS AUTHORITY

GUIDELINES FOR THE RETAIL AND WHOLESALE 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 shall regulate narcotics, psychotropic substances and precursor chemicals in accordance with the underlisted multilateral conventions which are currently in force:

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

This guideline is made to provide a guide to good practice in the management of controlled drugs in retail or wholesale settings.

2 GLOSSARY

In these Guidelines, unless the context otherwise states:

a) **“FDA”** means Food and Drugs Authority.
b) **“Controlled Substances”** or “Controlled drug” means a Narcotic drug, Psychotropic substance or Precursor chemical.
c) **“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.
d) **“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.
e) **“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.

f) **"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).

a) Controlled drugs should be dispensed only upon receipt of a valid prescription. The valid prescription for a controlled substance must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner on the date issued.
b) Sale records of controlled drugs and their respective prescriptions must be retained in the facility for at least two years.
c) 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 but not limited to Section 1 in the Appendix), methylphenidate and all other exceptions made by the FDA.

4.1 Storage & Display

Schedule 1 drugs 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, usually in an appropriate controlled drug cabinet or approved safe, which can only be opened by a person in possession of the controlled drug or a person authorized by that person.

4.2 Record Keeping

A record of all controlled drugs obtained and supplied must be kept in a register. All records related to controlled substances must be maintained and be available for inspection for a minimum of two years. Any person who purchases or supplies any product containing a controlled drug specified in Schedule 1 must maintain a Controlled Drugs Register (CDR).

4.2.1 Controlled Drugs Registers

The register must:

- be either a computerized system (FDA approved) or a bound book (which does not include any form of loose leaf register or card index)
- 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 or in a computerized form in which every entry can be audited
- 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)
- 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.

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.

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

8 APPENDIX

8.1 LISTS OF NARCOTICS SUBSTANCES

SECTION 1

Drugs Included in Schedule I of the 1961 Convention

NARCOTIC DRUGS	DESCRIPTION/CHEMICAL NAME
Cocaine	methyl ester of benzolecgonine
Fentanyl	1-phenethyl-4-N-propionylanilinopiperidine
Heroin	diacetylmorphine
Methadone	6-dimethylamino-4,4-diphenyl-3-heptanone
Morphine	
Opium	
Oxycodone	14-hydroxydihydrocodeinone
Pethidine	1-methyl-4-phenylpiperidine-4-carboxylic acid ethyl ester
Remifentanil	1-(2-methoxy carbonylethyl)-4-(phenylpropionylamino)piperidine-4-carboxylic acid methyl ester
Thebaine	
Tramadol	
Cannabis	

Section 2

Drugs Included in Schedule II of the 1961 Convention

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)

Section 3

Drugs Included in Schedule IV of the 1961 Convention

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

Including 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

8.2 LISTS OF PSYCHOTROPIC SUBSTANCES

Substances in Schedule II

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

Substances in Schedule III

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

Substances in Schedule IV

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-

International Non-proprietary name	Other non-proprietary or trivial names	DESCRIPTION/CHEMICAL NAME
		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

Including but not limited to UN Convention's green list and new substances 2018 links quoted below:-

https://www.incb.org/documents/Psychotropics/forms/greenlist/Green_list_ENG_08673.pdf

8.3 LIST OF PRECURSOR CHEMICALS SUBSTANCES

Substances included in Table I

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)

Including but 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