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THE TANZANIA FOOD, DRUGS AND COSMETICS ACT
(CAP 219)

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REGULATIONS

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(Made under section 122(1)(s)

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THE TANZANIA FOOD, DRUGS AND COSMETICS (CONTROLLED DRUGS) REGULATIONS, 2018

ARRANGEMENT OF REGULATIONS

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PART I
PRELIMINARY PROVISIONS

Citation

1.-These Regulations shall be cited as the Tanzania Food, Drugs and Cosmetics (Controlled Drugs) Regulations, 2018.

Scope of Application

2.-These Regulations shall apply in all regulatory controls related to controlled drugs in Mainland Tanzania.

Interpretation

3.-In these Regulations, unless the context otherwise requires-

"Act" means the Tanzania Food, Drugs and Cosmetics Act;

"Controlled drugs" means drugs which are prescribed in the First Schedule of these Regulations;

"Consumption" means a drug has been supplied to any person or hospital, enterprises for retail distribution, manufacture, medical use or scientific research;

"Dealer in controlled drugs" means a person who is authorised to carry on or otherwise the business of buying, selling, supplying, manufacturing and distributing controlled drugs;

"Dispense" means supply of a drug product by a pharmacist or authorised practitioner on and in accordance with a prescription lawfully given by medical practitioner, dentist or veterinary surgeon;

"Drug Control Conventions" means:

i. The Single Convention on Narcotic Drug 1961 adopted by the United nations conference in New York in March 1961

ii. The protocol amending the Convention mentioned is sub clause (a) adopted by United Nations Conference in Geneva in March 1972.

iii. The Convention on Psychotropic substances, 1971 adopted by the United Nations conference at Vienna on 19/12/1988. Any other international drug control convention or protocol or other instrument amending an international Drug Convention relating to narcotic drugs, precursors or psychotropic substances which may be or acceded to by the United Republic Tanzania

"International Narcotics Control board (INCB)" means a United Nations organ established by the 1961 Single Convection on narcotic drugs, which in collaboration with governments limit the cultivation, production, manufacture and use of controlled drugs to an adequate amount required for medical and scientific purposes;

"Manufacture" means all operations involved in the preparation, processing, compounding, formulating, filling, refining, transformation, packaging, repackaging and labelling of controlled drugs;

"Narcotic drugs" means any of the substances, natural or synthetic in schedule I and II of the Single convection on narcotic drug, 1961 and the respective amendments;

*"*Precursor Chemicals" means substances listed in the First Schedule of these Regulations used as medicinal products for treatment, prevention, mitigation or diagnostic of diseases;

"Prescription" means lawfully written direction by a medical practitioner, dentist, veterinary surgeon or any other authorized prescriber for the preparation and dispensing of controlled drugs by a pharmacist or authorized dispenser';

*"*Psychotropic substances" means substance, natural or synthetic or any natural material as ascribed to it under the First Schedule of these Regulations;

"Stock" means a drug has been kept or stored for the purpose of supplying to any person or hospital, enterprises for retail distribution or use in manufacture;

"Unfit controlled drugs" means a drug that has been condemned under the Act;

PART II
MARKETING AUTHORISATION

G.N. No. 314

4.-The application for registration of controlled drug as provided under the First Schedule shall be granted authorization after completion of the requirements of the regulation for registration of medicines in force.

5.-The Authority shall expedite the review of the applications in collaboration with other relevant stakeholders on demand at the time of evaluation.

6.-The Authority may, upon reasons given refuse, vary, extend, cancel, suspend or revoke any approval of a controlled medicine.

PART III
IMPORTATION AND EXPORTATION

Categories of Importers

7.- (1) There shall be a sole importer and distributor of narcotic drugs for human use to public, private and faith based hospitals as well as research institutions and registered non Governmental organisations to be known as the Medical Stores Department (MSD).

(2).-Psychotropic substances and chemical precursors may be imported by:-

a) Medical Stores Department.
b) Holder of import permit.
c) Pharmaceutical manufactures.
d) Holder of an ethical clearance certificate to conduct clinical trials.

Conditions for permits to other institutions

8.-Without prejudice to the conditions of regulations 7, any institution may be granted permit to import controlled drugs for medical or scientific purposes.

Procedure for importation

9.-(1) All applications for importation of controlled drugs shall be submitted to the Director General through an on-line portal.

(2).-The applications shall be accompanied by proforma invoice, letter of intent to import narcotics or psychotropic products or precursor chemicals and any additional conditions as indicated in the guidelines for dealing in controlled drugs applicable at the time of application.

(3).-Import permit of controlled drugs shall be valid for only six months from the date of issue and eligible for extension of a period not exceeding three (3) months.

(4).-The import permit of controlled drugs under First Schedule shall be accompanied by a controlled drugs import certificate with a validity period of six months from the date of issue and eligible for extension of a period not exceeding three (3) months.

(5).-All holders with import permits for controlled drugs shall be inspected by TFDA inspectors at the Point of Entry.

Donations

10.-Any donation approved by the Ministry responsible for Health will be handled and approved by the Authority upon proof from the Ministry at the time of import.

Travellers

11.-(1) Patient under treatment may be allowed to enter or leave the country with quantities of controlled drugs for personal use upon proof of prescriptions.

(2).-The travelling patient shall hold a valid prescription with patient name, name of

medicinal product both INN and trade name, treatment duration of less than 30days with possibility of extension within the country for a period that does not exceed 7 days.

(3).- The prescriptions shall be written in English language.

(4).- The limit of quantities of controlled drugs within which patients may be allowed to enter or leave the country shall be approved by the Authority

(5).-Unless it is expressly provided otherwise under these regulations;, Narcotic drugs that are listed in the First Schedule of these Regulations shall not be allowed to be carried by travellers except for personal use as may be indicated in the prescriptions.

Procedure for exportation

12.-(1).-Application for exportation of controlled drugs shall be submitted to the Director General through online portal.

(2).-The application shall be attached with an import certificate issued by a competent authority of the importing country.

Point of entry and exit of controlled drugs

13.-The import and export of any controlled drugs shall be through the designated Point of Entries indicated in the import and export permits as provided under the Second Schedule.

PART IV
STOCKING AND DISTRIBUTION

Requirement for stocking of narcotic drugs

14.-(1) Any authorised dealer may procure psychotropic substances and chemical precursors from any authorised importer, distributor or wholesaler.

(2).-Retail pharmacies shall sell psychotropic drugs only upon prescriptions.

(3).-Hospitals and health centres stocking narcotic drugs shall have a registered pharmaceutical personnel, storage space under lock and key, register or ledger for recording entry and issuance.

Application for Procurement of narcotic drugs

15.-(1) Application for procurement of narcotic drugs by private or public hospitals, Health centres or research institutions shall be submitted to the Director General in a prescribed form under the Third Schedule with the following details but not limited to:-

(a) The type of the drug;
(b) Strength; and
(c) Estimated quantity to be consumed for a period of twelve months.

(2).-The permit shall be renewed annually and the Authority may suspend or revoke the permit in case of violation of requirements.

Dispensing of controlled drugs

16.-(1) A registered pharmaceutical personnel or any authorized medical personnel shall dispense controlled drugs only pursuant to a valid written prescription signed by a licensed medical practitioner or dentist or veterinarian or any other authorized prescriber.

(2).-A valid prescription must include the following:-
(a) Patient name, age, sex and address;
(b) Prescribers name and registration number;
(c) Name, quantity, strength and dosage form of drug(s);
(d) Complete direction for use, date of prescription, date of dispensing; and
(e) Official seal of the health institution from which it is prescribed and signature of the prescriber.

(3).-Any pharmacist or any authorised prescriber shall issue or prescribe a prescription containing only one drug.

(4).- The validity period of the prescription shall not be more than 21 days from the day of issue.

(5).-A prescription shall be dispensed only once except if it is directed so by a prescriber and shall not be more than three times.

(6).- A pharmacist, in emergency situation, may dispense a verbal prescription and put records of it but a written prescription shall be provided within seven days by the responsible practitioner to be attached to the Pharmacist records.

(7).- Without prejudice to sub-regulations (1)-(6) of this regulation, stocking and distribution of Methadone shall not be done unless approved or recognised by the Drug Control and Enforcement Authority (DCEA).

PART V
RECORD KEEPING AND REPORTING

Record keeping

17.-(1) All facilities which stock controlled drugs shall keep complete and accurate records of the acquisition and disposition.

(2).-The facilities shall keep the records for a period of not less than five (5) years.

(3).- The facilities shall be made available to inspectors for inspection and photocopying all records pertaining to controlled drugs.

(4).-On permanent closure of any facility, the Director General shall be notified in writing within ninety (90) days by what means and as to whom controlled drugs were transferred or disposed off.

(5).- The quantities used and received shall be recorded in the ledger book as provided under Fourth and Fifth Schedule as the quantities issued and received of narcotic drugs.

(6).-The amount received shall be recorded in red ink and amount issued in blue or black ink and if an error occurs it shall only be cancelled once and signed.

Reporting

18.- Every authorised dealer shall furnish to the Authority records as provided under Sixth Schedule that include but not limited to:-
a) Quarterly consumption report;

b) Annual consumption report;
c) Consumption estimates for the coming year.

PART VI
DISPOSAL AND HANDLING OF LOSS

Disposal

19.-The facility shall dispose unfit controlled drugs under supervision of TFDA as per the Tanzania Food, Drugs and Cosmetics (Recall, Handling and Disposal of Unfit Medicines) Regulations in force.

Handling of loss of controlled drugs

20.- (1) In the event of loss of controlled drugs, the respective facility shall conduct complete inventory of the remaining controlled drugs within forty eight (48) hours of discovery of loss of controlled drugs and thereafter immediately report the matter to the police and the Authority for further action.

(2).- The facility shall send reports to the Authority that include but not limited to:-
a) Name and address of the institution.
b) License permit or registration number.
c) Date when a discrepancy was detected.
d) Police loss report.
e) Police case number.
f) Total amount lost.
g) Nature of loss.

PART VII
OFFENCES AND PENALTY

Offence

21.- Any person who contravenes or fails to comply with these Regulations or directly or indirectly aids any other person to do what is prohibited under these Regulations shall be guilty of an offence and on conviction, shall be liable to the penalty prescribed by the Act.

Compounding offences

22.-(1) The Director General, inspector or any other authorized person may, subject to and in accordance with the provisions of these Regulations, if he is satisfied that a person has committed an offence against these Regulations, compound such offence by accepting from such person a sum of money in respect of which the offence has been committed.

(2).- The sum of money payable under sub-regulation (1) shall not exceed five times the maximum amount of the fine prescribed as being payable in respect of such offence.

(3).- The Power conferred by this section shall be exercised where a person admits that he has committed an offence and agrees in writing in the prescribed form to the offence being dealt with under this regulation.

(4).- The Director General or officer exercising powers under this regulation shall give to the person from whom he receives any sum of money under sub regulation (2) a receipt which shall be in a prescribed form.

(5).-Any sum of money received under this regulation shall be paid into the Authority.

(6).- If any proceedings are brought against any person for an offence against these Regulations, it shall be a good defence if such person proves that the offence with which he is charged has been compounded under this regulation."

PART VIII
GENERAL PROVISIONS

23.-Any person selling, supplying, distributing, manufacturing, stocking or importing controlled drugs shall obtain a valid registration certificate from the Authority

24.-The registrant of controlled drugs shall be accountable for the safety and quality of the respective drug from the manufacturing site throughout the supply chain.

25.-The registration of the controlled drug shall remain valid for a period of five years subject to retention conditions that shall be in force.

26.-For purposes of these regulations, only controlled drugs as listed under the First Schedule of these Regulations or as updated by the International Narcotics Control Board (INCB) from time to time shall be deemed to be within the scope of these regulations.

27.-A person who shall be aggrieved or dissatisfied by any decision made under these regulations shall lodge a complaint to the Director General or appeal against such decision to the Minister.

First Schedule
(Made under Regulation 11(5)

LIST OF CONTROLLED DRUGS

a) Narcotic drugs

Acetorphine
Acetyl-alpha-methylfentanyl
Acetylmethadol
Alfentanil
Allylprodine
Alphacetylmethadol
Alphameprodine
Alphamethadol
Alpha-methylfentanyl
Alpha-methylthiofentanyl
Alphaprodine
Anileridine
Benzethidine
Benzylmorphine
Betacetylmethadol
Beta-hydroxyfentanyl
Beta-hydroxy-3-methylfentanyl
Betameprodine
Betamethadol
Betaprodine
Bezitramide
Cannabis
Cannabis resin and extract and tinctures of cannabis
Clonitazene
Coca leaf
Cocaine
Codoxime
Concentare of pop straw rich in morphine
Concentare of pop straw rich in thebain
Concentare of pop straw rich in codeine
Concentrate of pop straw rich in all varieties
Diethylthiambutene
Difenoxin
Dihydromorphine
Dihydroetorphine
Dimenoxadol
Dimepheptanol
Dimethylthiambutene
Diphenoxylate
Dipipanone
Drotebanol
Ecgonine
Ethylmethylthiambutene
Etonitazene
Etorphine

Etoxeridine
Fentanyl
Furethidine
Heroin
Hydrocodone
Hydromorphinol
Hydromorphone
Hydroxypethidine
Isomethadone
Ketobemidone
Levomethorphan
Levomoramide
Levophenacylmorphan
Levorphanol
Metazocine
Methadone
Methadone intermediate
Methyldesorphine
Methyldihydromorphine
3-methylfentanyl
3-methylthiofentanyl
Metopon
Moramide intermediate
Morpheridine
Morphine
Morphine methobromide
Morphine-N-oxide
1-methyl-4-phenyl-4-propnoxypiperidine
Myrophine
Noracymethadol
Norlevorphanol
Normethadone
Normorphine
Norpipanone
Opium
Oripavine
Oxycodone
Oxymorphone
Para-fluorofentanyl
Phenethyl-4-phenyl-4-piperidinol acetate (PEPAP)
Pethidine
Pethidine intermediate A
Pethidine intermediate B
Pethidine intermediate C
Phenadoxone
Phenampromide
Phenazocine
Phenomorphan
Phenoperidine
Piminodine
Piritramide
Proheptazine
Properidine
Racemethorphan
Racemoramide

Racemorphan
Remifentanil
Sufentanil
Thebacon
Thebaine
Thiofentanyl
Tilidine
Trimeperidine

Narcotic drugs in their original form

Acetyldihydrocodeine
Codeine
Dihydrocodeine
Ethylmorphine
Nicocodine
Norcodeine
Pholcodine
Propiram

Preparations of narcotic drugs exempted from controls (drugs containing narcotics in their original form in low strength)

i) Preparation compounded with one or more ingredients and containing not more than 2.5 percent in undivided preparations;

Acetyldihydrocodeine
Codeine
Dihydrocodeine
Ethylmorphine
Dihydrocodeine
Nicodicodine
Norcodine
Phocoldine

ii) Cocaine;
Containing not more than 0.1 per cent of Cocaine calculated as cocaine base and preparations of opium or morphine containing not more than 0.2 per cent of morphine calculated as anhydrous morphine base and compounded with one or more other ingredients and in such a way that the drug cannot be recovered by readily applicable means or in a yield which would constitute a risk to public health.

iii) Difenoxin:
Containing, per dosage unit, not more than 0.5 milligram of difenoxin and a quantity of atropine sulfate equivalent to at least 5 per cent of the dose of Difenoxin.

iv) Diphenoxylate:
Containing, per dosage unit, not more than 2.5 milligrams of diphenoxylate calculated as base and a quantity of atropine sulfate equivalent to at least 1 per cent of the dose of Diphenoxylate.

v) Propiram
Containing not more than 100 milligrams of Propiram per dosage unit and compounded with at least the same amount of methylcellulose.

vi) Pulvisipecacuanhae et opiicompositus,

Containing 10 per cent opium in powder, or 10 per cent ipecacuanha root, in powder well mixed with 80 per cent of any other powdered ingredient containing no drug.

b) Psychotropic Substances

i) Pyschotropic substances with limited medical values:

Brolamfetamine
Cathinone
3-[2-(diethylamino)ethyl]indole (DET)
(±)-2,5-dimethoxy-*alpha*-methylphenethylamine (DMA)
3-(1,2-dimethylheptyl)-7,8,9,10-tetrahydro-6,6,9-trimethyl-6*h*- dibenzo[*b,d*]pyran-1-olo (DMHP)
3-[2-(dimethylamino)ethyl]indole (DMT)
(±)-4-ethyl-2,5-dimethoxy-*alpha*-phenethylamine (DOET)
Eticyclidine (PCE)
Etryptamine
(+)-lysergide (LSD, LSD-25)
N-hydroxy MDA
(±)-*n*,*alpha*-dimethyl-3,4-(methylene-dioxy)phenethylamine (mdma)
Mescaline
Methcathinone
4-methylaminorex
2-methoxy-*alpha*-methyl-4,5-(methylenedioxy)phenethylamine (MMDA)
Parahexyl
4-MTA alpha methyl 4 methylphenethylamine
(±)-n-ethyl-*alpha*-methyl-3,4-(methylenedioxy)phenethylamine (N- ethyl MDA)
(±)-*n*-[*alpha*-methyl-3,4-(methylenedioxy)phenethyl]hydroxylamine (*n*-hydroxy MDA)
Parahexyl
p-methoxy-*alpha*-methylphenethylamine (PMA)
Psilocine
Psilotsin
Psilocybine
Rolicyclidine
STP, DOM
Tenocyclidine

ii) Pyschotropic substances with moderate or high therapeutic values:

Alprazolam
Amfepramone (Diethylpropion)
Amineptine
Amfetamine
Aminorex
Amobarbital
Barbital
Benzfetamine (Benzphetamine)
Bromazepam
Brotizolam
Buprenorphine
Butalbital
Butobarbital
Camazepam
Cathine
Chlordiazepoxide
Clobazam
Clonazepam
Clorazepate

Clotiazepam
Cloxazolam
Cyclobarbital
Delorazepam
Diazepam
Dexamfetamine
Dronabinol
Estazolam
Ethchlorvynol
Ethinamate
Ethylloflazepate
Etilamfetamine *(N*-ethylampetamine)
Fencamfamin
Fenetylline
Fenproporex
Fludiazepam
Flunitrazepam
Allobarbital
Flurazepam
Glutethimide
Halazepam
Haloxazolam
Ketazolam
Lefetamine
Loprazolam
Levamfetamine
Lorazepam
Lormetazepam
Mazindol
Mecloqualone
Medazepam
Mefenorex
Meprobamate
Mesocarb
Methylphenobarbital
Metamfetamineracemate
Methaqualone
Methyprylon
Midazolam
Nimetazepam
Nitrazepam
Nordazepam
Oxazepam
Oxazolam
Pemoline
Pentazocine
Pentobarbital
Phendimetrazine
Phenobarbital
Phentermine
Phencyclidine
Phenmetrazine
Pinazepam
Pipradrol
Prazepam
Pyrovalerone
Secbutabarbital
Secobarbital

Temazepam
Tetrazepam
Triazolam
Vinylbital
Zolpidem
Zipeprol

c) Precursor substances

Ephedrine
Ergometrine
Ergotamine
Norephedrine
Piperidine
Potassium permanganate
Pseudoephedrine

Second Schedule
(*Made under Regulation 9(4))*

Part I: Import Permit of Controlled Drugs

TANZANIA FOOD AND DRUGS AUTHORITY

IMPORT PERMIT FOR DRUG PRODUCT(S)

Import Permit No: .....

PART A: PARTICULARS OF IMPORTER

Name of registered Importer**.....**Postal address **.....**Tel. No**.....**

Exporting Country**.....**Invoice No**.....**Date**.....**

Exporter/Sender**.....** Postal address….**.....**

Arrival expected by ship, air or motor vehicle..... .....via **.....**Port of Entry

S/N	**Name of Product**		**Product**	**Quantity to be Imported**	**Value of Product(s)**
	Brand Name	**Common Name**	**Registration Number**		
	TOTAL (FOB Value)				

Fees **Receipt No.** **Date of Receipt**

.....

PART B: GRANTING PERMISSION

Permission is hereby granted to import the above mentioned product(s). The Importer has to contact the Port TFDA Inspector to examine the approved product(s) for fitness of the intended use before being granted entry into Tanzania Mainland.

Date **FOR: DIRECTOR GENERAL AND STAMP**

PART C: DECLARATION BY TFDA INSPECTOR

I.....being TFDA inspector at **.....** port office has

examined the above listed product(s) and found them **fit/unfit** for the intended use and I therefore **grant/not grant** entry into Tanzania Mainland.

_____ _____

Date **Signature of TFDA Port Inspector and Stamp**

Note:

- This Permit is for ***single consignment*** only and shall be valid for ***Six Months*** from the date of authorization.
- The Inspector has to return immediately a completed copy of this permit bearing **Release Stamp** to TFDA Zone Manager.

Part II: Certificate for Importation of Controlled Drugs
(Made under Regulation 9(4))

FORM A:
Import Certificate Issued
By the United Republic of Tanzania

Serial No.....
File No.....

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

Email: info@tfda.go.tz
Telephone:255 22 2450512, 2450751
Fax No.255 22 2450793
Direct line: 255 22 2450979
All letters should be addressed to Director General
In reply please quote:

TANZANIA FOOD AND DRUGS AUTHORITY
P.O.BOX 77150
DAR ES SALAAM

Certificate of Official Approval of Import

(*Section 78(1)* Food, Drugs and Cosmetics Act,2003)

I, being the person with the administration of the Law relating to Narcotic drugs/psychotropic substances/precursors to which the International Convention on Narcotic Drugs /Psychotropic Substances/Precursors apply, hereby certify that I have approved the importation by;-

.....

Of:.....

From:.....

Subject to condition that:-

i) the consignment shall be imported before the .....
and

ii) the consignment shall be imported by .....

through .....

and that I am satisfied that the consignment proposed to be imported is required:-
solely for medical purposes and scientific purposes:-

....

Signature and Stamp Of the
Director General, Tanzania Food and Drugs Authority

This document is solely for production to the Government of the country from which the drugs are proposed to be obtained

Part III: Export Permit

(Made under Regulation 12)

TANZANIA FOOD AND DRUGS AUTHORITY

EXPORT PERMIT

Export Permit No:

PART A: PARTICULARS OF EXPORTER

Name of Exporter.....Postal address .....Tel. No.....

Importing Country.....Invoice No.....Date.....

Importer/Receiver.....Postal address….....

Mode of Transport (i.e. ship,air or motor vehicle).....via.....Port of Exit

S/N	Name of Product(s)	Quantity	Value of Product(s)

PART B: GRANTING PERMISSION

Permission is hereby granted to export the above mentioned product(s). The Exporter has to contact the Port TFDA Inspector to examine the approved product(s) before being granted exit from Tanzania Mainland.

Date

FOR: DIRECTOR GENERAL AND STAMP

.....

PART C: DECLARATION BY TFDA INSPECTOR

I.....being TFDA inspector at **.....** port office has examined the above listed product(s) and I therefore **grant/not grant** exit from Tanzania Mainland.

_____ _____

Date **Signature of TFDA Port Inspector and Stamp**

This permit is valid from: ..... to .....

Note:

- The Inspector has to return immediately a completed copy of this permit bearing **Export Stamp** to TFDA Zone Manager.

Third Schedule

(Made under Regulation 15(1))

Application form for procurement of Narcotic Drugs

TFDA Tanzania Food & Drugs Authority	**APPLICATION FOR PROCUREMENT AND USE OF NARCOTIC DRUGS**	**F01/DMC/MCIE/G/010** **Rev #:0**

Director General,
Tanzania Food and Drugs Authority,
P.O.Box 77150,
DAR ES SALAAM

Name of Hospital:

Registration Number:

Postal Adress:

Physical Address:

Name of the Medical Officer in Charge/Superintendent:
Dr..... Registration .....
The Drugs will be under control of Pharmacist Incharge:
Name .....Profession .....
Registration Number .....
Pharmacist incharge Photograph

Attach photograph

I/We do hereby apply to procure and use the following narcotic drugs:

Name of narcotic drug:	Annual estimates”
1.....	.....
2.....	.....
3.....	.....

Name of the Medical Officer In charge .....

Signature..... Date.....

Fourth Schedule

(Made under Regulation 17(1))

TFDA Tanzania Food & Drugs Authority	**NARCOTIC DRUGS LEDGER BOOK Record of Dispensed Narcotic drugs in the Ward of Health Institution**	**F03/DMC/MCIE/G/010 Rev #:0**

Name of Health Institution.....

Address: P.O.Box ..... Tel.....

Name and Strength of Narcotic Drug.....

Serial/Page Number.....

Date	Name of Patient	Sex and Age	Diagnosis	Prescribed by	Dose	Prescription Serial No.	Quantity Dispensed	Given/ Dispensed /Administered	Checked/Witnessed by	Balance	Name &Signature of In charge

Note: The Prescriptions issued shall be kept whenever used

Fifth Schedule

(Made under Regulation 17(1))

TFDA Tanzania Food & Drugs Authority	**NARCOTIC DRUGS LEDGER BOOK Record of Used Narcotic drugs in a facility**	**F04/DMC/MCIE/G/010 Rev #:0**

Name of Health Institution.....
Address: P.O.Box ..... Tel.....
Name and Strength of Narcotic Drug.....
Serial/Page Number.....

Date	Received from	Quantity received	GRN	Issued to	Quantity Issued	Requisition No.	Remaining Balance	Name and Signature of Receiving Officer	Remarks

Note: The Prescriptions issued shall be kept whenever used

Sixth Schedule

(*Made under Regulation 18*)

TFDA Tanzania Food & Drugs Authority	**QUARTERLY CONSUMPTION REPORT FOR Narcotic Drugs /Psychotropic substances/ Precursor chemicals usage in a Health Institution**	**F05/DMC/MCIE/G/010 Rev #:0**

These statistics should be sent to the following address before the end of each quarter;

Director General,
Tanzania Food and Drugs Authority,
P.O.Box 77150,
Dar Es Salaam.
Tel:+255 22 2450512, 2450751 & 2450108
Fax: +255 22 2450793
Email:Info@tfda.go.tz

Name of Reporting Organization .....
Address: Region..... City/ Town.....
P.O. Box..... Tel.....
These statistics relate to the.....quarter of the calendar year.....

S/N	Name of Narcotic Drug/ Psychotropic substances /Precuursor chemical	Dosage form	Strength	Stock at the beginning of this quarter	Quantity Purchased/Imported	Purchased or Imported from	Quantity Consumed	Stock at the end of this Quarter	Remarks

Name and stamp of Authorized Reporting Officer .....

TFDA Tanzania Food & Drugs Authority	**QUARTERLY CONSUMPTION REPORT FOR Narcotic Drugs /Psychotropic substances/ Precursor chemicals used in a manufacturing facility**	**F06/DMC/MCIE/G/010 Rev #:0**

These statistics should be sent to the following address before the end of each quarter;

Director General,
Tanzania Food and Drugs Authority,
P.O.Box 77150,
Dar Es Salaam.
Tel:+255 22 2450512, 2450751 & 2450108
Fax: +255 22 2450793
Email:Info@tfda.go.tz

Name of Reporting Organization .....
Address: Region..... City/ Town.....
P.O. Box..... Tel.....
These statistics relate to the.....quarter of the calendar year.....

S/N	Substance Imported	Quantity Imported (Kg/gm)	Quantity Consumed for manufacturing (Kg/gm)	Name and Dosage form of the product (s) manufactured	Quantity held in stock at the end of the quarter(Kg/gm)

Name and stamp of Authorized Reporting Officer.....

TFDA Tanzania Food & Drugs Authority	**ANNUAL CONSUMPTION REPORT FOR Narcotic Drugs /Psychotropic substances/ Precursor chemicals usage in a Health Institution**	**F02/DMC/MCIE/SOP/006 Rev #:0**

These statistics should be sent to the following address before the end of each quarter;

Director General,
Tanzania Food and Drugs Authority,
P.O.Box 77150,
Dar Es Salaam.
Tel:+255 22 2450512, 2450751 & 2450108
Fax: +255 22 2450793
Email:Info@tfda.go.tz

Name of Reporting Organization .....
Address: Region..... City/ Town.....
P.O. Box..... Tel.....
These statistics relate to the calendar year.....

S/N	Name of Narcotic Drug/ Psychotropic substances /Precursor chemical	Dosage form	Quantity				Stock at the end of this Year	Remarks
			At the beginning of this year	Imported	Locally purchased	Distributed/ consumed		

Name and stamp of Authorized Reporting Officer .....

TFDA Tanzania Food & Drugs Authority	**ANNUAL CONSUMPTION REPORT FOR Narcotic Drugs /Psychotropic substances/ Precursor chemicals used in a manufacturing facility**	**F06/DMC/MCIE/G/010 Rev #:0**

These statistics should be sent to the following address before the end of each quarter;

Director General,
Tanzania Food and Drugs Authority,
P.O.Box 77150,
Dar Es Salaam.
Tel:+255 22 2450512, 2450751 & 2450108
Fax: +255 22 2450793
Email:Info@tfda.or.tz

Name of Reporting Organization .....
Address: Region..... City/ Town.....
P.O. Box..... Tel.....
These statistics relate to the.....quarter of the calendar year.....

S/N	Substance Imported	Quantity Imported (Kg/gm)	Quantity Consumed for manufacturing (Kg/gm)	Name and Dosage form of the product (s) manufacctured	Quantity held in stock at the end of the year (Kg/gm)

Name and stamp of Authorized Reporting Officer.....

Dodoma,

……. ……., 2018

UMMY A. MWALIMU

Minister for Health, community Development, Gender, Elderly and Children