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THE PHARMACY ACT,
(CAP. 311)

REGULATIONS

(Made under section 55(f))

THE PHARMACY (PRESCRIPTION HANDLING AND CONTROL) REGULATIONS, 2020

ARRANGEMENT OF REGULATIONS

THE PHARMACY ACT,
(CAP. 311)

REGULATIONS

(Made under section 55(f))

THE PHARMACY (PRESCRIPTION HANDLING AND CONTROL) REGULATIONS, 2020

PART I
PRELIMINARY PROVISIONS

Citation

1. These Regulations may be cited as the Pharmacy (Prescription Handling and Control) Regulations, 2020.

Interpretation

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

Cap.311 "Act" means the Pharmacy Act;

Cap.219 "controlled drug or controlled medicine" means a narcotic drug, psychotropic substance or precursor as listed under the Tanzania Medicine and Drugs Act;

"Council" means the Pharmacy Council established under section 3 of the Act;

"dispense" has the same meaning as ascribed to it under the Act;

"dispenser" means a pharmacist, pharmaceutical technician, pharmaceutical assistant or medicine dispenser recognized by the Council;

"electronic prescription" means a prescription that is generated electronically;

Cap.152 "medical practitioner" has the same meaning as ascribed to it under the Medical, Dental and Allied Health Professionals Act;

"Minister" means the Minister for the time being responsible for matters relating to health services;

"pharmaceutical personnel" means a speciality pharmacist, pharmacist, pharmaceutical technician, pharmaceutical assistant or dispenser recognized by the Council;

"pharmacist" means a person registered under section 16 of the Act;

"pharmacy" has the same meaning as ascribed to it under the Act;
"prescriber" means a medical and allied health practitioner;
"prescription medicine" has the same meaning as ascribed to it under the Act;
"prescription" has the same meaning as ascribed to it under the Act; and
"transmission" means the process where the prescription is sent by the prescriber to a pharmacy.

PART II
PRESCRIPTION HANDLING

Restriction on sell of prescription medicines

3.-(1) A person shall not sell by retail or dispense prescription medicines unless the buyer produces a valid prescription issued in accordance with these Regulations.

(2) A person who contravenes subregulation (1) commits and offence and on conviction shall be liable to a fine of not less than five hundred thousand shillings but not exceeding five million shillings or imprisonment for term not exceeding twelve months or to both.

Types and validity of prescriptions

4.-(1) The prescription under these Regulations may be generated manually or electronically.

(2) A prescription under subregulation (1) shall be in a manner set out in the First Schedule and contain the following particulars:

(a) serial number;
(b) name, level, registration number and address of health facility;
(c) day, month and year of prescription generation;
(d) name, age, sex, body weight and physical address of patient;
(e) disease code, where applicable;
(f) generic name of medicine (unless there is a clinical or safety reason for a particular brand in which the brand name should be specified), dosage form, strength and dosage;
(g) prescriber name, designation, registration and telephone number, signature and stamp;
(h) period of supply, refill (if any); and
(i) any other dispensing conditions as the prescriber may specify.

(3) A prescription shall be valid for a period of seven days from the date of generation.

(4) Notwithstanding the provisions of subregulation (3), a prescription shall be valid for one hundred and eighty days if such prescription contains refills for clinically stable patients which have been monitored for some time.

(5) A refill under subregulation (4) shall not be permitted for controlled drugs.

Generation and transmission of prescription

5.-(1) A prescriber shall, in generating a prescription-

(a) adhere to good prescribing standards and scope of practices;

(b) comply with standard treatment guidelines, national and international approved clinical guidelines or protocols;

(c) observe expert opinions and current available evidence;

(d) comply with essential medicines list per facility level;

(e) comply with regulations for scheduling of medicines and directives that guides prescribing practices for controlled drugs; and

(f) ensure that prescription is written in English or Swahili, legible and dully filled in.

(2) A prescriber shall, in transmitting a prescription, ensure that-

(a) each prescription is in triplicate;

(b) each prescription transmitted originates from the prescriber;

(c) the process of transmitting prescription maintains patient confidentiality; and

(d) the patient has a choice of pharmacy where the prescription is to be filled.

(3) A prescriber who contravenes the provisions of this regulation commits a professional misconduct and shall be dealt with in accordance with the procedures stipulated in the Act.

Dispensing of prescription

6.-(1) A dispenser shall, in dispensing a prescription-

(a) authenticate prescription and validity of a prescriber before dispensation;

(b) adhere to the good dispensing procedures;

(c) not dispense drugs on illegible or invalid prescriptions;

(d) consult with a prescriber when there are discrepancies, need of correction, adjustment, change of medicines or confirmation;

(e) ensure that such prescription is dully filled in and signed by all parties;

(f) retain original and second copy of a handwritten prescription when all medications are fulfilled in a prescription and handle third copy to the patient.

(2) Without prejudice to the provisions of subregulation (1), prescriptions for controlled drugs shall-

(a) contain only one type of drug;

(b) be completely written in the prescriber's hand writing;

(c) contain quantity of medicine or substances in both words and figures;

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(d) be handled pursuant to the Drug Control and Enforcement Act and Tanzania Medicine and Medical Devices Act; and

(e) be counter signed by a patient or *bonafide* representative during dispensing process.

(3) For purpose of ensuring safety and welfare of patient, a dispenser may dispense part fills.

(4) A dispenser who contravenes the provisions of this regulation commits a professional misconduct and shall be dealt with in accordance with the procedures stipulated in the Act.

Restriction on adjustment of prescription

7.-(1) A person shall not adjust prescription unless that person is a pharmacist and has consulted with the prescriber.

(2) Any adjustment in subregulation (1) shall be for purposes of-

(a) improving adherence of the medication;

(b) managing interaction between drugs;

(c) ensuring that the dosage is right based on clinical parameters; and

(d) preventing serious damage to health.

(3) Adjustment under this regulation shall-

(a) be completed by dully filled in form set out in the Second Schedule; and

(b) restricted to the following:

(i) change the formulation of a medication;

(ii) substituting different brands of the same generic medicines;

(iii) modify the regimen by adjusting the frequency or time of day the medication should be taken;
(iv) adjust the quantity to facilitate the management of medications;
(v) change the dose to reach a therapeutic target or reduce adverse effects; and
(vi) change or remove of medication when necessary within the health facility only.

(4) A person who contravenes the provisions of this regulation commits a professional misconduct and shall be dealt with in accordance with the procedures stipulated in the Act.

Prescriptions at various level of health facilities

8.-(1) For the purpose of controlling and monitoring the use of prescriptions, health facilities shall have different colors of prescription depending on the level of the facility as follows-

(a) white for tertiary level health facilities;
(b) yellow for secondary level health facilities;
(c) blue primary level health facilities; and
(d) any other category as the Council may determine.

(2) A person who contravenes the provisions of this regulation commits an offence and shall, upon conviction, be liable to a fine of not less than two million shillings but not more than ten million shillings or to imprisonment for a term of not less than twelve months or to both.

PART III
GENERAL PROVISIONS

Register

9.-(1) Every pharmacy shall keep and maintain a prescription register which shall contain the following information-

(a) date on which the medicine was dispensed;
(b) name, strength, dosage form, the quantity supplied and batch number;
(c) name and address of the person to whom the medicine was supplied;
(d) name, address, registration number and authenticity of a prescriber; and
(e) name and address of a prescribing health facility and prescription number.

(2) Prescription register may be in a paper based or electronic form, and shall be in serial number for reference.

(3) A person who contravenes the provisions of this regulation commits an offence and shall, upon conviction, be

liable to a fine of not less than one million shillings but not more than ten million shillings or to imprisonment for a term of not less than six months or to both.

FIRST SCHEDULE

(Made under regulation (4(2)

PHARMACY COUNCIL

Prescription

Serial No._____

NAME AND ADDRESS OF AN INSTITUTION
Name…….…… Level…...…… Registration No……..…
Region…..…….…… District…… Street/village……..…. P.O. Box..... Tel.....

A. PATIENT INFORMATION
Name of a patient ..... Age..... Sex ..... Kgs…....
address…….....Tel……

℞ No._____

Brief Diagnosis or Disease Code *(if applicable)*:

B. DRUGS PRESCRIBED (generic name, dosage form, strength and dosage)	DRUGS DISPENSED	
	TICK	QUANTITY
.....		
.....		
.....		
.....		
.....		
.....		
.....…….…		
……		
……..		

C. PRESCRIBER INFORMATION
Name..... Designation……..……
Reg.No……. Signature &
Stamp.....
Date.....

D. DISPENSER INFORMATION
Within the health Facility ( ) Tick
Remarks (if any) ie. prescription
adjustment.....
1. Name……. Designation…… Reg.No…… Signature.....
Tel……..……Date……
Community Pharmacies or ADDOs ( ) Tick
Remarks (if any) ie. prescription
adjustment……
Name of the pharmacy or ADDO…….. Region……...
District……..…… FIN……..……...……
2. Name (dispenser)……..……..…… Designation……
Reg.No…..…….. Signature.....
Tel……..……. Date……...…

E. AUTHENTIFICATION OF MEDICINES DISPENSED TO PATIENT
Patient / bona fide name……..….
Phone……...……...Signature…….……

F. REFILLS	Dates for subsequent refills and quantity	D1…… …..	D2…… ….	D3…… …..
	Name of Health Facility or Pharmacy			
	Name of dispenser			

SECOND SCHEDULE

(Made under regulation 7(3)(a))

PHARMACY COUNCIL

Prescription adjustment form

(Consultation shall be made between the pharmacist and the prescriber before adjustment by filling in this form)

PRESCRIPTION DETAILS
Prescription Serial No ……Issued by (prescriber)……...……Institution…….……Dated…..…….

A. MEDICINE (S) SUBJECT TO ADJUSTIMENT:

……

……

……

……

……

B. ADJUSTIMENT GROUNDS: (tick)

1. Prescription unacceptable		8. Quantity of a drug	
2. Formulation		9. Route/administration	
3. Potential drug interaction		10. Duration of treatment	
4. Non-Policy or formulary		11. Allergy	
5. Dose		12. ADRs	
6. Frequency		13. Drug choice	
7. Substitute brand			

14. Other (Specify)…… ……

…… ……

C. CONSULTATION WITH A PRESCRIBER
(Mode of consultation)
1. Phone ☐ 2. Writing ☐ 3. Email ☐ 4. Other (mention)…….

Prescriber opinions:……..…….
…….
Name……..……Qualification……. Reg. No……..... Tel…….

D. PHARMACIST OPINION
1. Prescription rejected (*Return the Prescription to the Prescriber if rejected)* ☐
2. Necessary adjustments made ☐

E. DETAILS OF ADJUSTIMENT MADE:
……
……
……
……
……
……

Pharmacist information
Name……..… Reg. No……... Signature.....Tel……..…..Date…….……
Name and address of the pharmacy
……..…….
(*Dispense the prescription if adjustments are made and attach a copy of this form to the original prescription*)

Dodoma,
27th December, 2019

UMMY A. MWALIMU,
Minister for Health, Community Development, Gender, Elderly and Children