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THE PHARMACY ACT
(CAP. 311)

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REGULATION

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THE PHARMACY (ACCREDITED DRUGS DISPENSING OUTLETS) (STANDARDS AND ETHICS FOR DISPENSATION OF MEDICINES) REGULATIONS, 2019

ARRANGEMENT OF REGULATIONS

PART VII
GENERAL PROVISIONS

SCHEDULES

GN. NO. 185 (contd)

THE PHARMACY ACT
(CAP.311)

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REGULATIONS

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(Made under section 55(r))

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THE PHARMACY (ACCREDITED DRUGS DISPENSING OUTLETS) (STANDARDS AND ETHICS FOR DISPENSATION OF MEDICINES) REGULATIONS, 2019

PART I
PRELIMINARY PROVISIONS

Citation

1. These Regulations may be cited as the Pharmacy (Accredited Drugs Dispensing Outlets) (Standards and Ethics for Dispensation of Medicines) Regulations, 2019.

Application

2. These Regulations shall apply to-

(a) every person or group of persons permitted or otherwise allowed by the Minister to dispense medicines or operate an Outlet pursuant to section 40 of the Act;

(b) every Outlet accredited pursuant to these Regulations.

Interpreta-tion

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

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"Act" means the Pharmacy Act;

"ADDO Prescription Medicines" means medicines prescribed under the Fifth Schedule of the Tanzania Food Drug and Cosmetic (Scheduling of Medicines) Regulation 2015;

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"business permit" means a permit issued in terms of regulation16(1) to operate an Outlet;

"Committee also prescribed as CFDC" means the Council Food and Drug Committee established pursuant to these Regulations;

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

"Outlet" also prescribed as "ADDO", "DLDM" or "*Duka la*

Dawa Muhimu" means premises accredited under these Regulations to provide drugs dispensing services to the communities in rural or peri-urban areas;

"dispenser" means a person who is permitted to work as a dispenser of medicines at an Outlet subject to the provisions of these Regulations;

"Certificate" means a dispensing certificate awarded to a dispenser as provided under regulation 26;

"health care worker" means a person who holds a basic knowledge in medical, pharmaceutical or related qualifications as recognized by the respective Council or Board;

"owner" means the proprietor of an Outlet;

"over the counter medicines" also described as "OTC medicines" means medicines prescribed under the Third Schedule of the Tanzania Food Drug and Cosmetic (Scheduling of Medicines) Regulation 2015;

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"pharmaceutical personnel'' means a registered pharmacist, enrolled pharmaceutical technician or enlisted pharmaceutical assistant and recognized medicine dispenser;

"pharmaceutical technician" means person enrolled under section 24 of the Act;

"pharmaceutical assistant" means a person enlisted under section 28 of the Act;

"medical practitioner" has the same meaning ascribed to it under the Medical Practitioners and Dentists Act;

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"medicines dispenser" means a person who has undergone at least one year training course in pharmaceutical sciences from a recognized academic institution and approved by the Council;

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"public servant" has the same meaning ascribed to it under the Public Service Act;

"ward health committee" means the committee of a respective ward of local government authority associated with health related matters;

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"peri – urban" has the same meaning ascribed to it under the Land Act.

PART II
ADMINISTRATIVE PROVISIONS

Objectives of operating Outlets

4. An Outlet shall be accredited for the purpose of :

(a) enhancing access to safe, good quality and efficacious medicines to the rural and peri-urban populations;

(b) ensuring that medicines are affordable to the rural and peri-urban populations;

(c) ensuring easy monitoring and control distribution of medicines;

(d) ensuring that adequate medicines information and services are provided to the public

Establishment and composition of CFDC

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5.-(1) For the better carrying out the objectives stipulated under regulation 4, the Council Food and Drugs Committees, also known by acronym "CFDC", established under the Tanzania Food, Drugs and Cosmetics (Delegation of Powers and Functions) Regulations, 2015 shall, subject to sub regulation (2), have mandates to perform functions and discharge duties stipulated under these Regulations.

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(2) Notwithstanding any provisions of the Tanzania Food, Drugs and Cosmetics (Delegation of Powers and Functions) Regulations, 2015, the Council Food and Drugs Committee shall be composed of the following members:

(a) District Executive Director who shall be the Chairman;
(b) District Medical Officer who shall be Secretary;
(c) District Pharmacist who shall be a coordinator;
(d) District Health Officer;
(e) District Trade Officer;
(f) District Legal Officer;
(g) District Treasurer;
(h) a representative of ADDO owners.

(3)The Committee may, for the purpose of exercising its mandate under these Regulations, co-opt any person to its meetings as the Committee may consider necessary.

(4)Subject to regulation 6, the Committee shall, for the purpose of these Regulations, oversee the management and operations of Outlets within the local authority area in which such Committee situates.

(5) The District pharmacist shall be responsible for coordinating all activities vested in the Committee in the respective District.

Function of the Committee

6. The Committee shall be responsible for -

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(a) performing functions stipulated under the First Schedule to the Tanzania Food, Drugs and Cosmetics (Delegation of Powers and Functions) Regulations, 2015;

(b) advising the Council on all matters relating to personnel, operations, and premises management, and in particular it shall:

(i) evaluate and recommend applications for approval;

(ii) recommend for revocation of permits issued pursuant to the Act;

(c) conducting supervision and inspection in Outlets;

(d) preparation and submission of quarterly reports to the Council and copy thereof to the Regional Food and Drug Committee;

(e) taking action in response to inspection from Ward Health Committee;

(f) advising the Council on matters pertaining to enforcement of the Act;

(g) renewal of ADDO business permits;

(h) handling complaints from the lower levels;

(i) carrying out such other functions as may be assigned to it by the Council;

(j) collection of fees and charges prescribed pursuant to these Regulations on behalf of the Council.

Vesting mandate to Ward Health Committee

7.-(1) A Ward Health Committee shall discharge duties stipulated under regulation 16, and any other duties assigned to it pursuant to these Regulations.

(2) In discharging its duties, the Ward Health Committee may, co-opt a pharmaceutical personnel or medicines dispenser of the respective ward.

(3) A Ward Health Committee shall prepare and submit quarterly reports to the Ward Development Committee and the CFDC.

PART III
ACCREDITATION OF OUTLETS

Restriction for operation of Outlet

8.-(1) A person shall not operate, sell or dispense medicinal products in any premises for which these Regulations relate except in premises accredited and issued with a valid business permit in accordance with these Regulations.

(2) A person who contravenes this regulation commits an offence.

Application for Accreditation

9.-(1) A person who wishes to operate an Outlet shall, apply for accreditation by filling in the application form provided under First Schedule of these Regulations upon payment of prescribed fees.

(2) Without prejudice to sub-regulation (1), an applicant shall, after filling in the application form, submit the duly completed application form to the Village Executive Officer of the village or street in which the prospective Outlet situates who shall review, recommend and submit the forms to the Ward Executive Officer.

(3) The Ward Executive Officer shall, upon receipt of the application form and recommendations of the Village Executive Officer, and within the earliest possible time, convene the Ward Health Committee with a view to decide on the application.

(4) In deciding the application, the Ward Executive Committee-

(a) may-

(i) make a site inspection of the prospective Outlet location, for the purpose of collecting necessary information and making recommendations thereof;

(ii) interview the applicant and proposed dispenser;

(iii) request for evidence of qualifications for the proposed dispenser;

(iv) undertake preliminary inspection of the premises; and

(v) prepare brief report using inspection checklist approved by the Council on their preliminary findings of inspection of premises;

(b) shall consider-

(i) applicant's citizenship;

(ii) applicant's attitude and behavior;

(iii) residential address;

(iv) the need for the service in the community;

(v) past and current business activities carried out by that applicant; and

(vi) location and physical address of the proposed premises.

(5) A Ward Health Committee shall not carry out inspection for the purpose of either refusing or approval of the application forms submitted.

(6) The application forms and report including the recommendations of the Ward Health Committee shall be submitted to the CFDC.

(7) The undertaking of the Ward Health Committee and submission of its report to the CFDC shall not take longer than twenty eight days from the date of receipt of completed application.

(8) Upon receiving the applications, the CFDC shall conduct physical inspection of premises for verification and compliance of premises and personnel as specified in these Regulations.

Scrutinization of applications

10.-(1) The District Pharmacist shall compile all applications received, prior to submission to the Committee for consideration.

(2) Upon receipt of compiled report, the Committee shall scrutinize the applications by previewing all application forms and attachment including inspection report and copy of contract between the owner and dispenser.

(3) The Committee may, at any reasonable time, require the applicant to furnish to it any additional information as it may consider appropriate.

Submission of report and recommendation to Council

11.-(1) The Committee shall, at least on quarterly basis, discuss all applications from the area of its jurisdiction, and prepare a report of applications and submit the recommended list of applicants to the Council for approval.

(2) The Committee shall forward to the Regional Administrative Secretary a copy of the report prepared in terms of sub regulation (1).

Determination of recommendation

12. -(1) The Council shall, not later than twenty one days from date of receipt of the report, determine the recommendations issued to it in terms of regulation 11.

(2) In making determination the, Council may approve or disapprove the recommendations,

Provided that, where the Council has disapproved the recommendations of the CFDC, the Council shall provide reasons for the disapproval.

(3) The determination under sub-regulation (2) shall be communicated to the respective Committee which shall notify the respective applicant accordingly.

(4) An applicant whose application has been approved by the Council shall, upon receipt of approval notification, pay to the Council, the prescribed fee.

Accreditation and issuance of permit

13.-(1) The Council shall, upon receipt of proof of payment of accreditation fee, issue a non transferable Outlet Certificate of Accreditation and Business Permit as prescribed in the Second Schedule.

(2) Every permit issued by the Council to the Outlet shall expire on 30th of June every year, and may be renewed subject to the fulfillment of the provisions of these Regulations.

(3) A person whose business permit is due to expire shall, at least three months before the expiry of the permit, apply to the CFDC for renewal of the permit as prescribed in the First Schedule.

Reaccreditation of Outlet

14.-(1) Notwithstanding the requirements provided under regulation 13 (2), an accredited Outlet shall be re-accredited after every three years, upon maintaining requirements as prescribed in these Regulations.

(2) Subject to the provisions of sub section 27 (4) of the Act, the Council shall have the power to approve or disapprove applications for re-accreditation depending on prevailing circumstances.

(3) An applicant for re-accreditation shall be required to pay re accreditation fee which shall be equal to the accreditation fee.

Allocation and distribution of funds to Committee

15.-(1) For the better carrying out of the functions of the Committee, all monies derived from payment of fees under these Regulations shall be allocated and distributed to each Committee as the Council shall determine.

(2) In determining an amount to be allocated to each Committee, the Council shall consider activities plan and amount collected by each Committee.

Conditions of operation of Outlets

16. A person duly permitted to operate an Outlet shall at all times-

(a) observe the standards, conduct and ethics of operation of Outlets as prescribed under these Regulations;

(b) comply with the good dispensing practice and relevant guidelines of a registered premises.

Revocation and cancellation of certificates and permits

17.-(1) The Registrar shall, upon satisfaction that a holder of dispensing certificate, accreditation certificate or business permit is operating an Outlet, in contravention to these Regulations or any other written law, cancel or revoke the dispensing certificates, accreditation and business permit, as the case may be.

(2) Notwithstanding sub-regulation (1), the Registrar, shall by notice remove or cancel from the register the name of any person or premises on the grounds that the person-

(a) has failed to comply with any provision of these Regulations or any other written law;

(b) has not fulfilled conditions to be recognized as ADDO dispenser;

(c) has requested that his name be removed from the register, in which case, such person shall be required to lodge with the Registrar an affidavit to the effect that no disciplinary or criminal proceedings are being or are likely to be taken against him;

(d) has failed to pay to the Council, within six months as from the date on which it became due for payment, any prescribed fee;

(e) is dead,

(f) is found unfit to practice;

(g) has been declared bankrupt by a competent court of law;

(h) has been convicted by a competent court of law of a criminal offence with serving sentence of more than one year; or

(i) has failed to furnish the Registrar, within a period of

two months with such information as the Registrar may require in terms of these Regulations.

(3) Notice of removal, under of sub regulation (2), shall be given by the Registrar in writing to the person concerned through the address of that person as appearing in the register, and such person shall, from the date on which notice has so been given, cease to practice as dispenser or owner of an Outlet or perform any act which he was entitled to perform under these Regulations; and any permit or certificate issued to him shall be deemed to have been cancelled.

(4) Any person who is aggrieved by the decision of Council under this regulation may, within twenty eight days from the date of receipt of decision of the Council, appeal to the Minister.

Surrender of certificates and permits

18. A person whose certificate or business permit is suspended or cancelled from the register shall, within twenty eight days, be required to surrender to the Registrar, his certificate, business permit and any other documents bearing identification or ownership of the Council.

Restoration of name to the register

19. Where a certificate or permit of an Outlet is suspended in terms of these Regulations, the Registrar may restore the ADDO to the register if the permit holder-

(a)applies in the prescribed form for such restoration;

(b)complies with, or remedies any matter that rendered his suspension;

(c)pays the prescribed fee in respect of such restoration; and

(d)complies with such other requirements as the Council may determine.

PART IV
STANDARDS OF OPERATION OF OUTLETS

(a)Personnel

Qualification of Dispenser at Outlet

20.-(1) A person shall qualify to be a dispenser of medicines at an Outlet if the person-

(a) is recognized by the Council as pharmaceutical personnel other than a registered pharmacist; or

(b) qualifies to practice as:

(i)trained nurse;
(ii)enrolled nurse;
(iii) clinical officer;
(iv) assistant clinical officer;
(v)assistant medical officer;
(vi)medical officer; or
(vii)community health worker

(2) Without prejudice to sub-regulation (1), a public servant shall not qualify to practice as dispenser of medicine at an Outlet.

Dispensers Training Course

21.-(1) Except for pharmaceutical personnel, persons referred to under regulation 23(1) (b) shall be required to complete the Dispenser Training Course approved by the Council.

(2) The Dispenser Training Course shall be conducted for a period of not less than five weeks.

(3) The content of the Dispenser Training Course shall be determined by the Council after taking into account the applicant's minimum qualification.

(4) A dispenser of medicine at an Outlet shall, upon successful completion of the Dispenser Training Course, be awarded a Dispensing Certificate as prescribed in the Seventh Schedule

Services to be provided at an Outlet

22. Save as otherwise provided in the Act, the services to be provided at an Outlet shall include:

(a)the purchasing, acquiring, keeping, possessing, using, supplying or selling of any general sale medicines, OTC medicines and ADDO prescription only medicines;
(b)taking care of the medicine related needs of clients, including-
(i) determining the indication, safety and effectiveness of therapy;
(ii)furnishing of relevant information and advice to any person with regard to medicine;
(iii) determining client's compliance to the therapy and follow-up to ensure that the client's needs are being met;
(c)nutritional and food supplements, sanitary toiletries,

hygienic products, cosmetics; and

(d) any other health services or acts as may be approved by the Council.

Categories of ADDO dispensers

23.-(1) Save as otherwise provided for in these Regulations, a person shall not dispense medicines at an Outlet unless that person is categorized as such pursuant to these Regulations or is, in any case, approved by the Council.

(2) The dispensation of medicines at an Outlet may be performed by any of the following categories of persons:

(a) Outlet dispenser;

(b) medicines dispenser;

(c) pharmaceutical technician; or

(d) pharmaceutical assistant.

Conduct of ADDO Dispensers

24.-(1) A dispenser of medicines at an Outlet shall-

(a) at all times of service:

(i) maintain a high standard of personal hygiene;

(ii) wear a prescribed attire;

(iii) wear an identification badge which bares his photo and that identifies him as a dispenser authorized to practice at the respective Outlet or at such other premises as the Council may approve;

(iv) not dispense or issue prescription drugs without prescription;

(v) not work under the influence of alcohol or illicit medicines; and

(vi) conduct himself in an appropriate and orderly behavior.

(b) ensure that the original copy of his dispensing certificate is displayed at a conspicuous place of the Outlet premises; and

(c) be accountable and answerable for all activities conducted at the respective Outlet.

(2) A person who contravenes the provision of this regulation commits an offence and shall be liable, on conviction, to-

(a) in the case of an offence under sub regulation (1)(a)(ii), a fine of fifty thousand shillings;

(b) in the case of an offence under sub regulation (1)(a)(iv), a fine of one million shillings;

(c) in the case of an offence under sub regulation

(1)(a)(vi) or (1)(b), a fine of one hundred thousand shillings.

Contract between owner and ADDO dispenser

25.-(1) The owner of an Outlet shall enter into a contract with dispenser of medicines, specifying the terms and conditions of employment as prescribed under the Third Schedule to these Regulations.

(2) A copy of the contract stipulated under sub-regulation (1), shall form part of the application for certificate and permit documents as prescribed in these Regulations, and a copy thereof shall be deposited with the Committee.

(3) Every contract shall comply with the respective employment laws.

(4) Without prejudice to freedom of parties to contract, a contract specified under sub regulation (1) shall not provide for terms or conditions that impede a dispenser of medicines at an Outlet to practice in accordance with the requirement of these Regulations.

ADDO owner's requirements

26.-(1) Save as otherwise provided in these Regulations, a person shall not own an Outlet unless the person-

(a) is a Tanzanian adult who is mentally fit;
(b) has attended ADDO awareness course;
(c) has no record of violation of any law;
(d) has no criminal record.

(2) Every owner of Outlet shall:

(a) ensure that operation procedures are in conformity with these Regulations;
(b) have valid business permit and certificate of accreditation which shall be conspicuously displayed at the Outlet premises;
(c) attend ADDO owners awareness programme organized or coordinated by the Council for that purpose;
(d) ensure that he has a certified copy of the Outlet dispenser certificate issued by the Council;
(e) ensure that, at all times of operation, the dispensation of medicines at the ADDO premises is only conducted by a person permitted to dispense medicines in terms of regulation 27 of these Regulations;
(f) promptly notify the Committee when the Outlet is

permanently closed.

(3) The Committee shall, upon receipt of the information provided under sub-regulation (2)(f), inspect the inventory and advise on the appropriate disposal of medicines or any item in the inventory.

(4) A person who contravenes the provision of this regulation commits an offence and shall, on conviction, be liable to-

(a)in the case of an offence under sub regulation (2)(b), a fine of one hundred thousand shillings;

(b)in the case of an offence under sub regulation (2)(e), a fine of one million shillings;

Occurrence of theft

27. An ADDO owner or such other authorized personnel shall, in the event of an occurrence of theft or such similar incident occasioning loss of medicines at an Outlet, report the incident at a nearest police station and notify the Committee or Council thereof.

Awareness program for ADDO owners

28.-(1) Every owner of an Outlet shall attend awareness program formulated and approved by the Council.

(2) Upon completion of the program referred to under this regulation, an Outlet owner shall be awarded a certificate of attendance by the Registrar or any other person authorized by the Registrar:

Provided that, the certificate of attendance shall be issued upon payment of the prescribed awareness program fee.

Continuing education for ADDO dispenser

29.-(1) An Outlet dispenser shall attend and complete annual continuing education prescribed by the Council.

(2) The continuing education program referred to under sub regulation (1) shall be an added advantage in the determination of renewal or grant of permit.

(b)Location and premises requirements

Location of ADDO premises

30.-(1) An Outlet shall be exclusively established in rural and peri-urban areas as determined by a local government authority.

(2) Every Outlet shall be located at a distance of not less than 500 metres in radius from pharmacy, 150 metres in radius from an Outlet in peri-urban areas, and 100 metres in radius from Outlet in rural areas, and such distances may be

determined or varied depending on the population of a particular area or any other factor as may be determined by the Council.

(3) Notwithstanding sub regulation (2), in case where the pharmacy is established at a distance less than 500 meters from an existing ADDO premises, a notice of two years shall be given to ADDO owner to upgrade his services.

(4) A person wishing to carry on a business of an Outlet shall, when applying for accreditation, clearly state the location and address of his premises in the application.

(5) The Council may, basing on local demand and need for pharmaceutical service, direct an applicant for an Outlet to locate his business in other appropriate locations so as to reduce unnecessary congestion and provide services to underserved community.

(6) Subject to sub regulation (5), an applicant who is not satisfied with decision of the Council may, within twenty one days from the date of receipt of the decision, appeal to the Minister.

Design and description of ADDO Premises

31.-(1) Every owner of an Outlet shall, for the purpose of registration, ensure that such Outlet-

(a) is durable and strong;

(b) is roofed with materials which shall make it free form leakages;

(c) is well protected from entry of rodents, birds, vermin and pets;

(d) has adequate space to carry out primary functions of storage, dispensation and sale of pharmaceutical products as follows:

(i) in the case of prescription only medicines, storage shall be in an exclusive area of the Outlet;

(ii) non-prescription medicines may be displayed in the dispensing area;

(e) is designed in a manner in which:

(i) doors and windows are well secured to prevent theft and unauthorized entry; and

(ii) a minimum of two rooms, one for dispensing and the other one for storage, whereby the dispensing room has at least 4 meters by 4 meters and height of 2.5 meters, while the store room has at least half size of the dispensing

room with shelves and adequate aeration;

(f) has surface with smooth finishing that can be cleaned with disinfectants;

(g) has sufficient space separate to allow for counseling of patients within the confines of the premises;

(h) has space within which ADDO prescription medicines shall be conspicuously displayed;

(i) has rooms that are painted with washable white colour;

(j) has adequate supply of clean and safe water, and includes having in place a hand washing sink; and

(k) is in compliance with general hygiene standards in terms of the surroundings and outer space of the premises.

(2) The premises shall have the following descriptions:

(a) standard logo in the design set out under the Fourth Schedule to these Regulations, and which shall be issued to an applicant upon payment of the prescribed fee to the Council;

(b) as a minimum requirement, the name of the Outlet to be clearly displayed on the front part of the premises; and

(c) "NO SMOKING" sign conspicuously placed to prohibit smoking in the premises.

(3) An ADDO owner or any other responsible person shall, at all times of operation of ADDO business, ensure the ADDO premises are maintained within the standards and requirements under sub regulation (1).

(4) A person who contravenes any provisions of this regulation commits an offence and shall, on conviction, be liable to a fine of two hundred thousand shillings.

Products for dispensation at ADDO
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32.-(1) Every Outlet shall stock authorized pharmaceutical products as stipulated under the Tanzania Food Drug and Cosmetic (Scheduling of Medicines) Regulations 2015.

(2) All pharmaceutical products for sale at an Outlet shall be registered in accordance with laws applicable for registration of medicines.

(3) The pharmaceutical products referred to under sub-regulation (2) shall be procured from a registered wholesaler or manufacturer.

(4) All pharmaceutical products held in inventory shall

be stored in the manufacturer's original packaging and properly labeled with the manufacturer's original label.

(5) A person who contravenes any provisions of this regulation, commits an offence and shall, on conviction, be liable to a fine of one million shillings.

Removal of labels and repackaging

33.-(1) A person shall not-.

(a) remove labels from containers of any pharmaceutical product;

(b) repack and re-label pharmaceutical products not for the purpose of immediate dispensing to the patients.

(2) Any person who contravenes any of the provisions under sub-regulation (1) commits an offence and shall be dealt with in accordance to the provisions of the Tanzania Food, Drugs and Cosmetics Act or Regulations made under it.

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Dispensation of registered pharmaceutical products

34.-(1) An Outlet dispenser shall only dispense pharmaceutical products registered in accordance with laws applicable for dispensation of medicines.

(2) Every Outlet dispenser shall ensure that:

(a)all necessary instructions and advice for proper use and care of the product is given to patient;

(b)ADDO prescription only medicines are dispensed against a prescription;

(c)records of all Outlet prescription only medicines dispensed by him is maintained in register approved by the Council; and

(d)no medicine is dispensed unless in accordance with medicines dispensing guidelines or any other written law.

(c)Record keeping and documentation

Invoices, receipts and ledger book

35.-(1) All invoices and receipts for non-prescription medicines and permitted prescription medicines shall be stored in the premises in an easily retrievable file for not less than five years.

(2) Save as provided in sub-regulation (1), the retrievable file, preferably a ledger book shall contain-

(a)name of supplier of prescription and non prescription medicines;

(b)amount of medicines received and issued for

dispensing; and

(c) balance remained in stock.

(3) A person who contravenes the provision of sub regulation (1) commits an offence and shall, on conviction, be liable to a fine of seven hundred thousand shillings.

Dispensing Register

36.-(1) An Outlet dispenser shall maintain permitted prescriptions and non prescription medicines in a Dispensing Register prescribed in the Fifth Schedule of these Regulations, and the register shall be used in recording and storing information of the patient in relation to the dispensed medicines.

(2) Save as provided in sub-regulation (1),the recorded information shall include-

(a) name and full address of the patient, including age and sex;

(b) diagnosed diseases;

(c) generic name and where applicable, trade name of the medicines dispensed;

(d) dose, dosage and quantity of medicines dispensed;

(e) name of the health facility such as dispensary where the patient was attended; and

(f) signature of the dispenser.

(3) The dispensing register shall be kept within the premises for not less than five years.

(4) The Council may require any owner of an Outlet to submit to the Council, records contained in the dispensing register.

(5) A person who contravenes the provision of this regulation commits an offence and shall, on conviction, be liable to a fine of seven hundred thousand shillings.

Register for expired products

37.-(1) There shall be a register for expired products which shall be kept and maintained by the dispenser of medicines at an Outlet.

(2) The dispenser of medicines shall seal, quarantine and label the expired products with the following red ink descriptive words "Expired Medicines – Not for Sale".

(3) The owner of an Outlet shall, on quarterly basis, submit the list of all expired products to the Committee.

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(4) Disposal of expired medicines shall be dealt with in accordance with Tanzania Food Medicines and Cosmetics (Handling and Disposal of Unfit Products) Regulations), 2015.

(5) A person who contravenes the provision of sub paragraph (1) commits an offence and shall, on conviction, be liable to a fine of seven hundred thousand shillings.

(d) Wholesaler Obligation

Obligation of wholesalers

38.-(1) A wholesaler shall not sell registered medicines to an Outlet unless the wholesaler is registered by the Council in accordance with the Act.

(2) The wholesaler referred to under sub-regulation (1), shall be the distributor of registered "over the counter medicines" and "ADDO prescription only medicines".

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(3) The wholesalers shall sell medicines and ADDO prescription only medicine to the Outlet as stipulated in the Tanzania Food Medicines and Cosmetics (Scheduling of Medicines) Regulations), 2015.

(4) A wholesaler shall be responsible for verifying credentials of an Outlet prior to the sale of medicines.

(5) A wholesaler who sells prescription medicines to Outlets shall keep records and invoices related to sale of all medicines.

(6) A wholesaler who-

(a) sells ADDO prescription medicines to non-accredited dispensing outlet; or

(b) sells to an Outlet any medicines other than medicines referred to in these Regulations,

commits an offence.

Establishment of ADDO Restricted wholesale

39. There shall be ADDO restricted wholesale shops to be established within local authorities for purposes of selling ADDO medicines on wholesale basis as provided under these Regulations.

Registration and permit for ADDO Restricted Wholesale

40.-(1)The procedure for registration of pharmacy, and issuance of permit for wholesale pharmacy under the Act shall apply *mutatis mutandis* to the registration and issuance of permit to ADDO Restricted Wholesaler.

(2)Notwithstanding sub-regulation (1), the Council shall not issue ADDO Restricted Wholesale permit to a District Council that owns a wholesale pharmacy.

Responsibilities of ADDO Restricted

41.-(1) An ADDO Restricted Wholesaler shall be supervised by a pharmaceutical technician.

Wholesale

(2) The ADDO Restricted wholesaler shall in addition to general sales medicines be permitted to stock or sell ADDO prescription only medicines.

(3) Notwithstanding the provisions of sub-regulation (2), it shall be the duty of the ADDO Restricted Wholesale supervisor to verify permits of the Outlet or licensed health care facilities prior to the sale of any prescription only medicines.

(4) Every ADDO Restricted Wholesale shall be required to maintain a register for the purchase, sale and dispensing of all medicines.

(5) An ADDO Restricted Wholesaler who sells general sales medicines and prescription only medicines to Outlets or licensed health care facilities shall:

(a)maintain a separate register for the sale of prescription medicines; and

(b)provide to the client an invoice or receipt listing all medicines sold.

(6) An ADDO Restricted Wholesaler who sells any medicines to non-registered medicine dispensing outlet commits an offence.

PART V
INSPECTION AND SUPERVISION

(a)Supervision levels

Mandate of supervision

42. Subject to the provisions of this Part, the mandate of supervision of Outlet shall vest in the following organs:

(a)in the case of supervision at ward level, the Ward Health Committee;

(b)in the case of supervision at district level, the Council Health Management Team; and

(c)in the case of supervision at regional level, the Regional Health Management Team.

Inspection at Ward level

43.-(1) A Ward Health Committee shall be responsible for conducting inspections and monitoring of Outlets at ward level.

(2) A ward inspector shall report the outcome of inspection to the Ward Health Committee.

(3) The Ward Health Committee shall, at least on quarterly basis, submit its inspection reports to the Council Food and Drugs Committee.

(4) The Ward Health Committee shall take actions against any violations of these Regulations within its mandate and report any other issues beyond its jurisdiction to the Council Food and Drugs Committee.

Inspection at district level

44. The Council Food and Drugs Committee shall-

(a)as a minimum requirement, conduct quarterly inspection of all Outlet premises.

(b)receive and review all inspection reports from Ward Health Committee, and;

(c)carry out further inspection in cases where the it determines that the report from the Ward Health Committee raises a cause for concern for which an inspection is required.

Inspection at regional level

45.-(1) The Regional Health Management Team, shall undertake monitoring and supervisory inspection responsibility over Outlets within its jurisdiction.

(2) The Regional Health Management Team may, where necessary, carry out audit inspection of Outlets and make recommendations to Committee and Council

(3) The Regional Health Management Team shall have the right to inquire into any steps taken by the Committee as described in its quarterly summary reports.

Inspection at national level

46.-(1) The Council shall be responsible for inspection and monitoring at the national level.

(2) The Council may carry out audit inspections in respect of any premises which provide pharmaceutical services.

(3) The Council or its official representative shall have a right to access all Outlets' inspection reports for information, advice, and recommendation or to re-address over any drug outlet malfunctions.

(b)Inspectors of Outlet

Appointment of inspectors

47.-(1) The Council shall appoint inspectors to conduct inspection for the purpose of these Regulations.

(2) Without prejudice to sub regulation (1), the following persons are hereby appointed as inspectors of their respective locality or jurisdiction:

(a)in the case of inspection at regional level, the Regional Medical Officer, Regional Pharmacist and

Regional Health Officer;

(b) in the case of inspection at district level, District Medical Officer, District Pharmacists and District Health Officer;

(c) in the case of inspection at ward level, in-charge of a government health centre or dispensary and ward health officer,; and

(d) any other person appointed by the Council for that purpose.

(3) Inspectors appointed by the Council shall be provided with special inspectors training course that will be conducted by the Council or any other agency approved by the Council.

(4) Inspectors appointed under these Regulations shall be issued with the Council inspector's identity card and inspection checklists.

(5) All Outlet inspectors appointed under these Regulations shall report to the Council.

Complaints against inspection

48. Any complaint or accusation against an inspector's findings made by an outlet owner or medicine dispenser shall be directed to the relevant inspection personnel at a hierarchy inspection levels referred to in these Regulations.

Determination of complaints

49.-(1) When dealing with complaints from the respective inspection level, an institution responsible for the particular inspection level shall act upon within two weeks on such accusations or complaints lodged within its mandate.

(2) All complaints which are not resolved at the particular inspection level shall be referred to the institution responsible for inspection at a higher level for appropriate action.

Powers of the Council in relation to inspectors

50.-(1) The Council shall have powers to revoke the appointment of an inspector where it is satisfied that the inspector has contravened any of the provisions of the Act or these Regulations.

(2) Decision of the Council under sub-regulation (1) shall be the final.

(3) All the powers of inspection vested to a person shall cease immediately after the revocation of appointment as inspector or the termination of employment of such person in the public service.

Declaration of interest

51. An inspector shall, before accepting an appointment, make a declaration of interest using a declaration form specified under the Sixth Schedule to these Regulations

Conduct of inspection

52.-(1) All inspections shall be conducted in team of at least two inspectors.

(2) Routine inspection shall be conducted-

(a) at least quarterly in the case of inspection at ward level;

(b) biannually in the case of inspection at Committee level; and

(c) in the case of inspection at Regional or Council level, at any time as the Regional Committee or Council may consider necessary.

(3) An inspector shall, in the course of a conduct of inspection at an Outlet-

(a) wear an official identification card during the whole process of inspection,

(b) introduce and inform the owner or Outlet dispenser the purposes of the inspection; and

(c) register himself in the visitors register book.

(4) Upon completion of inspection, an inspector shall write all required information in the inspection forms, and the inspector and owner or dispenser shall sign therein, and a copy shall remain with the owner or dispenser as proof of inspection.

(5) Upon completion of inspection, the inspector shall prepare an inspection report, copies of which shall be submitted to the inspectors' immediate supervisory body or respective authorities.

Quarterly reports

53.-(1) Every inspector shall prepare a quarterly inspection report and submit to the Committee through the respective Ward Health Committee.

(2) The Committee shall, during its scheduled meeting, deliberate on the reports, and may take action on the report or direct a Ward Health sub Committee to take any appropriate action in terms of these Regulations.

(3) The Committee shall submit copies of minutes and summary reports to the Regional Administrative Secretary and the Council.

Inspection supervision and

54. An Outlet may, for the purpose of this Part, be

monitoring

supervised by an appointed health authority, peer supervisor or any other person identified by the Council for that purpose.

PART VI
OUTLET ETHICS AND CONDUCT

Construction of Code of Ethics and Conduct

55. Save as otherwise provided in these Regulations, the provisions under this Part shall generally constitute ethics and conduct for which every ADDO owner, dispenser of medicines shall respectively comply with.

Honest and integrity

56. Every Outlet owner and dispenser shall in the course of discharging their duties, act with honesty and integrity.

Duty of care to patients

57.-(1) Outlet service providers shall exercise the duty of care in a compassionate manner.

(2)In determining the requirement under sub- regulation (1), the health well being of a patient shall be the core concern of the Outlet service provider, and in that regard, the person providing service shall ensure that the needs of a patient are afforded the first priority.

Special relation with patients

58. Outlet service providers shall-

(a) maintain an ethical patient-service provider fiduciary relationship;

(b) uphold moral obligations in return for the trust bestowed to them by the community;

(c) respect the autonomy, individuality and dignity of each patient, and avert from any form of discrimination;

(d) acknowledge the right of the patient to self-determination and individual self worth by encouraging patients to participate in decisions related to their health; and

(e) respect personal, cultural and religious differences.

Confidentiality

59. Every dispenser of medicines at an Outlet shall maintain confidentiality of patients' information acquired in the course of practice, dealings or conduct, and shall not disclose the information given except with the authorization of the patient or requirement of the law.

Restrictions to DLDM dispensers on quality of services

60.-(1) A dispenser of medicines at an Outlet shall-

(a)not dispense, promote or distribute medicines or provide such related services which are not of good quality;

(b)not in any way undertake clinical or laboratory services to patients or prescribe prescription medicines, except that he may offer limited patient advisory activities and counseling;

(c)preserve medicines that require preservation in refrigerator, cooling system or fan where applicable, and in any case, preserve medicines according to good pharmacy practice (GPP) as may be prescribed by the Council in the applicable guidelines;

(d)not participate in any promotional methods or campaigns which encourage the irrational use of medicines; or

(e)not undermine the role played by other health care providers.

(2) A person who contravenes the provision of this regulation commits an offence and shall, on conviction, be liable to a fine of not less than two hundred thousand shillings but not exceeding one million shillings.

Collaboration with other health care providers

61. Outlet dispensers shall collaborate with other health care providers to achieve the best possible outcome that ensures patients understand the role of other health care providers.

Competence building by ADDO dispensers

62. A dispenser of medicines at an Outlet shall be responsible for ensuring the improvement of personal competence, and shall strive for excellence and continuous improvement of the quality of service and care he provides.

Health promotion

63.A dispenser of medicines atanOutlet shall, at all times of service to individuals, community and society as a whole, advocate for health promotion, including the promotion of the use of cost effective therapies and rational use of medicine.

Restriction on commercial relationship

64.-(1) A relationship for commercial gain between a health care practitioner and Outlet dispenser or owner which renders an unreasonable cost of medicines to, or is in any way, detrimental to the beneficiary of Outlet services is, for the

purposes of these Regulations, prohibited.

(2) A person who contravenes the provisions of sub-regulation (1) commits an offence and shall, on conviction, be liable to a fine of five hundred thousand shillings.

Breach of code of ethics and conduct

65. A person who contravenes any provision in this Part commits a breach of the Code of Ethics and Conduct, and the breach shall be dealt with as professional misconduct in the manner and procedure prescribed under the Act and these Regulations.

PART VII
GENERAL PROVISIONS

Compounding of offences

66.-(1) Notwithstanding the provision of these Regulations relating to penalties, where a person admits in writing that he has commited an offence under these Regulations, the Registrar may, at any time prior to the comencement of the hearing by a court of competent jurisdiction, compound such offence and order such person to pay sum of money, not exceeding one half of the amount of the fine to which such person would otherwise have been liable to pay if he had been convicted of such offence.

(2) Where an offence is compounded in accordance with sub regulation (1) and proceeding are brought against the offender for the same offence, it shall be a good defence for the offender to prove to the satisfaction of the court that the offence with which the offender is charged has been compounded under sub regulation (1).

(3) Where the person fails to comply with the order issued under this regulation within the prescibed period, the Registrar-

(a) shall, in addition to the sum ordered, require the person to pay an interest at the rate prescribed in Nineth Schedule of these Regulations; and

(b) may enforce the order in the same manner as a decree of a court for the payment of the amount stated in the order.

(4) The list of offences prescribed in the Eighth Schedule shall be the offences compoundable under these Regulations.

Fee and Charges

67.-(1) All fees, charges, levies chargeable in terms of these Regulations shall be fees, charges, levies due to the

Council, and shall be as prescribed in the Ninth Schedule of these Regulations

(2) The fees and other charges payable under these Regulations shall be utilized as its funds for defraying expenses incurred in connection with the performance of its function as per the provisions of the Act.

(3) The fee and charges payable under these Regulations shall neither be refundable nor transferable.

Offences and penalties

68.- (1) Any person who-

(a)upon being requested lawful entry by an inspector or officer executing his duties under these Regulations fails to give or refuses access to any inspector or officer;

(b)obstructs or hinders an inspector or officer from the execution of duties under these Regulations;

(c)fails or refuses to give information that he may lawfully be required to give to an inspector or officer execution of duties under these Regulations;

(d)gives to the inspector or officer false or misleading information knowing it to be false or misleading; or

(e)abates or aides the commission of the offence,

commits an offence and is liable, upon conviction, to a fine of not less than five hundred thousand shillings or imprisonment for a period not exceeding six months or to both.

(2) A person who contravenes any provisions of these Regulations for which no other penalty has been prescribed, commits an offence and is liable on conviction to a fine of not less than one million shillings or to imprisonment for a term of not less than six months or both such fine and imprisonment.

Revocation and savings of GN. 358 of 2004 and GN 19 of 2009

69.-(1) The Tanzania Food, Medicines and Cosmetics (Standards and Code of Ethics for Accredited Drugs Dispensing Outlet) Regulations, 2004 and the Food, Drugs and Cosmetics (Standards and Code of Ethics for Accredited Drugs Dispensing Outlet) (Amendment) Regulations, 2009 is hereby revoked.

(2) Notwithstanding the revocation under sub regulation (1), any license, certificate, permit and administrative order, directions or instructions made or given or issued under or in pursuance of the provisions of the revoked Regulations, shall be deemed to have been made, issued, directed or issued under or

in pursuance of the provisions of these Regulations, and shall remain in force until revoked, replaced or rescinded by any subsidiary legislation , license, permit, directions, administrative Regulations or instructions lawfully given under these Regulations.

FIRST SCHEDULE

(Made under regulations 9(1) and 13(3))

WIZARA YA AFYA, MAENDELEO YA JAMII, JINSIA, WAZEE NA WATOTO
BARAZA LA FAMASI

FOMU YA MAOMBI YA KIBALI CHA KUANZISHA BIASHARA YA DUKA LA DAWA MUHIMU

SEHEMU A:IJAZWE NA MWOMBAJI

1. Jina la mwombaji…….....
   Anuani kamili…….....Umri.....Jinsia(ME).....(KE)..... Simu.....
2.Jina la duka……..…….....
3.Eneo ambalo duka lipo :
   Mkoa……..Wilaya……Kata……..……Kijiji/Mtaa……..
4.Jina kamili la Mtoa Dawa…..…..... Anuani.... Simu……...Namba ya usajili……ya tarehe……..……

Tarehe ya maombi……...Saini ya Mwombaji ……..

Angalizo:

i) Watoa dawa waliosajiliwa na Baraza la Famasi tu ndio watakaoruhusiwa kusimamia biashara ya DLDM

ii) Nakala ya vyeti vya mtoa/watoa dawa na mikataba iliyosainiwa viambatanishwe na ombi hili.

GN. NO. 185 (contd)

SEHEMU B: IJAZWE NA AFISA MTENDAJI WA KIJIJI (OMBI LA KIJIJINI) AU MTAA (OMBI LA MJINI) WA ENEO HUSIKA.

1. Jina la mwombaji……Uraia wa Mwombaji…….
2. Tabia ya mwombaji katika jamii anayoishi……
3. Taarifa fupi ya mwenendo wa mwombaji katika biashara yoyote aliyowahi kuwa nayo siku za nyuma au sasa katika kata hii ……
4. Mahitaji ya huduma ya biashara ya dawa kutoka kwa wananchi katika eneo: mwombaji aeleza kama wananchi katika eneo hilo wanahitaji huduma hii akitaja sababu ……
5. Mapendekezo/Maoni kuhusu ombi hili ……

Tarehe ya kupokelewa ombi……Tarehe ombi liliposhughulikiwa ……

……
Jina, Saini na Muhuri wa VEO au MEO

Angalizo:

(i) Baada ya kupokea na kujaza sehemu husika, VEO/MEO awasilishe fomu hii kwa WEO ambaye ataiwasilisha kwa wakaguzi wa kata.

(ii) VEO au MEO haruhusiwi kukataa au kutolea maamuzi ombi lolote.

SEHEMU C:IJAZWE NA WAKAGUZI WA KATA

Ijazwe kulingana na mahitaji ya The Pharmacy (Duka la Dawa Muhimu) (Standards and Ethics for Dispensation of Medicines) Regulations, 2017

1. Tarehe ya kupokelewa kwa ombi na nyaraka za mwombaji kutoka kwa VEO au MEO (Zingatia Sehemu A na B hapo juu)…….....
2. Tarehe ya kumhoji Mwombaji na Mtoa Dawa mtarajiwa kulingana na taarifa kutoka Sehemu A na Sehemu B …….....
3. Matokeo ya mahojiano…….....
4. Eleza usahihi wa nyaraka na taarifa zilizoambatanishwa**.....**
   Tarehe ya ukaguzi wa jengo……...
5. Usahihi wa eneo linapofunguliwa Duka la Dawa Muhimu kulingana na vigezo vilivyowekwa na Baraza la Famasi……

6.Mapendekezo/Maoni ya Wakaguzi wa Kata kwenda kwenye Kamati ya Chakula na Dawa ya Halmashauri (CFDC)……

7. Majina na saini za wakaguzi
   Jina……..
   saini…….....……...
   Jina……..
   saini…….....……..
   Jina……..
   saini…….....……..

8. Tarehe ya Afisa Mtendaji Kata alipopeleka mapendekezo au maoni kwenda kwenye Kamati ya Chakula na Dawa ya Halmashauri (CFDC)……

……..…….....
Jina, Saini na Muhuri wa Afisa Mtendaji Kata

Angalizo:

i) Wakaguzi wa Kata, na Afisa Mtendaji wa Kata haziruhusiwi kukataa ombi au kulitolea maamuzi ya mwisho ombi lolote, badala yake wapeleke mapendekezo au maoni ya maamuzi ya kikao husika (Kamati ya Chakula na Dawa ya Halmashauri-CFDC).

ii) Ukaguzi ufanyike kwa kutumia Dodoso la ukaguzi la PC na ripoti kuambatanishwa kwenda CFDC

iii) Kwa DLDM linalofunguliwa eneo la mjini: Umbali kati ya duka moja na jingine lisiwe chini ya mita 300 kila upande

iv) kwa maeneo ya miji midogo: Umbali kati ya duka moja na jingine lisiwe chini mita 200 kwa maeneo ya vijijini.

v) Umbali kati ya DLDM na duka la dawa moto lisiwe chini ya mita 500.

SEHEMU D:IJAZWE NA KAMATI YA CHAKULA NA DAWA YA HALMASHAURI (CFDC)

Ijazwe kulingana na mahitaji ya The Pharmacy (Duka la Dawa Muhimu) (Standards and Ethics for Dispensation of Medicines) Regulations, 2017

1. Tarehe ya kupokelewa kwa ombi husika kutoka kwa Mtendaji wa Kata....……
2. Tarehe ya kikao cha CFDC kujadili maombi ya DLDM ……
3. Maoni ya CFDC kutokana na ukaguzi wa eneo husika pamoja na nyaraka zilizowasilishwa (*Jaza iwapo CFDC ilibidi kufanya ukaguzi tena*)
   ……
4. Maamuzi ya CFDC kuhusu ombi la kufungua DLDM……
5. Masharti yoyote aliyopewa mwombaji ambayo anapaswa kuyatimiza kabla ya kupewa kibali
   (i)…….
   (ii)……
   (iii)…….

……..……
Jina, Saini na Muhuri wa Katibu, CFDC

……..……..
Jina, Saini na Muhuri wa Mwenyekiti, CFDC

GN. NO. 185 (contd)

WIZARA YA AFYA, MAENDELEO YA JAMII, JINSIA, WAZEE NA WATOTO
BARAZA LA FAMASI

FOMU YA MAOMBI YA KUHUISHA (RENEW) KIBALI CHA DUKA LA DAWA MUHIMU

Mwenyekiti,
Kamati ya Chakula na Dawa ya Halmashauri(CFDC)
……..……

SEHEMU A: IJAZWE NA MWOMBAJI

1. Jina la mwombaji……
2. Anuani kamili……Namba ya simu ……
3. Jengo la biashara ya Duka la Dawa Muhimu (DLDM) lipo katika
   a. Nyumba/ Ploti Na:……..……..……
   b. Kitongoji / Mtaa/kijijii……..……..……
   c. Kata……..……
   d. Tarafa……..……
   e. Wilaya ya……
   f. Mkoa……
4. Jina la Duka la Dawa Muhimu ……
5. Namba ya kibali (Accreditation Certificate No.)……
6. Biashara hii itasimamiwa na Watoa Dawa waliosajiliwa na Baraza la Famasi wafuatao:-
   (i) Jina kamili la Mtoa Dawa ….…..Anuani….....simu …
   Namba ya cheti cha utoaji dawa (Dispensing Certificate) …..cha tarehe.....

   (ii) Jina kamili la Mtoa Dawa.....……Anuani……...simu ……...
   Namba ya cheti cha utoaji dawa (Dispensing Certificate) ……cha tarehe ….....

Tarehe ya Maombi……. Saini ya Mwombaji……..

Kumbuka:
Ambatanisha (1) Nakala ya vyeti vya Watoa Dawa, (2) Mkataba wa makubaliano kati ya mmiliki na mtoa dawa
(3) Barua halisi za Watoa Dawa kukubali kuendelea kusimamia DLDM

……..……..……
Jina, Saini na Muhuri wa Katibu, CFDC

……..
Jina, Saini na Muhuri wa Mwenyekiti, CFDC

SECOND SCHEDULE

(Made under regulation 13(1))

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN
PHARMACY COUNCIL

CERTIFICATE OF ACCREDITATION

This is to certify that the Premises named..... owned by M/s.....which is located at.....Village/Street.....Ward.....District/Municipality in..... Region has complied with the requirements of the said Regulations and is hereby granted Facility Identification Number (FIN)..... of.....

_____ _____

DATE OF ISSUE SIGNATURE OF REGISTRAR AND STAMP

SUBJECT TO THE FOLLOWING CONDITIONS:-

1. The premises and the manner in which the business is to be conducted must conform to the requirements of the Pharmacy Act of 2011 or any other written law related to the Registration of premises at all times, failing of which this certificate shall be suspended or revoked.
2. Any change in the ownership, name and location of the registered premises shall be approved by the Council.
3. This certificate is not transferable to other premises or to any other person
4. This certificate shall be displayed conspicuously in the registered premises.
5. The Owner of the business is required to obtain the business permit annually from the his/her respective CFDC

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN
PHARMACY COUNCIL

DLDM BUSINESS PERMIT

Permit is hereby granted to M/S.....of.....to carry the business of Outlet at the Premises situated at .....Street, in..... Ward, ...in.....Region to sell over the counter drugs and a limited number of prescription drugs as provided in the *Tanzania Food, Drug and Cosmetic (Scheduling of Medicines) Regulations, 2015*after being issued with the Facility Identification Number (FIN)……from the Council

The following person(s) is/are hereby authorised to become dispenser(s) of this premises in accordance with provisions of these Regulations.....

This permit shall have and continue to have effect from and including the day when it is issued until it ceases to have effect on .....

Issued on ..... Fees Tshs.....

DATE: _____ *SIGNATURE OF REGISTRAR AND STAMP*

CONDITIONS:

i. This Permit does not authorize the holder to operate the business in unregistered premises or during the period of suspension, revocation or cancellation of accreditation of the premises in respect of which it was issued.
ii. This Permit is not transferable without a written approval of the Council.
iii. This Permit shall be displayed conspicuously in the registered premises.
iv. Any change including change of dispenser(s) of the registered premises shall be approved by the Council

THIRD SCHEDULE

(Made under regulation 25(1))

MKATABA WA KUENDESHA DUKA LA DAWA MUHIMU

MAKUBALIANO haya yamefanyika leo tarehe……..Mwezi……. Mwaka……

KATI YA

……. wa S.L.P …… (ambaye kwa mujibu wa mkataba huu ataitwa MMILIKI) kwa upande mmoja,

NA

…….(ambaye kwa mujibu wa mkataba huu ataitwa MTOA DAWA") kwa upande wa pili.

KWA KUWA MMILIKI anaridhia kuendesha biashara ya Duka la Dawa Muhimu kwa mujibu wa aya ya 32(1) ya *The Pharmacy (Duka la Dawa Muhimu) (Standards and Ethics for Dispensation of Medicines) Regulations, 2017*

KWA KUWA uendeshaji wa maduka haya unahitaji MTOA DAWA wa Duka la Dawa Muhimu kwa mujibu wa sheria; na

KWA KUWA MMILIKI anaridhia kuweka mtaalamu MTOA DAWA katika kuendehsa na kusimamia uuzaji wa dawa muhimu;

KWA PAMOJA MMILIKI na MTOA DAWA wanakubaliana kuendesha biashara ya duka la dawa Muhimu kwa maelezo na masharti yafuatayo: -

1. Baada ya kukamilika kuwekwa sahihi katika makubaliano haya MMILIKI atakuwa ndiye mmiliki wa Duka la Dawa Muhimu na MTOA DAWA atakuwa ndiye mtoa dawa katika duka liitwalo ……lilipo wilaya ya ……... kata ya ……. kijiji/mtaa …….
2. MMILIKI atamlipa MTOA DAWA mshahara na marupurupu kama ilivyofafanuliwa katika kifungu cha nne cha makubaliano haya.
3. MTOA DAWA atatakiwa kutii maadili ya utoaji wa dawa, kukidhi na kutunza dawa kwa kiwango kinachokubaliwa kwa mujibu wa Kanuni za Maduka ya Dawa Muhimu za mwaka 2017.
4. MMILIKI atatakiwa kuchukua hatua muhimu kuanzisha duka na kusimamia uuzaji dawa zilizothibitishwa kuwa ni dawa zinazoruhusiwa kuuzwa katika duka la dawa muhimu tu. Hatua hizo muhimu ni pamoja na kufuatilia na kupatiwa leseni, kibali au idhini kutoka BARAZA LA FAMASI na utunzaji wa DUKA LA DAWA MUHIMU katika hali ya inayokubalika kwa mujibu wa sheria.
5. Mmiliki atafanya malipo kwa ajili ya kukidhi mahitaji yafuatayo katika uendeshaji wa DUKA LA DAWA MUHIMU;
    a) Mshahara na marupurupu kwa MTOA DAWA shilingi …….. kwa kila mwezi kwa kipindi chote cha mkataba huu au vinginevyo watakavyokubaliana kubadili kiwango hicho kwa ajili ya utekelezaji wamajukumu yake kama ilivyo katika Kifungu cha 2 cha mkataba huu;
    b) Gharama zote kwa ajili ya marekebisho au ukarabati wa DUKA LA DAWA MUHIMU
    c) Maswala yote ya kitaalamu yatakuwa chini ya usimamizi na uangalizi wa MTOA DAWA;
    d) Kwa mujimu wa mkataba huu maswala ya kitaalamu ni pamoja na kutoa dawa, kuhifadhi dawa, kutunza kumbukumbu za dawa na utunzaji wa eneo la DUKA LA DAWA MUHIMU.

6. Mkataba huu utadumu kwa kipindi cha miezi kumi na miwili (12) na endapo Mmiliki na Mtoa Dawa wataridhia wanaweza kuurejea kwa kila mwaka isipokuwa tu pale ambapo sehemu moja ya mkataba huu itaonyesha nia ya kukatisha mkataba kwa taarifa ya maandishi itakayotolewa na upande huo kwa kipindi kisichopungua miezi mitatu (3)
7. Inapotokea kuwakuwa upande mmoja umeonyesha nia ya kukatisha mkataba na kutoa taarifa kwa upande mwingine kwa kipindi kisichopungua miezi mitatu (3), nakala ya taarifa hiyo lazima ipelekwe CFDC.
8. Mmiliki atatoa gharama zote za utengenezaji wa mkataba huu.
9. Bila kuathiri kilichoandikwa katika mkataba, Kamati ya Wilaya ya Dawa itatunza na kuhifadhi nakala ya mkataba itakayopelekwa kwake na MMILIKI.

KWA USHAHIDI WA PAMOJA MMILIKI na MTOA DAWA wnakubaliana na kuweka sahihi zao katika mkataba huu kwa tarehe na jinsi ulivyoandaliwa kama ifuatavyo:

Umesainiwa na kutolewa
Leo tarehe …….....…. {…. ……..}
Sahihi ya Mmiliki
Na Mmiliki (jina) ……..... {…. ……..}
Sahihi ya Mmiliki
Mbele ya (Jina la Shahidi) …… {…. ……..}
Sahihi ya Shahidi
Umesainiwa na kutolewa
Leo tarehe……..... .{.....}
Sahihi ya Mtoa Dawa
Na mtoa dawa (jina) …….....
Mbele ya (Jina la Shahidi) …… {…. ……..}
Saini ya Shahidi

Angalizo: Mkataba huu ni sampuli. Mmiliki na mtoa dawa wanaweza kuuboresha ili kukidhi mahitaji yao

FOURTH SCHEDULE

(Made under regulation 31(2)(a))

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

PHARMACY COUNCIL

STANDARD LOGO FOR OUTLET

GN. NO. 185 (contd)

FIFTH SCHEDULE

(Made under regulation 36(1))

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

PHARMACY COUNCIL

DISPENSING REGISTER

Name of dispenser……Date……
Serial No……
Patient name: ……..Sex M/F……..
Patient address:
Diagnosed disease
Name of medicines dispensed (Generic/Trade)
Dose & Dosage
Quantity Dispensed
Name of Health Facilities (dispensary or health centre)
Remarks e.g. ADR Reported etc

SIXTH SCHEDULE

(Made under regulation 51))

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

PHARMACY COUNCIL

DECLARATION FORM BY LOCAL INSPECTORS OF OUTLET AND ANY OTHER MEDICINES OUTLETS

1.First Name……..Last name……
2.Address……..
3.Name:Hamlet/Village/mtaa……
Ward……
District……..
4.Current position held in local government……
5.Do you own or hold share in any pharmaceuticals business (Yes/No) ……... if yes, state:
Name of the Business……
Hamlet/street/village…….
Ward……
District……..
6.Does anyone in your family own or hold share in pharmaceutical business within your ward? (Yes/No)……. If yes give details on the following
Name of the Business……..
Location Hamlet/street/village……
Ward……..……..
District……..……
Have you in past had any pharmaceutical business? No/Yes. If Yes state why you abandoned the business……
7.I,……..hereby declare that the information have provided here under is true and correct to the best of my knowledge, I also know that if eventually it is proved by the Council that the information I have given it false, fictitious or fraudulent or based on inadequately verified information, may result in appropriate, legal action by the Council.
8.Signature…….. Date……

SEVENTH SCHEDULE

(Made under regulation 21(4))

THE UNITED REPUBLIC OF TANZANIA

No XXXXX

Passport size

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN
Pharmacy Council Tanzania

DISPENSING CERTIFICATE

This certificate is awarded to
.....
Who has attended and passed a special pharmaceutical dispensing course
For Accredited Drugs Dispensing Outlets (Duka la Dawa Muhimu)

Held at.....from.....to.....

.....
Registrar-Pharmacy Council
Date .....

EIGHTH SCHEDULE

(Made under regulation 66(4))

LIST OF COMPOUNDED OFFENCES

S/No.	List of Compounded Offences	Contrary to Paragraph
1.	Non displaying of registration certificate by ADDO dispenser	24(b)
2.	Dispensing or Issuing prescription drugs without prescription	24(a)(iv)
3.	Non displaying of other registration certificates(e.g. of a ADDO, etc)	26(1)(b)
4.	Inappropriate and disorderly behavior by dispenser	24(a)(vi)
5.	A dispenser not wearing the prescribed attire	24(a)(ii)
6.	Poor sanitation and hygiene of premises	31(1)(k) &31(3)
7.	Poor record keeping (lack of registers for purchase, delivery, dispensing, prescription book or any other prescribed register)	34(2)(b), 38, 39(1) & 37(1)
8.	None preservation of medicines in a premises without running refrigerator, cooling system, or fan where applicable contrary to good pharmacy practice	60(c)
9.	ADDO premises not meeting standards, i.e not having adequate supply of clean and safe water, and includes having in place a hand washing sink	31
10.	Allowing the dispensation of medicines by a person who is not a categorized person or person approved by the Council	20
11.	ADDO dispenser conducting clinical or laboratory services	60(b)
12.	Stocking unauthorized medicines	32(1)
13.	Unethical commercial relationship for gain by ADDO Dispenser or owner	64(1)

NINTH SCHEDULE

(Made under regulation 66(3)(a))

LIST OF FEES AND CHARGES

ITEM	FEES/CHARGES
1.0 Registration	
1.1 Outlet Premises	60,000/=
1.2 Outlet Dispenser	20,000/=
1.3 ADDO Restricted Wholesale	250,000/=
2.0 Annual Renewal Fees	
2.1 DLDM Business Permit	40,000/=
2.2 Retention for ADDO Dispensers	10,000/=
2.3 ADDO Restricted Wholesale Business Permit	100,000/=
3.0 Restoration Fees	
3.1 Restoration of ADDO dispenser	200,000/=
3.2 Restoration of ADDO Premises	300,000/=
4.0 Other Fees and Charges	
4.1 Issuance of a duplicates (Course, Permit, Accreditation or Dispensing certificate extracts etc)	50,000/=
4.2 Application for Change of Premises	90,000/=
4.3 Application for Change of Name/Ownership	50,000/=
4.4 Issuance of ADDO Premises Logo	10,000/=
4.5 Inspection of ADDO Restricted Wholesale	100,000/=
4.6 Authentification of document (certificate etc)	10,000/=
4.7 Penalty for delays	25%

Dodoma,
26th February, 2019

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