PHARMACY GUIDELINES

Version 1

Health Policies and Standards Department

Health Regulation Sector (2021)

INTRODUCTION

Dubai Health Authority (DHA) is the responsible entity for regulating, licensing and monitoring health facilities and healthcare professionals in the Emirate of Dubai. The Health Regulation Sector (HRS) is an integral part of DHA and was founded to fulfil the following overarching strategic objectives:

Objective #1: Regulate the Health Sector and assure appropriate controls are in place for safe, effective and high-quality care.

Objective #2: Position Dubai as a global medical destination by introducing a value-based, comprehensive, integrated and high-quality service delivery system.

Objective #3: Direct resources to ensure happy, healthy and safe environment for Dubai population.

ACKNOWLEDGMENT

This document was developed in collaboration with Subject Matter Experts. The Health Policies and Standards Department would like to acknowledge and thank these professionals for their dedication toward improving the quality and safety of healthcare services.

The Health Regulation Sector

Dubai Health Authority

TABLE OF CONTENTS

EXECUTIVE SUMMARY

This guideline for Pharmacy provides information to assure compliance with pharmaceutical practices as per Federal Laws and local regulations. It also considers international best practices for Pharmacy.

This guideline is based on the pharmaceutical care given by pharmacist, their role in providing best practice, improve prescribing medications and advocate the safe use of medications. Pharmacist are obliged to ensure that the service provided to all patients within a hospital or community setting is of appropriate quality. The guideline covers how pharmacies can support the health and wellbeing of the local population. It describes high-quality care in priority areas for improvement.

The guideline covers the following areas:

- Health facilities and professionals;
- Good pharmacy and vigilance practice;
- Code of ethics for pharmacist;
- Medication management and use;
- prescribing and dispensing medication;
- Management of Narcotic, Controlled and Semi-Controlled Drugs;
- Patient medication counselling and family education;
- Patient communication and confidentiality;
- Record management and patient confidentiality; and
- Safety precautions for pharmaceutical facilities during pandemic communicable diseases.

The guideline does not detail every eventuality for Pharmacy setting but can be used a basis to guide good pharmacy practices in Dubai and assure the quality and safety of pharmaceutical services provided to patients and the general public.

DEFINITIONS

Adverse Drug Reaction (ADR): is any unexpected, unintended, undesired ,excessive response or presentation that appears on the user of the drug within the doses documented in the internal leaflet and the authorized uses within the marketing approval that occurs as a result of separate effects from those essential effects of the drug.

A serious adverse reaction: is one that requires inpatient hospitalization or prolongation of existing hospitalization, causes congenital malformation, result in persistent or significant disability or incapacity, is life threatening or result in death.

Ambulatory pharmacy: Any pharmacy that practices retail within an outpatient clinic setting/Day Surgical Centre (DSC) to serve the clinics/DSC patients only, where prescription medications are dispensed.

Authorized suppliers: are registered with Ministry of Health and Prevention (MOHAP) as the agent for medicine / medicinal products or registered as a wholesaler with MOHAP.

Batch: a certain amount of the production unit of a medical product that was manufactured in one batch and carries its own identification number in addition to the date of manufacture after passing the necessary examination and testing stages.

Batch number: a distinctive combination of numbers, symbols and/or letters which specifically identifies a batch.

Beyond Use Date (BUD): the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the date or time the preparation is compounded, its chemical stability, and the sterility limits.

Clean Room (Aseptic): is a room with defined environmental control of particulate and microbial contamination constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area.

Cleaning: refers to the removal of germs, dirt, and impurities from surfaces. Cleaning does not kill germs, but by removing them, it lowers their numbers and the risk of spreading infection.

Clinical pharmacist: A person who has accredited scientific certificates from higher institute, college or university in clinical pharmacy and possesses in-depth experience in this field as well fulfilling the requirements for Licensing in PQR.

Controlled Drug: is a medical and pharmaceutical products that contain any of the active substances in accordance with Federal Law No. (14) of 1995 in respect of of combating Narcotics and psychotropic substances and its amendments, and the lists of the International Narcotics Control Board (INCB) No. (1,2,3,4) contained in the United Nations Convention of 1971, which have a significant potential for abuse, addiction and/or illegal use.

Competent: is refers to every adult person, 18 years and above as presumed to be capable to give an informed consent, unless there is an evidence to verify incompetence.

Community/Retail Pharmacy: Any retail standalone pharmacy that practices the pharmaceutical services. This includes any retail establishment located on street level or the ground floor or situated in a larger complex such as a commercial center or shopping mall may be on a higher floor, where medications are dispensed.

Communicable diseases: Any infectious illness resulted from pathogen transmission, or its toxic products or excretion that can cause the disease direct or indirect to others.

Deficient product: is any product that does not comply with quality specification (as per manufacturer's approved specifications) or is contaminated, fake, mislabeled, and presents efficacy or safety issue that may harm patients.

Deputy in-charge: is a qualified and trained DHA licensed Pharmacist, Clinical Pharmacist or Anesthesiologist pre-assigned by the health facility to take over the responsibility of Narcotics, CD and SCD medications during the absence of the Person in-charge and/or to cover working shifts.

Disinfecting: refers to using chemicals to kill germs on surfaces. This process does not necessarily clean dirty surfaces or remove germs, but by killing germs on a surface after cleaning, it can further lower the risk of spreading infection.

Drug Discrepancy: means any inconsistency or disparity between the physical amount of a Narcotic, CD and SCD medications and the amount of medication recorded in the corresponding drug register.

Drug-Food Interaction is an adverse drug event that may include delayed, decreased, or enhanced absorption of the drug. And may also affect the bioavailability, metabolism, and excretion of certain medications, produced when some drugs and certain foods or beverages are taken at the same time.

Drug Store: means any facility or establishment inside the country registered by MOHAP which imports, stores, and distributes any medication as a wholesaler.

Emergency medications (Lifesaving items): means those drugs critical for patient care and for treating a life threatening situation, requiring administration within minutes or within less time than the pharmacy/hospital can be practically expected to respond.

Expiry date: reflects the shelf life of a commercially manufactured product when stored according to the manufacturer approved labelling, and in its original container. It is the date before which the quality of a medicine remains acceptable for intended use.

Facemask: is a loose-fitting, device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment.

Formulary: A list of all the medications decided by the healthcare organization or healthcare facility to be prescribed and ordered by health professionals.

Health Facility: Place permitted to provide health examinations for patients and help for diagnosis, treatment , nursing or admission for cure and recovery or any other related medical procedures relating to treatment or rehabilitation post treatment.

Healthcare Professional: is a natural person who is authorized and licensed by the DHA to practice any of the healthcare professions in the Emirate of Dubai.

Hospital Pharmacy: Is the healthcare service, which comprises the retail, practice, and profession of choosing, preparing, storing, compounding, and dispensing medicines and medical devices, advising healthcare professionals and patients on their safe, effective and efficient use.

In-patient Pharmacy: Any non-retail pharmacy that practices the pharmaceutical services which is limited to hospital inpatient and patients of Day Surgical Centers.

Isolation: is separation of patients and/or staff into a secluded area or room for infection control purposes. Isolation may include self-isolation in a room, home or residential institution.

Licensure: shall be defined as issuing an official permission to operate a health facility to an individual, government, corporation, partnership, Limited Liability Company (LLC), or other form of business operation that is legally responsible for the facility's operation.

Licensing: A process of granting a legally protected professional title by the authority.

Medical Director: A DHA licensed physician who manages and runs a health facility and has clinical oversight of a DHA licensed health facility and its clinical staff.

Medicine: Any product that contains an ingredient or group of active ingredients with biological effects for diagnosing, treatment protection of human beings or animals from diseases or for any other medical purpose such as: restoration, regeneration, modification, or correction of organ functions.

Medication Compounding: to combine, mix substances or alteration of dosage form or strength of a medicinal product; which includes the combination of two or more compounded preparations or substances.

Medication recall system: A group of processes intended for identifying, retrieving, returning or safely and properly destroying medications recalled by the manufacturer or supplier, national and international drug regulatory body.

Medication Treatment Plan: The plan that includes the use of medications based on the analysis of the medical patient's condition to obtain the best possible outcomes for his treatment which take account of, dose regimen, type, pharmaceutical dosage form, route of administration, amount per dose, number of doses per day, duration of the treatment and any other instructions such as the sequence of use of the medicine, gradual adjustment of dose.

Narcotic Drugs: Every natural or synthetic substance that includes group of medical and pharmaceutical products that contain any of the active ingredients listed in International Narcotics Control Board (INCB) schedules Nos. (1,2,3,4) in accordance with the Single Convention on Narcotic Drugs of 1961 and as amended in the protocol of 1972 , and Schedules mentioned in the Federal Law No. 14 of 1995 in respect of combating Narcotic drugs and Psychotropic substances and its amendments.

Over the Counter Medications (OTC): These medicinal products may be dispensed without a prescription in pharmacies and such products may be stored in direct access to the consumers.

People of Determination: under the UAE National Policy for Empowering People with Special Needs, or disabilities will be referred to as "People of Determination" to recognize their achievements in different fields.

Person In-charge: Is a full time qualified and trained DHA licensed healthcare professional (Anesthesiologist, Clinical Pharmacist or Pharmacist) as the Person in-charge to be responsible and

accountable for dispensing, monitoring, tracking, reporting, returning and disposing the Narcotics, CD and SCD.

Pharmacovigilance: has been defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding, prevention and reporting of adverse effects or any other medicine related problem.

Pharmacy: A facility licensed to store, prepare, compound, dispense, display or sell medicinal products to the public directly, through a fixed or mobile facility, permanent or temporary.

Pharmacist: A person who holds a scientific qualification not less than a bachelor's degree in pharmacy or its equivalent from a higher institute, college or university recognized in the country, and who is licensed to practice the profession of pharmacy in the country in accordance with the provisions of Federal Law no. (8) of (2019) Concerning Medical products, Pharmacy profession and Pharmacies and its executive regulations.

Pharmacist in-charge: is the pharmacist licensed by DHA on a licensed pharmaceutical facility, and is responsible for implementing the provisions of Federal Law no. (8) of (2019) Concerning Medical products, Pharmacy profession and Pharmacies and its executive regulations within the scope of the tasks assigned to him.

Pharmacy staff: pharmacy staff shall mean clinical pharmacists, pharmacists, pharmacy technicians and trainees.

Pharmacist only Medicine (PH-OM): are medicines restricted to Pharmacist Only, these medicinal products must be dispensed by a licensed pharmacist, however, a prescription from a healthcare professional is not required, and those products should not be stored in direct access to consumers.

Pharmacy Technician: A person who has an educational qualification of no less than a diploma in pharmacy and a period of study in pharmaceutical establishments no less than two years after high school or its

equivalent from a recognized entity in the country and licensed to practice the profession of pharmacy technician under the direct supervision of a licensed pharmacist.

Prescription: means a document signed by a licensed practitioner approved legally from prescriptive authority to prescribe, transmitted by the practitioner to a pharmacist through a based-paper or Electronic Prescription form.

Prescription Only Medicine (POM): An MOHAP registered/not registered medication that requires an official prescription to be dispensed to patients by licensed pharmacist.

Product recall: The process of withdrawing the entire medical product or a batch from it, due to a defect in the product or to verify the validity of a complaint about the presence of adverse reaction, dangerous side effect, or any other reasons that are clarified by the party requesting the withdrawal such as the manufacturer companies, suppliers, agents/ or from a decision of the concerned entity or the ministry.

Quarantine: is the restriction of movement of those who may have been exposed to a person with an infectious disease but do not have a confirmed medical diagnosis to ensure they are not infected.

Record: means any information recorded in any way, including, but not limited to, handwriting, printing, taping/recording, and electronic storage using computer diskette, film, microfilm, and microfiche.

Register: is a book issued from the concerned Health Authority (DHA) or Ministry of Health and Prevention (MOHAP) used by an authorized Healthcare Professionals at health facilities to record the transactions of Narcotics, CD and SCD medications within the pharmacy and inpatient units.

Semi Controlled Drugs: is a medical and pharmaceutical products not listed within the schedules attached to the Federal law No. 14 of 1995 in respect of combating of drugs and psychotropic substances and its amendments and not listed within the schedules attached to international conventions of the International Narcotics Control Board (INCB), and has medical benefits, but with long term use in high doses or use with other substances that might lead to habituation and addiction.

Storage area: The storing of pharmaceutical products up to the point of use.

Trainee Pharmacist: A person who is granted a temporary license by DHA , holding a minimum qualification of bachelor's degree in pharmacy or its equivalent from an accredited college or university recognized by the Health Authority in the UAE and Ministry of Education (MOE), and works under the direct supervision of a licensed pharmacist.

Unit dose: is packaging of each dose of each medication for patients in an individual pack to provide easy and uniform medication dispensing.

ABBREVIATIONS :

ADRs : Adverse Drug Reactions

BNF : British National Formulary

BUD : Beyond Use Date

CD : Controlled Drugs

CPD : Continuous Professional Development

DED : Department of Economic Development

DHA : Dubai Health Authority

DM : Dubai Municipality

DSC : Day Surgical Centre

FDA : Food and Drug Administration

GCP : Good Clinical Practice

GSDP : Good Pharmaceutical Storage and Distribution Practices

GVP : Good Vigilance Practice

HP : Health Professional

HRS	:	Health Regulation Sector
IV	:	Intravenous
LLC	:	Limited Liability Company
MOE	:	Ministry of Education
MOHAP	:	Ministry of Health and Prevention
OTC	:	Over the counter
PH-OM	:	Pharmacist only Medicine
POM	:	Prescription only medicine
PPE	:	Personal Protective Equipment
PQR	:	Professional qualification requirements
PV	:	Pharmacovigilance
SCD	:	Semi-Controlled Drugs
SOP	:	Standard Operating Procedure
TPN	:	Total Prenatal Nutrition
UAE	:	United Arab Emirates
USP	:	United States Pharmacopeia

1. BACKGROUND

The requirements for prescribing and supply of prescription medicines in the United Arab Emirates are governed by Federal Law no. (8) Of 2019 concerning Medical Products, Pharmacy Profession and Pharmacies and also mandated in relevant Ministerial Decrees. As health professionals, pharmacists play an important role in improving access to healthcare and in closing, the gap between the potential benefit of medicines and the actual value realized. Pharmacists manage medications, empower patients to manage their health and advising a range of healthcare professionals as the experts in medicines and drug therapy management. Pharmacist are often the first point of contact for advice and play a vital role in managing emergencies and reducing the overall cost burden within the health system. Pharmacists do not work in isolation and are often integrated within a system of healthcare providers, physicians, insurers and suppliers. Due to evolving health system needs, pharmacists are increasingly engaged with information management systems, electronic dispensing systems, care planning and public health programs.

The goal of pharmacy practice is to improve decision making and provide safe and effective medicines and other related healthcare products and services to patients and healthcare professionals. Pharmacists are also obligated to ensure the services they provide are transparent, ethical, evidence based, safe and of high quality as part to of Good Pharmacy Practice. Therefore, it is essential for pharmacists to have in place ongoing Continual Personal Development plans in order to maintain their competence, skillsets and expertise. The Pharmacy guidelines are intended to support community and hospital pharmacist and pharmacists provide appropriate and high quality care to fulfil the demands of the health system. The guide also serves as a reference point to consolidate obligations set out by law and best practice.

2. SCOPE

This document applies to any DHA licensed Healthcare Professional or DHA Licensed Health Facilities including, but not limited to, Pharmacies, General or Specialized Hospitals, Day Surgical Centres (DSC), Fertility Centres and Outpatient facilities dealing with Medications and pharmaceutics in the Emirate of Dubai, and includes storage, distribution, prescribing, dispensing, preparation, administering and/or handling drugs.

3. PURPOSE

3.1. To establish the minimum requirements of pharmacy services and to promote the provision of the highest level of safety and quality of patient care at all times.

3.2. To ensure the delivery of high quality care in a safe and secure environment.

3.3. To assure compliance with the Federal laws and local regulations concerning Narcotics, Controlled and Semi-Controlled Drugs.

4. APPLICABILITY

The guidelines applies DHA licensed Pharmacy in the Emirate of Dubai, including hospital and community pharmacies, pharmacies in governmental, semi-governmental, private and free zone areas, or any health facility providing pharmaceutical services and subject to licensure under the Dubai Health Authority establishment law. The guidelines excludes Dubai Healthcare City (DHCC).

5. **GUIDELINE ONE:** HEALTH FACILITY LICENSING

5.1. The requirement to be licensed:

5.1.1. A person or entity intending to open a pharmacy in the Emirate of Dubai requires to obtain a license from DHA as per the applicable local and federal laws. This applies to semi-governmental, private health facilities and facilities operating in free zone areas excluding DHCC.

5.1.2. Retail standalone pharmacy located on street level or the ground floor or situated in a larger complex such as a commercial centre or shopping mall may apply to obtain "Community/Retail Pharmacy" license.

5.1.3. Hospitals will apply for a separate DHA "Hospital pharmacy" license along with the hospital license.

5.1.4. Outpatient clinics may apply to obtain a DHA "Ambulatory pharmacy" license.

5.1.5. Day surgical centres class C may add a service of "Inpatient pharmacy" which does not require a separate DHA licence. The service will be delivered by a licenced pharmacist.

5.1.6. To obtain a license, the applicant will have to submit an application through SHERYAN (Dubai Health Licensing Online System), to HRS along with all the necessary documents which includes, but not limited to:

a. A copy of the Land Registration Certificate issued by Dubai Municipality (DM) specifying the land plot number.

b. Schematic design drawings in AutoCAD format showing the proposed floor layout with measurements for each room/ area and labels.

c. Proposal letter/business plan to describe the functional program of the pharmacy.

d. Trade name reservation issued by the Department of Economic Development (DED) or equivalent licensing authority in Dubai (when applicable).

e. Passport photocopy of the owner/partners with residency visa for non-locals (when applicable).

5.1.7. Upon receipt of a completed file and the applicable fee, HRS will conduct a detailed review of the submitted material to determine suitability for further processing.

5.1.8. Upon approval of the application, the facility will receive an inactive facility license which will be valid for a period of one (1) year (until the final approval is granted), this pending approval necessary to obtain the trade license by the DED or equivalent licensing authorities.

5.2. Registration, licensing and cancellation

5.2.1. Issuing of License

a. Upon completion of the pharmacy setup, the applicant will submit an online request for final inspection. Accordingly, the Drug control section will conduct an onsite pre-operational assessment (Final inspection), or remote-virtual inspection.

b. The applicant is required to provide the following requirements:

i. To appoint an in charge pharmacist who licensed by DHA or holding a valid eligibility letter issued by DHA.

ii. To provide a suitable infrastructure as per the DHA pharmacy design requirements and according to the services provided by the pharmacy.

c. As a result of the onsite or on-line assessment and after meeting the DHA requirements and recommendations, the HRS will issue the DHA pharmacy license.

d. An online report, with recommendations will be issued within five (5) working days, the license will be activated, and the pharmacy management is responsible to fulfill these recommendations prior to the next inspection visit by the Drug control section team.

e. In non-compliant circumstances, the application will be rejected, and an online report will be issued within five (5) working days. The facility management is required to act accordingly on all the recommendations mentioned in the report and resubmit a new request for a final inspection.

f. The issued license by HRS to the pharmacy includes: the facility name, address, DED license number, validity of license and name of the pharmacist in-charge.

g. 24 hours Pharmacy service minimum licensing requirements are:

   i. Four (4) licensed DHA pharmacists, one full time and the others may be part time.

   ii. Clear signage to direct people that the facility is operating 24 hrs.

h. Pharmacies incorporating clinic services "Walk-in Clinic" minimum licensing requirements are:

   i. Facility has to apply for new facility license as an outpatient clinic.

   i. The clinic can be either with full outpatient set-up such as but not limited to: examination bed, physician's office, sterilization devices, medical waste, laundry etc.) Or one spacious room to provide the required clinical services.

ii. Clinic space requirements for one room set-up; (minimum 18 m^2) with smooth movement in it and without obstacles / barriers.

iii. Clinic specialties may include GP, Family Medicine and Internal Medicine.

iv. Clear signage that the pharmacy incorporates clinical service "Walk-in Clinic".

v. The clinic operating hours is concomitant to the pharmacy operating hrs.

5.2.2. License Renewal

a. The applicant shall submit an application through SHERYAN to HRS for renewal of the pharmacy license. The application may be submitted three (3) months prior to expiry date.

b. After fulfilling the HRS requirements for license renewal, DHA pharmacy license will be renewed for a period of one year (calculated from the expiry date).

c. Renewal of the pharmacy license shall conform to all DHA renewal requirements. For further details regarding the license renewal procedure, please visit DHA website:https://services.dha.gov.ae/sheryan/wps/portal/home/services-facility/service-description?scode=RFL&CATALOGUE_TYPE=FACILITY

5.2.3. License Cancellation

a. The pharmacy owner is required to submit an application through SHERYAN to HRS for cancellation of the pharmacy license.

b. The applicant must comply with DHA regulations regarding cancellation of the license. For further details regarding the cancelation procedure, please visit DHA website:https://services.dha.gov.ae/sheryan/wps/portal/home/services-facility/service-description?scode=CFL&CATALOGUE_TYPE=FACILITY

5.2.4. Modifications Requiring DHA Approvals

a. The pharmacy management are required to obtain prior approval from the HRS for the following changes or modifications, this includes, but not limited to:

i. Ownership.

ii. Pharmacist in charge.

iii. Pharmacy trade name.

iv. Pharmacy location.

v. Temporary closure of the pharmacy.

vi. Adding an extension or annex to the existing pharmacy building.

vii. Adding a service e.g. (24 hours Pharmacy, clinical training, Telehealth/Pharmacy Delivery).

5.2.5. Audit and Inspection

a. HRS may audit the pharmacy to determine the pharmacy compliance with UAE federal laws and DHA regulations. These audits may be scheduled or un-announced.

b. The HRS inspectors and/or any duly authorized representative may request documentations/files.

c. For every audit the authorized inspectors should issue an onsite electronic inspection report which will be reflected on the facility's account stating the outcome of the inspection visit.

5.2.6. Null and Void License

a. As per the UAE Federal Law number no. (8) Of 2019 concerning the Medical products, Pharmacy profession and Pharmacies, the pharmacy license is considered null and void in the following conditions:

i. The Pharmacy practices an unlicensed activity.

ii. Submitting false documents, data or incorrect information for obtaining the license to open the pharmacy.

iii. The pharmacy is not operational for a period of six (6) consecutive months from the date of issuing the facility license.

iv. Closure of the pharmacy for more than three (3) consecutive months without an acceptable excuse or/DHA permission.

v. Committing gross violations or handling fake or unusable medical products.

5.3. Facility general consideration and design requirements

5.3.1. Community/Retail Pharmacy should be located on the ground floor and may be located on a higher floor if it is within a commercial center or mall.

5.3.2. It is recommended for the pharmacy to provide adequate space wise for Patient Counselling (counselling area) to enhance patient convenience.

5.3.3. The Pharmacy is required to provide a display board on its working hours and the pharmacy shifts' schedules (if applicable).

5.3.4. The pharmacy display board matches the pharmacy name as per the DHA and DED license.

5.3.5. Pharmacy is expected to meet the building standards required by Dubai Municipality or free zone authorities.

5.3.6. Consideration shall be given to provide access to "People of Determination".

5.3.7. Pharmacy should enforce a strict "No smoking" policy within the pharmacy premises.

5.3.8. The size and type of services provided by the Pharmacy will be dependent on the type of drug distribution system used, number of patients to be served and extent of shared or purchased drugs to be administered.

5.3.9. Pharmacy space requirements depends on the pharmacy categories as follows:

a. Community/Retail Pharmacy (minimum 30 m^2).

b. Hospital Pharmacy (minimum 30 m^2).

c. Ambulatory care pharmacy (minimum 25 m^2).

d. Inpatient Pharmacy (minimum 15 m^2).

5.3.10. The minimum ceiling height is not less than 2.70 m (8 feet 8 inches).

5.3.11. For Design Requirements refer to DHA Health Facility Guidelines 2019-Part B: Health Facility Briefing and Design -350 Pharmacy Unit.

6. **GUIDELINE TWO:** HEALTH PROFESSIONAL LICENSING

6.1. The requirement to be licensed

6.1.1. Pharmacist qualifications requirements are available on the unified healthcare professional qualification requirements (PQR) on DHA website: https://www.dha.gov.ae/Documents/HRD/Healthcare%20Professionals%20Qualification%20Requirements%20(PQR)%202014-1.pdf

6.2. Registration, licensing and cancellation

6.2.1. All the pharmacists and pharmacy technician should have a valid licenses issued by DHA.

6.2.2. Pharmacy Trainees are required to obtain training permit from DHA.

6.2.3. Pharmacists who have an interruption in their clinical practice exceeding two (2) years and opting to be licensed in the UAE are required to follow the CME/CPD requirements available in (PQR).

6.2.4. Non-UAE nationals will not be permitted to apply for a license if they have a gap of clinical practice for more than 5 years (and more than 10 years for UAE nationals).

6.3. Approved professional categories in the UAE are:

6.3.1. Clinical Pharmacist.

6.3.2. Pharmacist.

6.3.3. Pharmacy Technician.

6.3.4. Pharmacy Trainee.

7. **GUIDELINE THREE:** STAFF ROLES AND RESPONSIBILITIES

7.1. The Role of Clinical Pharmacist

7.1.1. Plays an active role in monitoring prescriptions, managing drug use, counselling and reporting Adverse Drug Reactions (ADRs) to the concerned authorities.

7.1.2. Chronic disease managements to ensure rational use of drugs and reduction of costs.

7.1.3. Locate or modify patient's medication treatment plan based on scientific analysis of the patient's condition and reports on the diagnosis of his condition.

7.1.4. Prepare an interdisciplinary care plans for patients which includes dosage adjustment, drug interactions, side effects etc.

7.1.5. Evaluate and provide recommendations on the medication treatment plan for the patient and optimal use of the prescribed therapy for both healthcare professionals in the health team responsible for the patient and the patient himself.

7.1.6. Describe any amendments to the patient's medication treatment plan; including replacing one medical product with another, unless a written or an electronic instruction have been issued by the treating physician to prevent any modification.

7.1.7. Notify the attending physician of the application of the treatment plan or its amendment in writing by registering the data in the patient's record prepared within (24) hours after starting the application of the plan.

7.1.8. Assist physicians in creating and managing the drug regimens of patients with chronic disease states (e.g. diabetes, asthma, congestive heart failure, etc.). This may include, but not be limited to, activities such as meeting with patients, adjusting medication dosages, monitoring, and performing other services within the professional area of expertise.

7.1.9. Advise physicians concerning the safety, appropriateness, and the cost-effective use of medications, and assist in the selection of the most cost effective, evidence-based regimen case related.

7.1.10. Commitment to guide patients and provide them with specialized information about their medical condition, the use of medical products, and the medication treatment plan.

7.1.11. Provide consultation and advice to health professionals concerning their patients' medication management plan.

7.1.12. Identify prescriptions that might present risks to patients and aid in resolving the relevant issues prior to its dispensing.

7.1.13. Recognize and discern prescribing or administration errors, assessing potential risk and strategies to manage this risk.

7.1.14. Consult the primary physician to ensure that the patient is on the proper medication treatment plan, with documentation in the patients' Medical records.

7.1.15. Educate patients on the importance medications adherence.

7.1.16. Additional tasks in accordance with the health facility internal policies and international best practices and recognized protocols such as:

a. Request routine checks to assess the patient's condition related to the selection and determination of a medication treatment plan, which includes pulse, temperature, blood pressure, and Spirometry.

b. Requesting laboratory tests related to the selection and determination of the medication treatment plan.

c. Give the patient the dose of treatment in accordance with the doctor's instructions, such as injections and various vaccinations.

7.2. The Role of the Pharmacist

7.2.1. Provide advice and information to patients and the public on the usage of medications.

7.2.2. Cooperate effectively with prescribers to ensure a common approach to patients in the provision of advice and rational use of medications.

7.2.3. Adequately inform patients and the public about side effects of medications. In addition, to monitor such unwanted effects and their consequences in collaboration with other health care professionals and the appropriate authorities.

7.2.4. Checking prescriptions to ensure that they are clear and in accordance with legal requirements, and to ensure that prescriptions are dispensed, in accordance with prescribers' intentions.

7.2.5. Registering all CD/SCD dispensed prescriptions in the corresponding DHA register books.

7.2.6. Supervising pharmacy technicians and pharmacy trainees.

7.2.7. Provide advice and counselling about non-prescription medications and/ or over-the-counter drugs.

7.2.8. Assist in providing a symptom assessment leading to over the counter medication provision and lifestyle advice for community-based health concerns (e.g. head colds, or smoking cessation).

7.3. The Role of Pharmacy Technician

7.3.1. Receiving and checking prescriptions.

7.3.2. Preparing the medication for patients.

7.3.3. Dispensing medications under the direct supervision of a licensed pharmacist.

7.3.4. The pharmacy Technicians shall NOT dispense any Narcotics, Controlled and Semi Controlled medications.

7.3.5. Helping with insurance claims.

7.3.6. Handling almost all patients' related paperwork.

7.3.7. Stocking and pricing the medication in the inventory.

7.3.8. Stock and take inventory of prescription and over-the-counter medications.

7.3.9. Disinfecting and maintaining hygiene protocol.

7.3.10. Clean pharmacy equipment, help with the maintenance of equipment and supplies.

7.3.11. Manage the cash registry.

7.4. The Role of Training Pharmacist

7.4.1. Training pharmacists should have a valid DHA license.

7.4.2. Pharmacy management should ensure that there is at least one (1) DHA licensed pharmacist is present per shift to supervise the trainees at all times.

7.4.3. The pharmacists responsible for training is required to fulfil the following criteria:

a. Provide direct supervision of the pharmacy trainees at all times.

b. Provide adequate and appropriately maintained facilities and learning resources to support the goals and objectives of the training program.

c. May have a mechanism in place to monitor trainer/instructor performance through a program evaluation form.

d. Maintain an attendance register for the pharmacy trainees.

7.4.4. The pharmacy trainees shall NOT dispense any Narcotics, Controlled and Semi Controlled medications.

7.4.5. The pharmacy trainees may dispense other medications under direct supervision of the pharmacist available.

8. **GUIDELINE FOUR:** STAFF TRAINING AND EDUCATION

8.1. It is recommended that all newly joining staff and the current staff regardless of their job duties to receive an orientation of their required duties and the facility internal policies before performing their assigned duties and responsibilities.

8.2. All training checklists are required to be filled and a copy of the job description is to be kept in the pharmacists' employee file.

8.3. A continuous training process is recommended to maintain pharmacists' skills and capabilities toward patient care.

8.4. Pharmacists are required to be trained on their technical skills at a monthly basis.

8.5. It is recommended for pharmacist to receive a monthly meeting to discuss the updates in pharmacy practice.

8.6. It is recommended to have a scientific pharmaceutical reference in the pharmacy either as hard copy or electronic format, such as but not limited to: BNF, Martindale: The Complete Drug Reference.

9. **GUIDELINE FIVE:** CODE OF ETHICS FOR PHARMACIST

9.1. Pharmacists are expected to maintain an acceptable and appropriate standards of practice; by adhering to the DHA Code of Ethics and Professional Conduct governing the profession and protecting patient's confidentiality.

9.2. Pharmacists are expected to retain the integrity and value of the therapeutic and workplace relationships.

9.3. It is recommended for pharmacists to provide advice, associated with the dispensing or sale of medicines, in a quiet area within the pharmacy as well as serving the patient in a private and confidential manner.

9.4. Pharmacist promises to help individuals achieve optimum benefit from their medications, to maintain their trust.

9.5. Pharmacists are expected to respects each other values and that of other health care professionals.

10. **GUIDELINE SIX:** MEDICATION MANAGEMENT

10.1. Medications Organization and Management

10.1.1. The pharmacy is required to identify how medication is organized and managed throughout the health facility and how the pharmacy system is working in terms of:

a. Selection and procurement of medications.

b. Storage.

c. Ordering and transcribing.

d. Preparing and dispensing.

e. Administration and monitoring.

f. Monitoring resulting from any changes in the formulary, such as addition of medications.

g. Monitoring of medication errors and near misses.

h. Educational need.

i. Emerging evidence-based practices and local regulations

10.1.2. It is recommended that all settings, services, and individuals who manage medication processes is included in the organizational structure.

10.1.3. The medication management system is to be reviewed at least once within 24 months.

11. GUIDELINE SEVEN: MEDICATION SELECTION AND PROCUREMENT

11.1. Selection and Procurement

11.1.1. The pharmacy should create a list of medications (formulary) available in the facility.

a. Drug Formulary may be created by multidisciplinary committee in healthcare facility.

11.1.2. Each pharmacy decides on the list of medications available for prescribing and ordering.

11.1.3. Medication selection based on the efficacy and safety as well as economics and types

of services provided.

11.1.4. It is recommended that all healthcare professionals involved in ordering, dispensing, administering, and patient-monitoring processes to be involved in evaluating and maintaining the medication list.

11.1.5. When newly introduced/developed medications are added to the list, there should be a process or mechanism to monitor how the drug is used and any unanticipated adverse events.

11.1.6. The medication reviewed on an annual basis to assure efficacy, effectiveness and patient safety.

11.1.7. Hospital pharmacies and Ambulatory pharmacies in DSC are prohibited from purchasing and dispensing medications, pharmaceutical products, vitamins with medical claims that are not registered by MOHAP unless a special import permit is issued from MOHAP for unregistered life-saving medications that does not have other alternatives in the country.

11.1.8. Official purchase invoices/import permits are required be maintained in the pharmacy (original or copy) and may need to be provided to DHA if requested.

11.1.9. Purchase invoices should contain the batch number and expiry date of each purchased item.

11.1.10. The pharmacy is required to ensure that pharmaceutical products are adequately stocked and are available to patients.

11.1.11. In case of un available medication, the pharmacy is requested to:

a. Notify physicians and recommend substitutions to ensure an uninterrupted availability/supply of the drug.

b. Report such shortages to DHA.

12. GUIDELINE EIGHT: PRESCRIBING AND DISPENSING MEDICATION

12.1. Prescribing and Dispensing

12.1.1. It is recommended for the pharmacy to establish and implement a process for safe dispensing of medications within a health facility or pharmacy.

12.1.2. Pharmacists need to have knowledge on the prescribing privileges' of the healthcare professionals including the prescription of Narcotics, Controlled Drugs (CD) and Semi Controlled (SCD) as per the UAE Federal laws and regulations.

12.1.3. The pharmacy staff should review each prescription prior to dispensing and consider the following:

a. Appropriateness of the drug, dose, frequency, and route of administration.

b. Prescription validity e.g. POM Prescriptions are valid for Three (3) month.

c. Therapeutic duplication.

d. Real or potential allergies, sensitivities or interactions between the medications or food.

e. Patient's weight and other physiological information.

f. Other contraindications.

12.1.4. The pharmacy staff are prohibited from selling medications, pharmaceutical products, vitamins and food supplements with medical claims that are:

a. Not registered and approved by MOHAP and/or did not receive marketing approval /Dubai Municipality (DM) approval.

b. Expired or defective.

c. Recalled medications.

d. Introduced illegally to the country.

e. Free medication samples.

f. Prescription Only Medicines (POM) without a formal prescription that complies with the DHA rules and regulations.

12.1.5. Pharmacies should not exceed the selling price specified by MOHAP on the package of the medications or pharmaceutical products.

12.1.6. Pharmacies should not offer additional discounts from those prices specified by MOHAP.

12.1.7. Medications should be sold in their original packs. If part packs/strips are required, then they:

a. Could be sold as per the MOHAP approved price list.

b. May be kept in a pack/container specifying the medicine name, dose, strength, route of administration, batch/lot number and expiry date.

12.1.8. The pharmacy staff may not direct customers to purchase medical products other than those prescribed by their healthcare professional.

12.1.9. The pharmacy staff should not accept any returned medications previously dispensed to patients.

12.1.10. In case the pharmacist finds an error or mistake in the prescription or is in doubt regarding certain contents, the pharmacist is encouraged to contact the healthcare professional who issued the prescription to clarify the matter. The healthcare professional who issued the prescription should underline and sign next to any amendments.

13. GUIDELINE NINE: MEDICATION PREPARATION, COMPOUNDING AND LABELLING

13.1. Medications Preparation

13.1.1. The extemporaneous preparation of medicines is to be maintained in accordance with the guidelines for good manufacturing and distribution practices.

13.1.2. It is the pharmacist's responsibility to assure that medication preparation takes place in a clean and safe area.

13.1.3. It is recommended that pharmacists dispense medications in the most ready to administer form.

13.1.4. Ingredients which are used to prepare sterile products are to be stable, compatible and appropriate for the product to be prepared.

13.1.5. The pharmacist should ensure that all medications are properly prepared, labeled, checked and recorded.

13.1.6. The product label must include all necessary information for appropriate administration and the initials of the persons who prepared and checked the product.

13.1.7. The final product may also include any necessary auxiliary labels, storage requirements and expiration date.

13.2. Medications Compounding

13.2.1. The compounding of medications is a fundamental part of pharmacy practice.

13.2.2. Medication compounding in the Inpatient Pharmacy should adhere to UAE Federal laws, DHA regulations, healthcare professionals' scope of practice, and should have in place policies and standard operating procedures.

13.2.3. It is recommended that all inpatient pharmacies dealing with medications

compounding to develop and implement internal policies and procedures based on UAE federal laws, local regulations, and MOHAP ministerial decrees.

13.2.4. All significant procedures performed in the compounding area is recommended to be covered by written standard operating procedures (SOPs).

13.2.5. A standard operating procedure (SOP) is recommended to cover all significant procedures performed in the compounding area to ensure consistency and may be include but not limited to the followings:

a. Active ingredients.

b. Inactive ingredients.

c. Equipment used.

d. Compounding process.

e. Environmental Quality and Control.

f. Beyond Use Dating (BUD).

g. Post-compounding process.

h. Storage handling and Instructions.

13.2.6. It is expected that all personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations to be trained for the type of compounding conducted.

a. Pharmacists preparing sterile products need to be trained on the principles of medication compounding.

b. It is the responsibility of the pharmacist in-charge to ensure that a training program has been implemented.

c. It is required to maintain an ongoing competency evaluation process for pharmacy personnel involved in compounding, besides documentation of all training related to compounding undertaken by pharmacy personnel.

d. It is required to maintain documentation of all training related to compounding undertaken by pharmacy personnel.

13.2.7. Medications must be prepared in clean and safe areas (Clean Room/Aseptic Room) with appropriate medical technology, equipment, and supplies.

13.2.8. The Aseptic Room and the Cytotoxic Room are Clean Rooms for the manufacturing of medications in a sterile environment. The room will contain laminar flow cabinets and/ or isolators for sterile preparation, and must be accessed via an Anteroom.

13.2.9. Special air-conditioning systems that provide either positive pressure or negative pressure will be required in sterile medication preparation.

13.2.10. The Cytotoxic room should have a negative pressure while any other clean room may have a positive pressure.

13.2.11. All intravenous admixtures e.g. (IV/TPN/Cytotoxic preparations) should be prepared using an aseptic technique, to avoid the risk of contamination of sterile needles, syringe parts (e.g., plunger, syringe tip), and other critical sites during medication preparation and maintain the sterility of prepared products prior to dispensing/and administration.

13.2.12. Hospital must comply with room requirements in relevant international Clean Room standards for sterile and cytotoxic manufacturing.

13.2.13. Compounding medication and intravenous admixtures is recommended to adopt international and national guidelines and Good Compounding Practices for sterile

and non-sterile preparations in reference with (GCP) manual and USP 797 and 795 guidelines.

13.2.14. Pharmacists are responsible for compounding and dispensing sterile products and preparations of correct ingredient identity, purity (freedom from physical contaminants, such as precipitates, and chemical contaminants), strength (including stability and compatibility) and sterility.

13.2.15. The ingredients of the preparation is predetermined to be suitable to result in a final product that meet physiological norms for solution osmolality and pH, as appropriate for the intended route of administration.

13.2.16. Each ingredient and container should be inspected for defects, expiration date, and product integrity before use. Expired, inappropriately stored or defective products should be promptly reported to the pharmacist in-charge.

13.2.17. Mathematical calculations should be performed before initiating the preparation process.

13.2.18. Nonessential material (e.g., labels, calculators, excess syringes or needles, pens, pencils, etc.) should not be placed near the preparation/buffering area.

13.2.19. All jewelry should be removed from hands, fingers, and wrists when preparing sterile products.

13.2.20. Hand-washing facilities shall be provided in each room where open medication is handled. Sterile suites shall have scrub facilities.

13.2.21. Hand hygiene should be performed before handling all IV equipment.

13.2.22. After proper hand hygiene a non shedding gown with sleeves that fit snugly around the wrists and an enclosed neck shall be donned.

13.2.23. The surfaces of ampoules, vials, and container closures (e.g., vial stoppers) should be disinfected by swabbing with 70% isopropyl alcohol) before being used.

13.2.24. The sterile areas of the syringe (e.g., plunger shaft, tip or needle) should not be touched to avoid contamination.

13.2.25. During compounding, volumes of additives in syringes should be examined to confirm accurate measurements. The volumes of solutions remaining in vials and ampoules should be determined to compare to the theoretical volumes required to make the formulation. A mass balance of materials should be evident.

13.2.26. Additive containers and syringes should be available (not discarded in the trash) until the product checks are completed.

13.2.27. Before, during and after the preparation of sterile products, the pharmacist who did the preparation should carefully check the identity and verify the amount of the ingredients in sterile preparations against the original prescription, medication order, or other appropriate documentation (e.g., patient chart, label) before the product is released or dispensed.

13.2.28. A second Pharmacist should countercheck the identity and verify the final preparation against the original prescription.

13.2.29. The pharmacist should verify that the product was compounded accurately with respect to the use of correct ingredients, quantities, containers, and reservoirs; different methods may be used for end-product verification (e.g., observation, calculation checks, and documented records).

13.2.30. Formulations should be subjected to quality control tests as outlined in the formulation records and compounding records. These are generally the physical

tests that can be conducted within the pharmacy and may involve weight variation, specific gravity, pH, filtration membrane integrity, etc.

13.2.31. Formulations that are not distributed promptly should be inspected again before leaving the preparation area. The purpose of the pre-distribution inspection is to check for defects such as precipitation, cloudiness, and leakage which may have developed during storage.

13.2.32. Compounded products should be tested and assessed for safety, stability, contamination and content.

13.2.33. Labels for compounded sterile products must not limit visual inspection of the container contents and the name of the diluents, where possible.

13.2.34. The concept of the environmental controls is to eliminate the number of particles in each area by properly cleaning and garbing as personnel go from a dirty areas to cleaner areas.

13.2.35. Quality assurance practice and environmental quality and control may include, but not limited to the following:

a. Written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, efficacy, quality, and labeled strength, including the frequency of testing.

b. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document.

c. A schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

d. Written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside minimum standards for integrity, potency, quality, or labeled strength.

e. Written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for re dispensing.

f. Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination.

g. Visual confirmation that compounding personnel are properly wearing appropriate items and types of protective garments, including eye protective and face mask.

h. Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded.

i. Visual inspection to ensure the absence of particulate matter in solutions.

13.2.36. Documentation and records should be kept and maintained for all compounded products.

13.3. Medications Labelling

13.3.1. Hospital /Inpatient pharmacies: all medications prepared in the facility, which is not intended for immediate dispensing to a patient is recommended to be identified as follows:

a. Single dose (unit dose) or multi-dose drugs, except parenteral solutions in which a drug has been added, should be labelled with drug name; strength; amount; dose as applicable; route of administration ; expiry date; lot number or reference code.

b. Parenteral solutions, which have drugs added to contain the following information on the outer label: name of each drug; strength and amount including base parenteral solution; date and the time of the preparation; rate of infusion, Instructions for storage, handling, and administration, expiry date/BUD, the time of the admixture; lot number and the reference number or code.

13.3.2. Community/Ambulatory pharmacies: medication prepared by the pharmacy for immediate dispensing to a patient is recommended to be identified clearly with the following information:

a. Patient name;

b. Date of prescription fill;

c. Facility name and address;

d. Name of the prescriber;

e. Drug name;

f. Strength and dosage form;

g. Quantity dispensed;

h. Route of administration;

i. Directions for use and cautionary statements (where applicable);

j. Expiry date of the medication; and

k. Name, initials or unique identifier of the pharmacist that filled or refilled the prescription.

14. GUIDELINE TEN: DRUG SHORTAGES, STORAGE, EXPIRY AND MEDICATION RECALL

14.1. Drug shortages:

14.1.1. It is recommended that all pharmacies in health facilities to establish and implement a documented policy for the storage, maintenance, and protection of emergency medications.

14.1.2. Emergency medications should only be available in the units where they will be needed or are readily accessible within the facility to meet emergency needs.

14.1.3. Emergency medications will need to be monitored and replaced in a timely manner after use.

14.1.4. In case of shortage in a pharmaceutical stock, prescribers should be notified and may asked for suggestion to a substitution.

14.1.5. For out of stock Critical, Life-saving items (emergency medications) pharmacist should manage the following:

a. Calling the physician and suggesting, if possible, to substitute with a therapeutically equivalent item.

b. If no supply can be located, the pharmacist should notify the pharmacist in charge for a decision.

c. If there is no supply of the item with the pharmaceutical companies, agents/suppliers. The pharmacist in charge will attempt to arrange a loan

of the item from other DHA licensed hospital. For further information, refer to DHA Policy for purchasing emergency medications.

14.2. Storage:

14.2.1. It is recommended for all pharmacy staff to receive training on Good Pharmaceutical Storage and Distribution (GSDP) and related rules and regulations.

14.2.2. All Drug Storage Areas is to be fitted with temperature and humidity controls.

14.2.3. Medications should be stored within an adequate storage area in the pharmacy, inpatient care units or the nursing station in the clinical unit, if applicable.

14.2.4. It is recommended that storage areas are of a sufficient capacity to allow the orderly storage of the various categories of products, namely bulk and finished products, products in quarantine, released, rejected, returned and recalled products.

14.2.5. It is prohibited for pharmacies to distribute or store medications and pharmaceutical products of other pharmacies with its storage area.

14.2.6. Storage areas are designed to ensure the following good storage conditions:

a. Keeping storage at least 50cm below the ceiling.

b. Proper cleanliness and hygiene.

c. Dryness (relative humidity not more than 60%).

d. Temperature within acceptable limits (8-25 degrees Celsius).

e. All stored goods and materials are kept off the floor.

f. Suitable spaces to permit cleaning and inspection.

g. Pallets are to be kept in a good state of cleanliness and repair.

14.2.7. It is recommended for all medications, vaccines, and pharmaceutical products to be properly and safely stored within the pharmacy according to the manufacturer storage recommendations stated on the outer packaging:

a. For medications and pharmaceutical products that require be stored at room temperature; the temperature should be maintained between 15-25 degrees Celsius.

b. For medications and pharmaceutical products that require be stored in a relatively cool area; the temperature should be maintained between 8-15 degrees Celsius.

c. For medications and pharmaceutical products that require be stored in a cold place; the temperature should not exceed 8 degrees Celsius.

d. For medications and pharmaceutical products that require storage in a refrigerator; the refrigerator temperature should be maintained between 2-8 degrees Celsius.

e. For medications and pharmaceutical products that require storage in a freezer; temperature should not exceed 0 degree Celsius.

f. Vaccines, should be stored in a separate refrigerator where temperature control is between 2 and 8 degrees Celsius. Refer to DHA Immunization Guidelines for further details.

14.2.8. Food and drink are not be stored in the medication refrigerator or in areas for mediation storage.

14.2.9. A temperature monitoring system is required to be installed and may be connected to a centralized alarm/ warning system.

14.2.10. A sufficient back-up emergency power supply for the refrigerator should be available to ensure protection and safety of medication in the event of an emergency power cut.

14.2.11. A digital thermometer is required to be available in the pharmacy, storage area and medication refrigerator to ensure the validity and stability of the products.

14.2.12. Temperature and humidity monitoring charts readings should be logged on a separate sheet at least twice daily.

14.2.13. The pharmacy cabinets/shelves used to display/store medications appropriately includes the following:

a. A secured double locked steel cabinet(s) for Narcotic drugs (in hospitals/DSC only).

b. A secured lockable steel cabinet(s) for Controlled and Semi controlled Drugs.

c. Cabinets/shelves for Prescription Only Medication (POM).

d. A dedicated and labeled cabinet(s)/area for the storage of expired medications or returned/withdrawn medications

e. These cabinet(s) must be placed away from the general sales area.

14.2.14. The pharmacy should establish and implement a documented policy for the storage of medications that require special consideration, such as but not limited to:

a. Narcotic, controlled and semi controlled drugs.

b. High alert medications.

c. Emergency medications.

d. Look Alike, Sound Alike Medications.

e. Light sensitive Medications.

f. Nutritional products.

g. Radioactive medications.

h. Inflammable materials.

i. Sample medications, if applicable.

j. Recalled medications.

14.2.15. It is recommended that medication in storage to be inspected on a monthly basis by the pharmacist.

14.3. Expiry:

14.3.1. It is recommended that the pharmacy maintains a record for checking expired medications and pharmaceutical products in the pharmacy and clinical areas at least once a month.

14.3.2. The expiration date should always be checked upon receiving medications from suppliers.

14.3.3. The expiration date on the product must be visible and clear.

14.3.4. The First Expired First Out (FEFO) rule may be adopted during medication checking and record keeping.

14.3.5. The expiration date of the product may be written in the format “d/m/y” or “m/y”:

a. If written as d/m/y, then the product is expired on that specific date.

b. If written as m/y, then the product is expired on the last day of the month.

14.3.6. Any medication with an unknown expiration date may be treated as an expired medication and disposed.

14.3.7. All expired and outdated medications has to be collected, labeled clearly as expired or outdated, and isolated from usable stock in a designated area in the pharmacy. Refer to the DHA policy for Medications Disposal and Waste Management.

14.4. Medication Recall:

14.4.1. It is recommended for the pharmacy to put in place a medication recall system. The system may be managed by the pharmacist in charge to ensure the proper process is in place for identifying, recall and return of medications to the manufacture or supplier and /or destruction of medications recalled by the supplier or manufacturer.

14.4.2. As per MOHAP recommendation, drug and healthcare products identified or suspected to have deficiencies should be withdrawn from health facilities.

14.4.3. Deficient and suspected products are kept on hold until MOHAP investigates and issues its final decision.

14.4.4. All medication storage areas and clinical area of the health facility should be inspected by pharmacists in charge for the recalled batch of drug, if any quantity of the recalled batch is available in any clinical area should be removed directly by the pharmacist and replaced by a new batch.

14.4.5. All recalled batch medications has to be returned to the drug stores from which they were purchased.

14.4.6. All patients should be contacted and requested to stop taking recalled

medication and to return them to the pharmacy.

14.4.7. All information pertaining to drug recalls needs to be maintained in a chronological order for a minimum period of one (1) year in the pharmacy.

15. GUIDELINE ELEVEN: MEDICATION TRANSFER, DELIVERY AND WASTE MANAGEMENT

15.1. Medications Transfer

15.1.1. The transfer of registered medications (except CD/SCD) between different health facilities' pharmacies or between the facility/pharmacy branches does not require approval from HRS.

15.1.2. For the transfer/purchase of emergency and unregistered medications, refer to DHA Policy for Purchasing Emergency Medications and Transfer of Controlled and Semi-Controlled Drugs Policy.

15.1.3. The transfer of CD and SCD between health facilities and pharmacies shall abide by the DHA policy for Transfer of Controlled and Semi-Controlled Drugs.

15.2. Medications Delivery

15.2.1. DHA licensed health facilities providing pharmaceutical services are responsible to ensure all relevant UAE federal and local laws, regulations, and standards are met for delivery of medicines and medical products.

15.2.2. DHA licensed pharmacies pursuing to provide Medications Delivery services are required to seek DHA approval for dispensing medications via a delivery system (Telepharmacy) through the (health facility/third party).

a. For application of delivering POM, OTC and general medical products via a delivery system the facility should seek the approval of Telepharmacy

services and must meet the licensure requirements such as but not limited to electronic platforms, online websites and mobile applications. For further information refer to DHA Standards for Telehealth Services on the following link: https://www.dha.gov.ae/Documents/HRD/RegulationsandStandards/standards/Standards%20for%20Telehealth%20Services%20Final.pdf

b. For application of delivering OTC medications and general medical products via a delivery system the facility should seek the approval of add on services to the facility (Home delivery service).

15.2.3. The DHA licensed Pharmacy may engage in third party agreement for delivery of Medications.

15.2.4. The pharmacy has to mention the third party's name in their application form along with photos of the third party's vehicle.

15.2.5. A copy of the contract and an undertaking letter signed by the pharmacist in-charge should be provided.

15.2.6. The pharmacy may provide a guideline detailing and outlining the criteria for safe dispensing and patient counselling if using a delivery systems.

15.2.7. Delivery of medication and medical products to patient shall be undertaken through secure and traceable means.

15.2.8. The DHA licensed Pharmacy and pharmacists in charge must take full responsibility for any medication errors or adverse events resulting inappropriate or unsafe delivery of medications through the facility delivery service or/third-party delivery company services.

15.2.9. Medication supply with delivery services will encompass a review of the prescription and patient counselling including; provision of information on how to use their medication safely, management of potential side effects, ADR, and when to seek medical attention, if required.

15.2.10. Delivery of medication should be transported using packaging or devices, which will ensure that they are maintained within appropriate standards pertaining to temperature, light, humidity and storage as described in the manufacturer's specifications to prevent deterioration.

15.2.11. Medications must be supplied in their original manufacturer packs and leaflets, and delivered in appropriately sealed delivery containers that conceal the contents and maintain patient confidentiality.

15.2.12. Cold chain products are packed in a way to ensure that the required temperature is maintained throughout its transport.

15.2.13. The pharmacy may provide a special temperature and humidity-controlled containers designed for medication requiring cold chain during transporting e.g. insulated Styrofoam coolers, refrigerant gel packs and storing should be within the recommended temperature range of +2 to +8 degrees Celsius (°C).

15.2.14. The delivered medicines and medical products should not encounter any damage to quality or effectiveness during the delivery process.

15.2.15. Soft packaging materials such as cushioning, foam or packing Peanuts may be provided to absorb shocks.

15.2.16. Liquid medicines e.g. syrups are required to be delivered to the patient intact and in good condition through leak-proof bag /absorbent material to deliver

glass bottles safely.

15.2.17. Pharmacist should be able to supply documentary evidence that the pharmaceutical product has not exceeded the acceptable limits temperature and humidity, as determined by the manufacturer's instructions.

15.2.18. The delivery system is required to be conducted in a secured manner, and the delivery of medicines and medical products must comply with patient privacy and confidentiality.

15.2.19. It is recommended to have a secured way for the pharmacist to confirm delivery of medicines and medical products to the adult patient or guardian for patient under eighteen (18).

15.2.20. An emirates/patient ID will be required from the patient/guardian upon receiving on the situation of delivery of POM.

15.2.21. The person in charge of the actual delivery should avoid any contact with the patient regarding any medication related information.

15.2.22. The pharmacy may develop a mechanism for contacting patients regarding delays in delivering medication and medical products in addition to communicating any known recalls.

15.2.23. A comprehensive audit trail of all deliveries is essential to be recorded in a delivery record book (manual/electronic) including patient information and delivery address and patient counseling logs.

15.2.24. A receipt is required on delivery of medicines with the full name of the pharmacist who dispended the medications and the facility name. The pharmacist will need a mechanism to do this, and emailed acknowledgment of

receipt would be reasonable.

15.2.25. A customer satisfaction survey for the provision of medication delivery services may be provided.

15.2.26. It is recommended to have a contact person details for the patients to raise a complaint about the delivery of medicines and medical products.

15.2.27. It is prohibited to deliver Narcotic, CD and SCD medications via a delivery system.

15.3. Waste Management

15.3.1. Medical waste should not be disposed via the routine garbage collection system.

15.3.2. All expired/unusable medications, except the Narcotics, needs to be returned to the drug stores from which they were purchased.

15.3.3. The expired/unusable Narcotic medications shall be returned to the MOHAP Central Drug Stores, after obtaining an approval letter from DHA.

15.3.4. The expired CD and SCD medications that could not be returned to the drug stores/authorized agent shall be discarded by the health facilities and witnessed by DHA inspection team. For further details, refer to DHA policy for Medication Disposal and Waste Management.

16. GUIDELINE TWELVE: OVER THE COUNTER MEDICATIONS

16.1. Over the counter medications (OTC) or nonprescription medicine. All these terms refer to medicine that may be dispensed without a prescription.

16.2. Food and Drug Administration (FDA) classifies these medications categories as:

16.2.1. Allergy.

16.2.2. Cough.

16.2.3. Cold medications.

16.2.4. Pain relievers.

16.2.5. Digestives.

16.2.6. Antiseptics and Disinfectants.

16.3. OTC medications can still carry a risk, even though they do not require a prescription. There is the possibility of side effects, drug interactions, or harm due to excessive doses.

16.4. Pharmacist may advice patients to read the "safety precautions" label that is found on all OTC products.

16.5. Pharmacist may counsel the patients on the possible drug-drug interactions and drug-food interactions should always be considered upon dispensing an OTC medication.

17. **GUIDELINE THIRTEEN**: NON-REGISTERED MEDICATIONS

17.1. Health facilities should always procure registered drugs from qualified registered suppliers in UAE order to protect the patients from any counterfeit or substandard drugs.

17.2. Health facilities intend to apply for MOHAP non-registered drug for the following circumstances:

17.2.1. No available alternatives have been registered by MOHAP.

17.2.2. Discontinued marketing of the drug by the authorized agent or evidenced interruption in drug supply i.e. out of stock items.

17.2.3. Quality defect, efficacy, and safety concerns about the registered brand.

17.2.4. Emergency cases or other justified need for such drugs.

17.3. Health facilities are authorized to apply for MOHAP non-registered medicine approval through the issuance of an import permit.

17.4. If a Hospital/DSC requires any non-registered with MOHAP, authorized distributers may be contacted directly to import the required drugs with:

17.4.1. Official justification/declaration letter from the health facility

17.4.2. An expected consumption (should not exceed six (6) months' supply).

17.4.3. After importing and receiving the required drugs, a copy of the authorized distributers import permit letter should be kept in the health facility for HRS audits.

18. GUIDELINE FOURTEEN: NARCOTIC, CONTROLLED AND SEMI CONTROLLED DRUGS

18.1. As part of the medicine registration process by the MOHAP, and when a medicine is approved (registered) for use in the UAE, the mode of dispensing will be determined, as per the list mentioned below:

18.1.1. Over the counter (OTC).

18.1.2. Pharmacist only Medicine (PH-OM).

18.1.3. Prescription only Medicine (POM).

18.1.4. Semi Controlled Drugs (SCD).

18.1.5. Controlled Drugs (CD).

18.1.6. Narcotic.

18.2. Narcotic, CD and SCD are classified based on the level of control of the active ingredient according to the UAE federal laws and level of controls in the source country.

18.3. Medications Organization and Management

18.3.1. Health facilities dealing with Narcotics, CD and SCD shall develop and implement internal policies and procedures to identify management and organization of such medication, based on local regulations, MOHAP ministerial degrees and UAE federal laws which includes, but is not limited to:

a. Prescribing, dispensing and administering.

b. Storing, security and medications access.

c. Distributing from, to and within the health facility, pharmacy and patient care settings.

d. Returning, disposing and destroying.

e. Specific roles, responsibilities and accountability of Healthcare Professionals.

f. Reporting process for any unanticipated side effect, unpredicted adverse effect or serious adverse event related to Narcotics, CD and SCD.

18.3.2. It is recommended that all health facilities conduct regular educational and training for Health Professional (HP) regarding handling and dispensing of Narcotics, CD and SCD to ensure quality of handling and practice.

18.3.3. All HP and health facilities are required to comply and cooperate with the DHA inspectors, and provide all required reports and registers. The inspectors can have access to the Narcotics, CD and SCD cabinets (to check the balance), registers, prescriptions, invoices and delivery notes.

18.3.4. Health facilities may have to follow a process to ensure that the Person in-charge gets appropriate clearance from the responsibility of Narcotics, CD and SCD medications before leaving/resigning.

18.4. Narcotics and Controlled Drugs Person in-charge

18.4.1. Health facilities should assign an appropriately qualified and trained full time DHA licensed healthcare professional (Anesthesiologist, Clinical Pharmacist or Pharmacist) as the Person in-charge to be responsible and accountable for dispensing, monitoring, tracking, reporting, returning and disposing the Narcotics, CD and SCD.

18.4.2. An experienced licensed nurse(s) (head or in-charge nurse) should be responsible for the Narcotics, CD and SCD in the health facility's medication rooms e.g. in-patient units, emergency room.

18.4.3. The health facility is required to inform the HRS of the nominated in-charge staff by completing the form in (**Appendix 1**).

18.4.4. The Person in-charge for each setting is set out below:

a. In Hospital/Inpatient pharmacy: full time DHA licensed Clinical Pharmacist or Pharmacist.

b. In Day Surgical Centers (DSC) /Ambulatory pharmacies: full time DHA licensed Clinical Pharmacist, Pharmacist, or Anesthesiologist.

i. For further details, refer to the DHA Standards for Standalone Day Surgery Centres.

c. Community (only CD and SCD): full time DHA licensed Clinical Pharmacist or Pharmacist.

18.4.5. The Person in-charge is responsible to monitor, track and accurately report all Narcotics, CD and SCD within the health facility to HRS.

18.4.6. The Narcotics, CDs and SCDs In-Charge seeking annual leave/emergency leave

resignation or others are expected to adhere to the following steps:

a. Handover of Narcotics, CD and SCD stock to another responsible licensed Pharmacist, Clinical Pharmacist or Anesthesiologist termed Deputy in-charge within the same facility.

b. Notify HRS using Narcotics, CDs and SCDs Stock Handover form (**Appendix 2**).

c. Ensure HRS approval of the hand over responsibility.

d. Inform HRS of the full list of the available stock.

e. Narcotics and CD/SCD cabinet keys shall be handed over to the Deputy in-charge.

f. At the time of hand-over, there must be a full stock count (inventory) and both the Person in-charge, Deputy in-charge and the facility's medical director must sign a detailed list of all Narcotics, CD and SCD names, quantities, batch numbers & expiry dates stored in the health facility to confirm the stock.

18.5. Procuring Narcotics, CDs and SCDs

18.5.1. Purchased Narcotics from MOHAP, are required to be directly transferred to the health facility, and the quantities shall be entered into the Narcotic register book on the same day by the Person in-charge.

18.5.2. CD and SCD may be purchased directly from licensed drug stores in the UAE. The delivery notes/vouchers should be signed by the Person in-charge at the time of delivery and the received quantities shall be entered into the CD/SCD register books on the same day.

18.5.3. All delivery notes/vouchers shall be retained for five (5) years and made available for review by DHA inspectors at any time.

18.6. Storage of Narcotics, CD and SCD

18.6.1. All HP and health facilities dealing with Narcotics, CD and SCD should understand and abide by the Good Pharmaceutical Storage and Distribution Practices and other related rules and safety regulations.

18.6.2. Narcotics, CD and SCD should be properly and safely stored within the pharmacy according to the manufacturer recommendations.

18.6.3. All Narcotics, CD and SCD cabinet(s) should be placed away from the general sales area and shall be inaccessible to the public.

18.6.4. The main storage area for Narcotic drugs, Narcotic register books and Narcotic prescription books are stored in a special secured lockable cabinet(s) with the following features:

a. Made of steel with internal hinges.

b. Have a double locking system.

c. Be securely fixed to the wall or floor.

d. Non-duplicable keys.

e. Security/alarm system and/or security camera.

18.6.5. Narcotic drugs stored outside the pharmacy (in the inpatient units or medication room) should be placed in a double locked steel cabinet inside a secured medication room.

18.6.6. CD and SCD register book should be stored in separate cabinet in a special secured lockable cabinet made of steel with a single locking system.

18.6.7. The cabinet should be designated by a label and the key(s) must be kept in the custody of the Person in-charge or the authorized Deputy in-charge.

18.7. Prescribing Narcotics, CD and SCD

18.7.1. All HP and Medical Director of health facilities shall understand and abide by the Ministerial Decree number (888) of the year 2016 and all other local UAE federal laws, regulations and circulars concerning the prescribing and dispensing of Narcotics, CD and SCD Using the Unified Controlled Medication Platform.

18.7.2. If the physician or dentist prescribe Narcotics, CD and SCD for incompetent patients, dispensing shall be limited to the patient's parents or legal guardian.

18.7.3. Prescribing **Narcotics,** shall abide by the following:

a. DHA licensed physicians, including only consultants and specialists (within the scope of their specialty) can prescribe Narcotics for inpatient and Emergency units in government and private hospital settings.

b. Prescribing, dispensing and use of Narcotics should be limited to in-patient wards of government and private hospitals.

i. An exception to this in outpatient setting is for cancer patients, treatment of severe pain and post major surgeries. The prescription of Narcotic medicines in the dosage forms of (tablets, capsules and patches) for use by patients outside the hospital is limited to a maximum of thirty (30) days only.

c. Prescribing Narcotics for outpatients shall be only be prescribed, through the Unified Controlled Medication Platform.

d. Each Narcotic dose shall be prescribed on a separate prescription (for Inpatient Units).

e. Refill prescriptions for Narcotics is prohibited.

18.7.4. For prescribing **CD**, physicians and dentists should abide by the following:

a. GP and general dentists are authorized to prescribe CD for a period not exceeding (3) days and only for one time "for the same diagnosis and treatment".

b. Specialist physician (within the scope of specialty) is authorized to prescribe CD for a period not exceeding (15) days.

c. Consultant physician (within the scope of specialty) is authorized to prescribe CD for a period not exceeding thirty (30) days.

d. CD prescription should be carried using the Unified Controlled Medication Platform.

e. Refill prescriptions shall not be issued for CD, a specific exceptional list has been issued to define CD which can be refilled by specialist and consultant physician only as per the Ministerial Decree No (680) for the year of 2017.

18.7.5. For prescribing **SCD**, the physicians and dentists shall abide by the following:

a. GP and general dentists are authorized to prescribe SCD for a period not exceeding thirty (30) days and no refill is authorized.

b. Specialist physician (within the scope of specialty) is authorized to prescribe SCD for a period not exceeding thirty (30) days and one refill for thirty (30) additional days.

c. Consultant physician is authorized to prescribe SCD for a period not exceeding thirty (30) days, and two refills for thirty (30) days each.

d. The refill shall only be dispensed at the end of the initial prescription for thirty (30) days.

18.8. Dispensing Narcotics, CD and SCD

18.8.1. Narcotics dispensing

a. When a Narcotic drug requires administration by infusion e.g. (IV/Epidural), another member of clinical staff must be present to witness the infusion.

b. After administration of the Narcotic drug, the dose should be recorded and signed by DHA licensed treating physician and another member of clinical staff in the Narcotic prescription form. The form shall be stamped and filed completely.

c. All dispensed quantities in the pharmacy needs to be recorded in the Narcotic register book by the Pharmacist/Person in-charge, and the authorized personnel in the inpatient units/clinical areas.

d. Each entry into the Narcotics register book must be accurate, legible, with clear handwriting and includes the prescription number and patient name and their health record number.

e. In the inpatient units and other clinical areas, the Narcotic nurse in-charge shall dispense Narcotics to the patient through a formal Narcotic prescription.

f. In the pharmacy, the Pharmacist in-charge shall reconcile the Narcotic order with the Narcotic prescription and check the authorized personnel signature prior to dispensing the drug.

g. The Pharmacist in-charge shall review the elements and validity of each prescription prior to dispensing the Narcotics to inpatients units/clinical areas.

h. The validity of the Narcotic drug prescription shall not be more than three (3) days from the date of issuing the prescription by the treating physician.

i. The pharmacist should not dispense the Narcotic prescription after three (3) days from the prescription date.

j. The Pharmacist in-charge shall sign on the Narcotic drug prescription prior to dispensing and should retain all the prescriptions in the facility for a minimum of five (5) years.

k. Discarding all unused Narcotic shall be recorded and signed on the Narcotic prescription form and counter-signed by a witness.

l. When the Narcotic drug has been opened and prepared for administration, but cannot be given for any reason (e.g. patient refuses), the drug shall not be returned to stock and shall be discarded in the presence of clinical staff.

m. The discarded amount of the unused dose shall be recorded on the Narcotic prescription form on the same day and countersigned clinical staff.

n. The dose shall be recorded in the Narcotics register book.

18.8.2. CD dispensing

a. Pharmacist shall review the elements and validity of each CD prescription prior to dispensing.

b. The validity of the CD prescription shall not be more than three (3) days from the date of issuing the prescription by the treating physician or dentist.

c. Pharmacist shall retain all the Electronic prescription records in the health facility for a minimum of five (5) years.

d. All dispensed quantities of CD shall be recorded in the CD register book by the Person in-charge.

18.8.3. SCD dispensing

a. Pharmacist shall review the elements and validity of each SCD prescription prior to dispensing.

b. The validity of the SCD prescription shall not exceed three (3) days from the date of issuing the prescription by the treating physician/dentist.

c. SCD Electronic prescriptions shall be retained in the health facility for a minimum of two (2) years.

d. The dispensed drugs shall be recorded in the SCD register book by the Person in-charge.

18.9. Monitoring and Record Keeping

18.9.1. The health facility should maintain a copy of patient's emirates ID or passport copy for any non-resident patients.

18.9.2. All Health facility should use the following registers by the authorized person as follows:

a. Narcotic Register book (MOHAP).

b. CD and SCD Register book (DHA).

18.9.3. Narcotics, CD and SCD register books shall be used only by the authorized persons.

18.9.4. Entries into the register books should be maintained as per the below requirements:

a. Handwriting should be clear and legible with indelible ink.

b. Contain separate sections for each individual drug.

c. Have the name, dosage form and strength of the drug specified at the top of each page.

d. Have the entries in chronological order without leaving blank line; the date of each transaction should be clear and each entry should be made on the same day of the transaction.

e. Erasing, over writing, crossing out or using corrective pens may lead to violation.

f. Documentation in the "Remark" column is used, if there is an error with drug entry with signature next to it, and another line can be used for new entry in the registry book.

18.9.5. The Narcotic, CD and SCD register books should be stored in the health facility for five (5) years after completion.

18.10. Reporting Narcotics, CD and SCD

18.10.1. Pharmacies and other health facilities shall monitor, track accurately Narcotics, CD and SCD that are stored, prescribed, dispensed, administered, returned and disposed within their health facility.

18.10.2. Regular reports shall be submitted to HRS by email, to includes the following:

a. Quarterly reports on the consumption of Narcotics (**Appendix 3**).

b. Monthly reports on the consumption of CD and SCD (**Appendix 4**).

18.10.3. Reporting forms are available on the DHA website link:

https://www.dha.gov.ae/en/HealthRegulation/Pages/processandforms.aspx

18.11. Drug Discrepancies

18.11.1. Health facilities shall develop and implement an ongoing system for notification, monitoring and investigation of any identified discrepancies related to Narcotics, CD and SCD.

18.11.2. All HP dealing with Narcotics, CD and SCD should know their duties and responsibilities as below:

a. Reconcile any discrepancies in Narcotics, CD and SCD stocks by the end of their shift.

b. All Narcotic and CD stocks are counted at the beginning and end of each shift.

c. The Narcotic and CD count of is recorded and signed by each of the in charge shift who perform and witness the count in the facility CD checklist.

d. Report and document all drug discrepancies discovered during their shift, to the responsible personnel if it cannot be reconciled.

18.11.3. Any drug discrepancies are to be reported to HRS as an incident using the Drug Incident Report Form (**Appendix 5**).

18.12. Transferring of Narcotics, CDs and SCDs

18.12.1. Narcotics cannot be transferred between health facilities.

18.12.2. Transferring CD and SCD between pharmacies and other health facilities is strictly prohibited. Exceptions may be granted within a group of health facilities with the same owner for specific reasons such as temporary or permanent closure, or emergency cases only.

18.12.3. The health facilities should fill and submit to the HRS a Transfer Request Form (**Appendix 6**). Accordingly, HRS inspection team shall visit the health facilities, adjust, and sign the balance in the register books. For further details, refer to the DHA Policy for Transfer of CD and SCD medications.

18.12.4. In exceptional emergency cases, transfer of registered or non-registered CD and SCD between health facilities may be permitted by Drug Control Section at HRS. In such case, an official letter should be submitted by the Medical Director of health facility with clear justification of the request. For further details, refer to the policy for purchasing emergency medications.

18.12.5. Any other transfer of registered or non-registered CD and SCD would be considered as illegal supply, and may result in disciplinary action.

18.13. Medications Return and Waste Management

18.13.1. All inpatient units and clinical areas within the Hospital setting shall return any expired/damaged/unusable stock of Narcotic, CD and SCD to the hospital pharmacy.

18.13.2. Upon return, the Pharmacist in-charge shall isolate the unused or expired drugs and re-issue the exact amount and type of medication to the inpatient unit or clinical area.

18.13.3. All expired/unused Narcotic drugs shall be subject to DHA Narcotic Disposal request approval (**Appendix 7**) and subsequently returned to the MOHAP Central Medical Stores.

18.13.4. Disposal of used empty Narcotic drugs ampoules shall be done in the sharp containers and shall be documented by hand writing on the back of the Narcotic prescription and signed by the person Incharge and another witness from healthcare professionals.

a. All documents related of the disposal of used empty Narcotic drugs ampoules shall be retained for a legal period of 5 years, for the purposes of auditing and supervision.

18.13.5. All expired/unused CD and SCD shall be returned to the distributing drug stores.

18.13.6. If the distributing drug store will not take back the CD and SCD (short shelf life or damaged), it should be approved by DHA inspection team, then discarded by the health facility as medical waste.

18.13.7. The health facilities should fill and submit to the HRS "Medication Disposal Request Form" (**Appendix 8**) available on the DHA website link: https://www.dha.gov.ae/en/HealthRegulation/Pages/processandforms.aspx

a. Upon receiving the completed form, the inspection team from HRS shall visit the health facility and audit the drugs to be disposed, deduct the expired amounts from the CD and SCD registers and sign the form.

b. The health facility must dispose the drugs by a contracted medical waste management company approved by Dubai Municipality (DM) within thirty (30) days of the inspection visit.

c. Disposal reports should be maintained at the health facility and a copy should be submitted to Drug Control Section at HRS , through email drugcontrol@dha.gov.ae .

d. All such transactions related to the disposal should be documented by the inspection team in the corresponding registers. For further details, refer to DHA Policy for Medications Disposal and Waste Management.

18.14. Incidence Reporting

18.14.1. Narcotics, CD and SCD incidents should be documented and reported to HRS. This includes the following but not limited to:

a. Missing, broken, leakage, or empty or manufacture damaged ampoules.

b. Missing register book or a Narcotic prescription pad.

c. Drug discrepancies.

d. Missing of physician or dentist stamp.

e. Stolen CD and SCD drugs.

18.14.2. All relevant incidents shall be reported to HRS by email to Drugcontrol@dha.gov.ae using the Drug Incident Report form (**Appendix 5**) within 48 hours.

18.14.3. Reporting theft or losses of controlled drugs/prescriptions to the nearest police station and submitting the police report to HRS in a timely manner for taking the necessary required action.

18.14.4. The health facility are required to develop a corrective action plan, which should be document for HRS audit purposes.

19. GUIDELINE FIFTEEN: USE AND APPROVAL OF MEDICAL DEVICES AND CONSUMABLES

19.1. Local authorized suppliers and agents are required to follow the requirements of MOHAP for the registration of medical equipment in the UAE.

19.2. Product information includes a detailed description of the formulation, type, size, model, accessories, side effects, contraindications, warnings, precautions, usage guidelines, photos of the package, brochures and usage manual.

19.3. All medical equipment and instruments are required to conform with the MOHAP technical and manufacturing standards.

19.4. It is the responsibility of the Pharmacist Incharge to inspect incoming medical equipment and instruments with the representative from the supplier before approval is granted for the Equipment.

19.5. The authorized agent is required to adhere to the post-marketing monitoring requirements and technical assessment of the medical equipment's. E.g. equipment's which require periodic calibration.

20. GUIDELINE SIXTEEN: PATIENT COUNSELLING AND FAMILY EDUCATION

20.1. Pharmacists are required to have the knowledge and skills to provide effective and accurate patient education and counselling.

20.2. It is recommended for pharmacists to use verbal and non-verbal communication skills with their patients and may refer to the use of teaching aids, interpreters, or cultural guides.

20.3. At the time of dispensing medications to the patient, pharmacists are recommended to counsel the patient, and provide relevant health information and/or leaflets if available for the drug being dispensed (in addition to the instructions already included on the label).

20.4. The pharmacist may counsel the patient for any ADRs and/or Drug-food interactions.

21. GUIDELINE SEVENTEEN: GOOD VIGILANCE PRACTICE

21.1. Monitoring and assessing the effect of the medication includes direct observation of the patient during assessments, evaluations or other patient contact to determine the patient's physiological response to the medication administered and any problems or adverse effects associated with the medication.

21.2. Patient-medication monitoring may include a collaborative approach between patient care providers, physicians, pharmacists, the patient and the family or caregivers.

21.3. For medications or categories of medications known to commonly produce side effects or sensitivities in patients, It is recommended for the patient to be physically observed for the potential side effects and sensitivities for 24-hour.

21.4. It is recommended for patients to receive a test dose, for certain medications such as antibiotics if given for the first time in an effort to identify potential ADRs, allergy or sensitivity to the medication.

21.5. Other Clinical Laboratory studies may be ordered as appropriate to monitor the patient's response to medications that are new to his or her system to prevent unnecessary side effects or adverse reactions (i.e., peak and trough levels).

21.6. In the event of side effects or adverse reactions the following forms are required:

21.6.1. The Adverse Drug Reaction Reporting Form (**Appendix 9**)

21.6.2. The Medication Errors Reporting Form (**Appendix 10**)

21.7. Subsequently, submit the report by Email to drug control section via DrugControl@dha.gov.ae.

21.8. Medication Errors, ADRs of medicines and medical products should be reported to Drug Control Section /HRS-DHA, by within fifteen (15) days.

21.9. An advisory committee constituted at DHA will provide recommendations and may initiate further actions on the reported cases.

21.10. Based on the advisory committee recommendation, DHA will follow up with all the concerned parties and decide whether actions need to be taken in the light of the information obtained.

21.11. All health facilities and professionals are required to follow the UAE MOHAP Guidelines in Good Vigilance Practice (GVP) 2018 For Marketing Authorization Holders/Pharmaceutical Manufacturers in UAE, which includes the updated methods for reporting the side effects and adverse reactions of medical products, which are registered, marketed, and used in public and private health institutions in the UAE.

21.12. For further information, contact the Drug Control Section in DHA at: DrugControl@dha.gov.ae.

22. GUIDELINE EIGHTEEN: SAFETY PRECAUTIONS FOR PHARMACEUTICAL FACILITIES DURING PANDEMIC COMMUNICABLE DISEASES

22.1. Pharmacy operations and facilities

22.1.1. Professional oversight/managing pharmacist should be available if pharmacist Incharge cannot assure his/her presence and role at the pharmacy, these can be taken up by a second pharmacist who may not be part of the the pharmacy's personnel.

22.1.2. The "second" pharmacist should take up the responsibility for the supervision of all activities of the pharmacy and all the personnel (part time pharmacist).

22.1.3. The new opening hours should be communicated to the public in a visible place outside the pharmacy. The new opening hours need to assure minimal service to the community in terms of medicines supply.

22.2. Preventive Measures

22.2.1. Pharmacists and the pharmacy workforce can play a key role in preventing the spread of communicable diseases by having a clear understanding of the nature of the disease, how it is transmitted, and how to prevent it from spreading further.

22.2.2. Have a clear understanding on how to access their national level information sources regarding the communicable diseases management.

22.2.3. Strengthen infection exposure management.

22.2.4. Ensure adequate cleaning and disinfection management.

22.2.5. Protect pharmacy personnel.

22.2.6. Supplying appropriate personal protective equipment (PPE).

22.2.7. Develop emergency plans and workflow.

22.2.8. Carry out full staff training.

22.2.9. Informing, advising and educating the community.

22.3. Personal Protection

22.3.1. The commitment of all pharmacists and pharmacy staff to wear personal protection supplies or equipment, including masks, gloves, and others.

22.3.2. Pharmacists and pharmacy technicians should always wear a facemask while they are in the pharmacy for source control.

22.3.3. When available, facemasks are generally preferred over cloth face coverings for healthcare professionals for source control.

22.3.4. Providing and easy access to soap and water or hand sanitizer for staff.

22.3.5. Pharmacy staff should provide hand sanitizer containing at least 60% alcohol at the pharmacy entrance encouraging customers to use them before entering the pharmacy and on counters.

22.3.6. Use strategies to minimize close contact between pharmacy staff and customers and between customers.

22.3.7. Maintain at least one and a half meter distance between the customers inside the pharmacy at all times.

22.3.8. Maintain at least one and a half meter distance between the pharmacist and the customer at all times.

22.3.9. Encourage home delivery services, taking into considerateness the conditions and controls for the transportation of medical products and maintaining their safety and quality.

22.3.10. Ensure good ventilation and increase the frequency of pharmacy cleaning and sterilization.

22.3.11. Ensure that anyone who enters the pharmacy is wearing a facemask regardless

of symptoms, for source control (i.e., to protect other people in case the person is infected).

22.3.12. Ensure that pharmacy staff who develop upper respiratory symptoms or fever suggestive of must seek medical advice.

22.3.13. Pharmacists and their assistants may also develop information materials posters, flyers, etc.) around the facility for the community, including the information contained in these guidelines and any other information that may be relevant to local needs.

22.4. Workplace Settings

22.4.1. Consider designing and installing engineering infection control measures to reduce or eliminate exposures and close contact and control where the customer and pharmacy staff interact, such as the pharmacy counter.

22.4.2. To shield against droplets from coughs or sneezes, pharmacy should install a section of clear plastic at the customer contact area to provide barrier protection (e.g., Plexiglas type material or clear plastic sheet). Configure with a pass-through opening at the bottom of the barrier for people to speak through or to provide pharmacy items, if feasible.

22.4.3. If necessary, a tray may be used to collect prescriptions, hand over medicines and process the payment in order to overcome this distance.

22.4.4. Minimize physical contact with customers and between customers.

22.4.5. Limit the number of customers in the pharmacy at any given time to prevent crowding at the pharmacy counter or checkout areas.

22.4.6. Maintain social distancing (1.5 - 2 Meters) for people entering the pharmacy as

much as possible. Use signage/barriers and floor markers to instruct waiting customers to remain (1.5 - 2 Meters) back from the counter, from other customer interfaces, and from other customers and pharmacy staff.

22.4.7. Promote social distancing by diverting as many customers as possible to drive-through windows, Telepharmacy, or Medication delivery, where feasible.

22.4.8. Include text or automated telephone messages that specifically ask sick customers to stay home and request Medications Delivery or send a well family member or friend to pick up their medicine.

22.4.9. For hard non-porous surfaces, pharmacy should clean with detergent or soap and water if the surfaces are visibly dirty prior to disinfectant application.

22.4.10. Frequently clean and disinfect all customer service counters and customer contact areas. Clean and disinfect frequently touched objects and surfaces such as workstations, keyboards, telephones, and doorknobs.

22.4.11. Pharmacy must discontinue the use of magazines and other shared items in pharmacy waiting areas. Ensure that the waiting area is cleaned regularly.

22.4.12. Promote the use of self-serve checkout registers, clean, and disinfect them frequently.

22.5. Pharmacy Personnel Infected with Communicable Diseases

22.5.1. The health facility should develop emergency communications plans covering pharmacy personnel infected with any Communicable Diseases.

22.5.2. The health facility should Identify potentially exposed pharmacy personnel including clarification of where and how exposure to risk could happen.

22.5.3. The health facility may evaluate workers' individual risk factors (e.g. employees

of older age (typically above 50), presence of chronic or specific medical conditions, etc.), and separate them in accommodation and in their work shifts.

22.5.4. The suspected pharmacy staff should be investigated, managed and isolated as per the government's guidelines for suspected cases.

22.5.5. All close contact staff must be away from other personnel with regular monitoring throughout the 14-day quarantine period.

22.5.6. If a case developed symptoms during the 14-day quarantine period, the staff should seek immediate medical advice.

22.5.7. All close contacts staff are advised to stay in quarantine for 14 days the last exposure and should self-monitor for any respiratory symptoms.

22.6. Medicines Supply

22.6.1. During pandemic and emergency communications, pharmacies should prioritise the dispensing of medicines and medical devices over non-essential products.

22.6.2. Medications supplied through wholesale distributors for the delivery of medicines should be cleaned and disinfected before they are taken inside the pharmacy facilities.

22.6.3. Access to products on self-selection by customers should be restricted to avoid multiple people touching these products. They should be accessed only by pharmacy personnel.

22.6.4. Health professionals should be encouraged to submit prescription orders electronically.

22.6.5. The pharmacy may develop procedures to minimize handling paper prescriptions, in accordance with appropriate local rules and regulations.

22.6.6. After a prescription has been prepared, the packaged medication can be placed on a counter for the customer to retrieve, instead of being directly handed to the customer.

22.6.7. Avoid handling insurance or benefit cards. Instead, it's advisable to take a picture of the card for processing.

22.6.8. Avoid touching objects that have been handled by customers.

22.6.9. If transfer of items must occur, pharmacy staff should wash their hands afterwards with soap and water for at least 20 seconds or use an alcohol-based hand sanitizer containing at least 60% alcohol. They should always avoid touching their eyes, nose, or mouth with unwashed hands.

22.6.10. Pharmacies that are able to offer this service are encouraged to do so, especially for patients who may be in home quarantine or isolation, or who may belong to a higher risk group or have reduced mobility.

22.6.11. Delivery of medication to patient shall be undertaken through secure and traceable means.

22.6.12. The delivery of medicines and medical products must comply with patient privacy and confidentiality.

22.6.13. Delivery of medication should be transported using packaging or devices, which will ensure that they are maintained within appropriate standards pertaining to temperature, light and humidity as described in the manufacturer's specifications.

22.6.14. The person in charge of the actual delivery should avoid any direct contact with the patient and their personal objects.

22.6.15. Medicines and other items may be left outside the door of the patient/customer or in another designated place, and the deliverer should move to keep a safe distance of 1–2 meters while visually ensuring that medicines are collected by the patient or an authorised person.

22.6.16. For the supply of Chronic medications during pandemic and emergency circumstances;

a. Pharmacists who are providing patients with chronic disease management services, medication management services, and other services that do not require face-to-face encounters should make every effort to use telephone, telehealth, or Telepharmacy strategies.

b. Patients who have been prescribed chronic medications are able to get their medicines for a period of three (3) months.

c. Advise the patient to send a copy of his Emirates ID to the healthcare facility mentioning the name of the treating physician, at least two days before the refill time, in order to enter the prescription and to prepare the medication in the pharmacy.

d. Medicines can be received based on the submitted patient's Emirates ID copy without the need the patient's personal attendance to the healthcare facility or to the pharmacy.

22.6.17. For the supply of CD and SCD medications during pandemic and emergency circumstances;

a. Patients who have been prescribed CD and SCD medication through the unified electronic platform is able to get their medicines for a period of

three (3) months.

b. The patient is advisable to send a copy of his Emirates ID to the healthcare facility mentioning the name of the treating physician, at least two (2) days before the refill time, in order to enter the prescription in the electronic unified platform and to prepare the medication in the pharmacy.

c. Medicines can be received based on the submitted patient's Emirates ID copy without the need for the patient's personal attendance to the healthcare facility or to the pharmacy.

23. GUIDELINE NINETEEN: RECORD MANAGEMENT AND DATA PROTECTION

23.1. All prescriptions should be documented in the patient's medical record in compliance with the applicable rules and regulations.

23.2. All electronic invoices and related commercial transactions in the pharmacy are required to be maintained and available for periodic inspection.

23.3. All DHA Pharmacy Circulars are required to be maintained and available in the pharmacy either soft or hard copies.

23.4. The pharmacy record system should be able to address medication recalls and isolate lot numbers/mix of lots.

23.5. Accessibility and retention of health records should be consistent with the requirements of the applicable Federal laws and local regulations. Please refer to the DHA guidelines in managing health records.

24. GUIDELINE TWENTY: PATIENT COMMUNICATION AND CONFIDENTIALITY

24.1. Pharmacy duty is to comply with patient privacy, consent, confidentiality, protection and security of patient data and maintain systems and processes for data collection, storage and backup of patient health information.

24.2. Patients' information in both electronic and manual based medications prescriptions are to be kept confidential and secured.

24.3. An Access Control system to the facility electronic system is required to all pharmacists and is not to be disclosed or accessed by an unauthorized personnel.

24.4. Pharmacists and health professionals must assure professionalism and confidentiality during the provision of medication services to the patient.

25. GUIDELINE TWENTY-ONE: KEY PERFORMANCE INDICATORS FOR PHARMACY PRACTICE

25.1. It is recommended for the pharmacy to establish, implement, maintain and continually improve a documented policy for key performance indicators (KPIs), data collection, and calculation and submission management system.

25.2. It is recommended that all KPIs across all pharmacy service areas, to be defined.

25.3. It is recommended for the pharmacy to maintain a quality improvement system.

25.4. Measurement and assessment of KPIs on pharmacy practice serves to advance clinical pharmacy practice and improve patient care.

25.5. Medication use evaluation is a quality improvement system that focuses on evaluating and improving medication use and/or medication use processes with the goal of optimal patient outcomes.

25.6. Medication use evaluation is a proactive, criteria based, designed and managed by multidisciplinary team and systematically carried out.

25.7. Priorities for the selection of medications for evaluation may include but not limited to :

25.7.1. The number of patients affected by a given medication (frequency of use).

25.7.2. The degree to which the usage of the medication is known or suspected to be problem prone.

25.7.3. The responsibility for the monitoring and evaluating the Pharmaceutical Services is assigned to Pharmacy Incharge.

25.7.4. Key Performance Indicators which are selected and monitored including Medication Errors and near misses as well as ADRs, are an indication to the safety and effectiveness of the medication management and use.

REFERENCES

1. Cabinet Decision No. (21) of 2019 amendment to Federal Law No. (14) of 1995 on the combat of Narcotic drugs and Psychotropic substances.
2. Cabinet Decision No. (47) of 2018 adopting the unified national standards for hospitals.
3. Centers for Disease Control and Prevention (2019). Novel coronavirus, Wuhan, China. Information for Healthcare Professionals. Available on: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html (accessed on February 14, 2020).
4. Centers for Disease Control and Prevention (2019). Prevention Strategies for Seasonal Influenza in Healthcare Settings. Available on: https://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm (accessed on February 14, 2020).
5. Covid-19 Command and Control Centre (2021). Home Isolation and Quarantine Guidelines during Coronavirus (COVID-19) Pandemic. Third Issue.
6. Dubai Health Authority (2013). Dubai Community Pharmacy Licensure and Pharmaceutical Practices Guideline. Available on: https://www.dha.gov.ae/Documents/Regulations/Dubai%20Community%20Pharmacy%20Licensure%20and%20Pharmaceutical%20Practices%20Guide.pdf (accessed 31 March 2020).
7. Dubai Health Authority (2019). Guidelines for Clinical Training Facilities. Available on: https://www.dha.gov.ae/Documents/HRD/Policies/Guidelines%20for%20Clinical%20Training%20Facilities.pdf (accessed 31 March 2020).

8. Dubai Health Authority (2019). Health Facility Guidelines. Guidelines for design and construction of hospitals and outpatient facilities. Available on: https://eservices.dha.gov.ae/CapacityPlan/HealthFacilityGuidelines/Guidelines/Index/DHAHFG?locale=en (accessed 31 March 2020).
9. Dubai Health Authority (2019). Health Facility Guidelines. Part B – Health Facility Briefing & Design, 370 – Pharmacy Unit. Available on: https://eservices.dha.gov.ae/CapacityPlan/HealthFacilityGuidelines/Guidelines/FileContent/Preview/DHAHFG/DHA_part_b_pharmacy_unit (accessed 31 March 2020).
10. Dubai Health Authority (2019). Standards for Telehealth Services. Available on: https://www.dha.gov.ae/Documents/HRD/RegulationsandStandards/standards/Standards%20for%20Telehealth%20Services%20Final.pdf (accessed 30 November 2020).
11. Dubai Health Authority (2020). Policy for Medications Disposal and Waste Management.
12. Dubai Health Authority (2020). Circular 2020/0001176 on the Permission for all licensed Health Professionals to work between DHA licensed Health Facilities for handling COVID-19.
13. Dubai Health Authority (2020). Circular 2020/0001176 on the Permission for all licensed Health Professionals to work between DHA licensed Health Facilities for handling COVID-19.
14. Dubai Health Authority (2020). Circular updates (2) on precautionary measures and instructions against spread of COVID-19 in Private health facilities.
15. Dubai Health Authority (2020). Circular updates (3) on precautionary measures and instructions against spread of COVID-19 in Private health facilities.
16. Dubai Health Authority (2020). Circular updates (4) on precautionary measures and instructions against spread of COVID-19 in Private health facilities.
17. Dubai Health Authority (2020). Policy for Purchasing Emergency Medication.

18. Dubai Health Authority (2020). Policy for Transfer of Controlled and Semi-Controlled Drugs.
19. Federal Decree no. (8) of (2016). Concerning combating Narcotic and Psychotropic substances.
20. Federal Law No. (8) of (2019). Concerning Medical products, Pharmacy profession and Pharmacies.
21. General Circular pursuant to the Health Insurance Law (No 11 of 2013) of the Emirate of Dubai eClaimLink General Circular Number 04 of 2018 (GC 04/2018).
22. Health Authority-Abu Dhabi (2007). A Guide to the Management of CD in the Private Sector.
23. Health Authority-Abu Dhabi (2007). A Guide to the Management of Controlled Drugs in the Private Sector.
24. Health Authority-Abu Dhabi (2015). HAAD Standards for the Management of Narcotics, Controlled and Semi- Controlled Medicinal Products.
25. Joint Commission of International (2017). Accreditation Standards for Hospitals; 6th Edition.
26. Ministerial Decree No. (888) for the year (2016) in respect of Rules & Regulations for Prescribing and Dispensing of Narcotic, Controlled and Semi Controlled Drugs.
27. Ministerial Resolution No. (4192) for the year (2021) issued by Ministry of Health and Prevention, regarding the modification on the method of disposal of empty narcotic ampoules.
28. Ministerial Resolution No. (397) of (2019) concerning the unified electronic platform for prescribing and dispensing narcotic, controlled and semi-controlled medication.
29. Ministerial Resolution No. (677) of (2019) concerning the procedures and regulations for carrying Narcotics, Controlled and Semi-controlled drugs with travelers to and from the UAE.
30. Ministerial Resolution No. (932) of (2012) concerning the sanitary and technical conditions to be available in private pharmacies.

31. Ministry of Health and Prevention (2003). Guideline and Minimum Standards for Good Pharmacy Practice (GPP).
32. Ministry of Health and Prevention (2006). Good Pharmaceutical Storage and Distribution Practices (GSandDP).
33. Ministry of Health and Prevention (2014). Ministry of Health Services Manual Customers Service Centers.
34. Ministry of Health and Prevention Guidelines (2018). Concerning Good Vigilance Practice (GVP) For Marketing Authorization Holders / Pharmaceutical Manufacturers in UAE.
35. UAE National Guidelines (2020). Concerning Clinical Management and Treatment of COVID-19. Version 4.3.
36. World Health Organization (2019). Novel Coronavirus technical guidance. Available on: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance (accessed on February 14, 2020).
37. World Health Organization (2020). Coronavirus disease (COVID-19) advice for the public.
38. World Health Organization (2020). Modes of transmission of virus causing COVID-19 implications for IPC precaution recommendations.

APPENDICIES

APPENDIX 1 - Narcotics, CDs and SCDs In-Charge

عهدة الأدوية المخدرة والمراقبة وشبه المراقبة

Narcotics, CDs and SCDs in-charge

Date:	التاريخ:.....
Health Facility name:	اسم المنشأة الصحية: .....
Health Facility Unique ID No:	رقم ترخيص المنشأة الصحية: .....
The person mentioned below is the in-charge of Narcotics, CDs and SCDs at our facility.	**الشخص المذكور أدناه هو المسؤول عن عهدة الأدوية المخدرة والمراقبة وشبه المراقبة.**
Anesthetist / Pharmacist in-charge name:	اسم طبيب التخدير / الصيدلي المسؤول: .....
Anesthetist / Pharmacist in-charge license No:	رقم ترخيص طبيب التخدير / الصيدلي المسؤول: .....
Anesthetist / Pharmacist in-charge signature:	توقيع طبيب التخدير / الصيدلي المسؤول: .....
In the absence of the in-charge, the below anesthetist / pharmacist will take over the responsibility of CDs and SCDs ONLY.	**في حال تغيب الشخص المسؤول، تنقل عهدة الأدوية المراقبة وشبه المراقبة فقط إلى طبيب التخدير / الصيدلي المذكور أدناه.**
Deputy in-charge name:	اسم المسؤول بالإنابة: .....
Deputy in-charge license No:	رقم ترخيص المسؤول بالإنابة: .....
Deputy in-charge signature:	توقيع المسؤول بالإنابة: .....

Health Facility Medical in-charge name:	اسم المدير الطبي للمنشأة الصحية: .....
Facility Medical Director signature:	توقيع المدير الطبي للمنشأة الصحية: .....
ختم المنشأة الصحية **Health Facility Stamp**	ختم هيئة الصحة بدبي **DHA Stamp**
Please attach copy both persons licenses	يرجى إرفاق صورة من تراخيص مزاولة المهنة

APPENDIX 2 - Narcotics, CDs and SCDs Stock Handover

نقل عهدة الأدوية المخدرة والمراقبة وشبه المراقبة		
Narcotics, CDs and SCDs stock handover		
DHA/HRS/DC/NCH		
Date 2020		التاريخ 2020
Health Facility name		اسم المنشأة الصحية
Health Facility Unique ID No		رقم ترخيص المنشأة الصحية
The person in - charge below will be relieved from his / her responsibility of Narcotics, CDs and SCDs at our facility		الشخص المسؤول المذكور أدناه سيخلي طرفه عن عهدة الأدوية المخدرة والمراقبة وشبه المراقبة
Professional in-charge name		اسم المهني المسؤول
Professional in-charge license No		رقم ترخيص المهني المسؤول
Reason	Other	السبب
Date		تاريخ
Anesthetist / Pharmacist in-charge signature		توقيع المهني المسؤول
accordingly, the below mentioned Professional will take over the responsibilities of Narcotics, CDs and SCDs in-charge based on the facility classification		وعليه تنقل عهدة الأدوية المخدرة والمراقبة وشبه المراقبة إلى المهني المسؤول المصرح له حسب تصنيف المنشاة المذكور أدناه
Professional in-charge name		اسم المهني المسؤول
Professional in-charge license No		رقم ترخيص المهني المسؤول
Professional in-charge signature		توقيع المهني المسؤول
Health Facility Medical in-charge name		اسم المدير الطبي للمنشأة الصحية
Facility Medical Director signature		توقيع المدير الطبي للمنشأة الصحية

ختم المنشأة الصحية	توقيع وختم قسم الرقابة الدوائية
Health Facility Stamp	Drug Control Section Stamp and Signature
Kindly attach a report of Narcotics and Control Drug balances that will be handed over signed by the Professional in-charge and the authorized medical director of the facility	يرجى إرفاق تقرير عن ارصده الادويه المخدره والمراقبه وشبه المراقبه التي سيتم تسليمها على ان تكون موقعه من المهني المسؤول والمخول بالاستلام والمدير الطبي للمنشأة

APPENDIX 3 - Quarterly Report for Narcotics Drugs

QUARTERLY REPORT FOR NARCOTICS DRUGS

Month /Year :					**الشهر/السنة :**
Health Facility / Pharmacy Name					**اسم المنشأة الصحية / الصيدلية:**
Health Facility / Pharmacy ID No:					**الرقم الموحد للمنشأة الصحية/الصيدلية:**
Health Facility / Pharmacy License No:					**رقم ترخيص المنشأة الصحية/الصيدلية:**
Anesthetist / Pharmacist in-charge Name & license No:					**اسم ورقم ترخيص طبيب التخدير / الصيدلي المسؤول:**
Telephone : **الهاتف:**	**Fax:** **الفاكس:**	**Email:** **البريد الإلكتروني:**		**P.O.Box:** **صندوق البريد:**	

No.	Narcotic Drug Name	Std Stock	Quantity received	Quantity issued	Current balance	Remarks
1						
2						
3						
4						
5						
6						
7						
CONT.						

توقيع الصيدلي المسؤول/ طبيب التخدير **Pharmacist/Anesthetist in-charge Signature**	**ختم الصيدلية/المنشأة الصحية** **Pharmacy/Health Facility Stamp**

APPENDIX 4 - Monthly Report for CD and SCD

Month /Year :													
Health Facility / Pharmacy Name:													اسم المنشأة الصحية / الصيدلية:
Health Facility / Pharmacy ID No:													الرقم الموحد للمنشأة الصحية/الصيدلية:
Health Facility / Pharmacy License No: :													رقم ترخيص المنشأة الصحية/الصيدلية:
Anesthetist / Pharmacist in-charge Name & license No:													اسم ورقم ترخيص طبيب التخدير / الصيدلي المسؤول:
Telepone : الهاتف :						Email: البريد الإلكتروني:					P.O.Box:		صندوق البريد:

Serial No.	اسم الدواء التجاري Trade Name of Drug	التركيبة العلمية Active Ingredient	التركيز والوحدة/الشكل الصيدلاني Strength & Dosage form Unit/	CD/SCD	الرصيد السابق Previous stock	الكمية الواردة Quantity received	الكمية المنصرفة Quantity dispensed	الرصيد الفعلي Actual balance	تاريخ الانتهاء Expiry Date	رقم التشغيلة Batch. No	المصدر المورد Source Of Supply	رقم السند Voucher. No	تاريخ السند Voucher Date
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
توقيع الصيدلي المسؤول/ طبيب التخدير												ختم الصيدلية/المنشأة الصحية	
Pharmacist/Anesthetist in-charge Signature												Pharmacy/Health Facility Stamp	

APPENDIX 5 - Drug Incident Report Form

Drugs Incident report

محضر تحقيق للأدوية

Date: التاريخ:.....	Time: الوقت:.....
Health facility name: ..... اسم المنشأة الصحية:	
License No.: ..... رقم الترخيص:	Tel:..... رقم الهاتف:
Incident location: ..... مكان الحادث:	
Drug name: ..... اسم الدواء:	Strength & unit: ..... التركيز والوحدة:
Drug category: ☐ Narcotic ☐ Controlled ☐ Semi Controlled ☐ Others	فئة الدواء: ☐ أدوية تخدير ☐ أدوية مراقبة ☐ أدوية شبه مراقبة ☐ أخرى
Dosage form: ..... الشكل الصيدلاني:	Number of units: ..... عدد وحدات الدواء
Batch No.: ..... رقم التشغيل:	Expiry date: ..... تاريخ انتهاء الصلاحية:
Type of incident: ☐ Broken / Damaged ☐ Administration Error ☐ Missed / Stolen ☐ Others (specify)	**نوع الحادث:** ☐ كسر / تلف ☐ خطأ إداري ☐ فقدان / سرقة ☐ أخرى، يرجى ذكر السبب ....

Details	Name الاسم	License No. رقم الترخيص	Signature التوقيع
المتسبب بالحادث Involved Person			
الشاهد Witness			

مسؤول العهدة In-charge			

إفادة الشخص المتسبب بالحادث Details of the incident: (to be filled by the person involved)

.....

.....

التوقيع ..... Signature

إجراءات مسؤول العهدة Actions taken by the in-charge

.....

التوقيع ..... Signature

تقرير مفتشين هيئة الصحة بدبي DHA inspectors report

.....

.....

.....

الاسم والتوقيع ..... Name & Signature

الاسم والتوقيع ..... Name & Signature

توقيع رئيس قسم الرقابة الدوائية ..... Head Of Drug Control Section Signature

APPENDIX 6 - CD & SCD Medication Transfer Request Form

GOVERNMENT OF DUBAI

طلب نقل أدوية مراقبة و شبه مراقبة
Transfer Request for CD&SCD

DUBAI HEALTH AUTHORITY

Reference number: رقم الطلب:	Date: التاريخ:
Facility ID: هوية المنشأة:	Facility ID: هوية المنشأة:
اسم المنشأة المستلمة: Facility Receiving Name:	اسم المنشأة المزودة: Facility Providing Name:
اسم المدير الطبي: Medical Director Name:	اسم المدير الطبي: Medical Director Name:
رقم ترخيص المدير الطبي: Medical Director License No:	رقم ترخيص المدير الطبي: Medical Director License No:
الهاتف: Telephone No:	الهاتف: Telephone No:
البريد الإلكتروني: E-mail:	البريد الإلكتروني: E-mail:

Below medication will be transfer for the following reason(s) سيتم نقل الأدوية المذكورة أدناه وذلك للأسباب التالية

	اسم المنتج Product Name	التركيز Dose strength	الشكل الصيدلاني Dosage form	الكمية Quantity	رقم التشغيلة Batch number	تاريخ انتهاء الصلاحية Expiry date
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

*CD: Control Drug

GOVERNMENT OF DUBAI
DUBAI HEALTH AUTHORITY

I hereby the undersigned testify that the information mentioned above is correct

اقر انا الموقع أدناه بصحة ما ورد بالطلب

Pharmacist signature and providing facility stamp	توقيع الصيدلي وختم المنشأة المزودة

Pharmacist signature and receiving facility stamp	توقيع الصيدلي وختم المنشأة المستلمة

للاستعمال الإداري

For Admin use

Health inspector finding : ملاحظات المفتش الصحي:

Signature: التوقيع:

Head of Section Approval: اعتماد رئيس القسم :

Signature: التوقيع:

Note: The receiving pharmacy should have DHA registers for CD&SCD if not should apply for it.

APPENDIX 7 - Narcotic Disposal Request Approval

Ref: HRS/DC/NRD/ 20 / 0000

التاريخ: 202

السادة/ إدارة الدواء

وزارة الصحة ووقاية المجتمع

تحية طيبة وبعد،

طلب التخلص من الأدوية المخدرة

اسم المنشأة /

رقم التسجيل لدى هيئة الصحة بدبي:

رقم الرخصة التجارية:

يرجى العلم بان المنشأة المذكورة أعلاه، مرخصة ك ، وترغب بالتخلص من الأدوية المخدرة المدونة أدناه وذلك لسبب وهي تحت إشراف والذي يحمل ترخيص رقم

SN	Drug	Strength	Pharmaceutical form	Quantity	Supplier	Expiry Date
1						
2						
3						
4						
5						
6						

- ملاحظة: تعتبر هذه الموافقة لاغية بعد مرور ثلاثين يوما على إصدارها
- إذا رغبتم في أي استفسارات أو معلومات إضافية، يرجى التواصل مع قسم الرقابة الدوائية عبر البريد الالكتروني DrugControl@dha.gov.ae

شاكرين لكم تعاونكم الدائم،

رئيس قسم الرقابة الدوائية

إدارة التدقيق والرقابة الصحية

قطاع التنظيم الصحي

APPENDIX 8 - Medication Disposal Request Form

GOVERNMENT OF DUBAI
DUBAI HEALTH AUTHORITY

طلب إتلاف أدوية
Medications Disposal Form

DHA-MDR- 2020

Time: 12 : 25 PM الوقت:	Date: 05 NOV 2020 التاريخ:
Facility name: اسم المنشأة:	
Pharmacist in-charge name: اسم الصيدلي المسؤول:	
Pharmacist in-charge license No: رقم ترخيص الصيدلي المسؤول:	
Facility license No: رقم ترخيص المنشأة :	Telephone: الهاتف:
Location: الموقع:	Email: البريد الإلكتروني:

Below medications will be disposed for the following reason(s)							سيتم إتلاف أصناف الأدوية المذكورة أدناه وذلك للأسباب الآتية
ادوية حكومية Governmental medications		غير مسجلة بوزارة الصحة Non registered in MOH		انتهاء تاريخ الصلاحية Expired medication			
تالفة Damaged		عينات مجانية غيرمعدة للبيع Free samples not for sale		لا يوجد تاريخ صلاحية No expiry date			
ممنوع تداولها بالدولة Prohibited to be traded in UAE		محفوظة خارج الثلاجة Stored outside refrigerator		غير مسعرة من قبل وزارة الصحة Not priced by MOH			
أسباب أخرى Other reasons		يوجد تغيرات فيزيائية Physically changed		غير مطابقة لتسعيرة وزارة الصحة Not compatible with MOH price list			
Notes: ملاحظات:							

	اسم المنتج Product name	التركيز Concentration	الشكل الصيدلاني Dosage form	الكمية Quantity	رقم التشغيل Batch number	تاريخ انتهاء الصلاحية Expiry date
1						01/08/2020
2						DD/MM/YYYY
3						DD/MM/YYYY
4						DD/MM/YYYY
5						DD/MM/YYYY
6						DD/MM/YYYY
7						DD/MM/YYYY
8						DD/MM/YYYY
9						DD/MM/YYYY
10						DD/MM/YYYY

رئيس قسم الرقابة الدوائية Head of Drug Control	المفتش الصحي Health Inspector	الصيدلي المسؤول/المدير الطبي Pharmacist in-charge/Medical Director

Submit the Medication Disposal Certificate to DCS within One Month and keep copy in the pharmacy.

APPENDIX 9 - Adverse Drug Reaction Reporting Form

A. Patient Details (see confidentiality section)

Name:	Age/D.O.B:	Health care Institution:
Sex: ☐ M ☐ F	Weight(kg):	Medical Record No:
Patient contact Details:		

B. Medical Products used:

		Medical product Name "Generic & Brand" (Manufacturer and Batch No. If known)	Dose, Route and Frequency	Therapy Starting Date	Therapy Stopping Date	Indications
Suspected	1					
	2					
	3					
Others	1					
	2					
	3					

Please Check in case of ☐ Medication Error ☐ Drug Abuse ☐ Self-Medication ☐ Poisoning

C. Adverse Reaction

Description of the reaction(s):	
Onset date of reaction:	**End date of reaction:**
Action taken towards Adverse Reaction: ☐ Drug withdrawn ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable	
Reaction abated after use stopped or dose reduce	**Reaction reappeared after reintroduction** ☐Yes ☐No ☐Not applicable

☐Yes ☐No ☐Not applicable	
Treatment of Adverse Reaction: ☐ No ☐Yes (medications and/or other therapy) include dates.	
Relevant tests / laboratory data including dates:	
Other relevant History, including pre-existing medical conditions (e.g. allergies, pregnancy, smoking, renal dysfunction etc.)	

D. Outcome of Adverse Reaction

☐ Recovered	☐ Recovering	☐ No improvement	☐ Unknown

E. Seriousness of Adverse Reaction (Tick all applicable)

☐ Death (include date)	☐ Permanent Disability
☐ Hospitalization	☐ Life threatening
☐ Prolonged hospitalization more than 24 hr	☐Congenital Anomaly
☐ Required intervention to prevent permanent impalement/ damage	☐ Others .....

F. If this is a follow up of an already reported ME case, please place an 'X' in this box ☐

G. Reporter details

Name and complete address: Profession (specialty): Date and filing report:			
Phone:	Fax:	Email:	Signature:

Report no: ☐

APPENDIX 10 - Medication Errors Reporting Form

A. Patient Details (See confidentiality section)

Name:	Age/D.O.B:	Health care Institution:
Sex: ☐ M ☐ F	Weight(kg):	Medical Record No:
Patient contact Details:		

B. Date and Time of event

(Please describe error, sequence of events, staff involved, work time and shift add separate sheet if needed)

_____

_____

_____

_____

_____

_____

C. Medical Product Involved in the Event

Medical Product Name		Strength	Dosage Form	Manufacturer	Expiry Date	Type and Size of Container
Drug(s) used	1					
	2					
	3					

D. Impact of the Error

Did the error reach the patient ☐ Yes ☐ No

E. Consequences:

☐ No Harm to Patient ☐Monitoring/Intervention to prevent harm was require ☐ Patient Suffered temporary harm ☐ Patient was hospitalized

☐ Permanent patient harm ☐ Live-saving intervention was required ☐ Error caused death

F. Intervention

☐ Administered antidote ☐ Change to correct dose

☐ Change to correct drug

☐ Change frequency ☐ No action was required

☐ Other intervention

☐ Comments _____

G. If this is a follow up of an already reported ME case, please place an 'X' in this box ☐

H. Reporter details

Name and complete address: Profession (specialty): Date and filing report:			
Phone:	Fax:	Email:	Signature:

Report No: