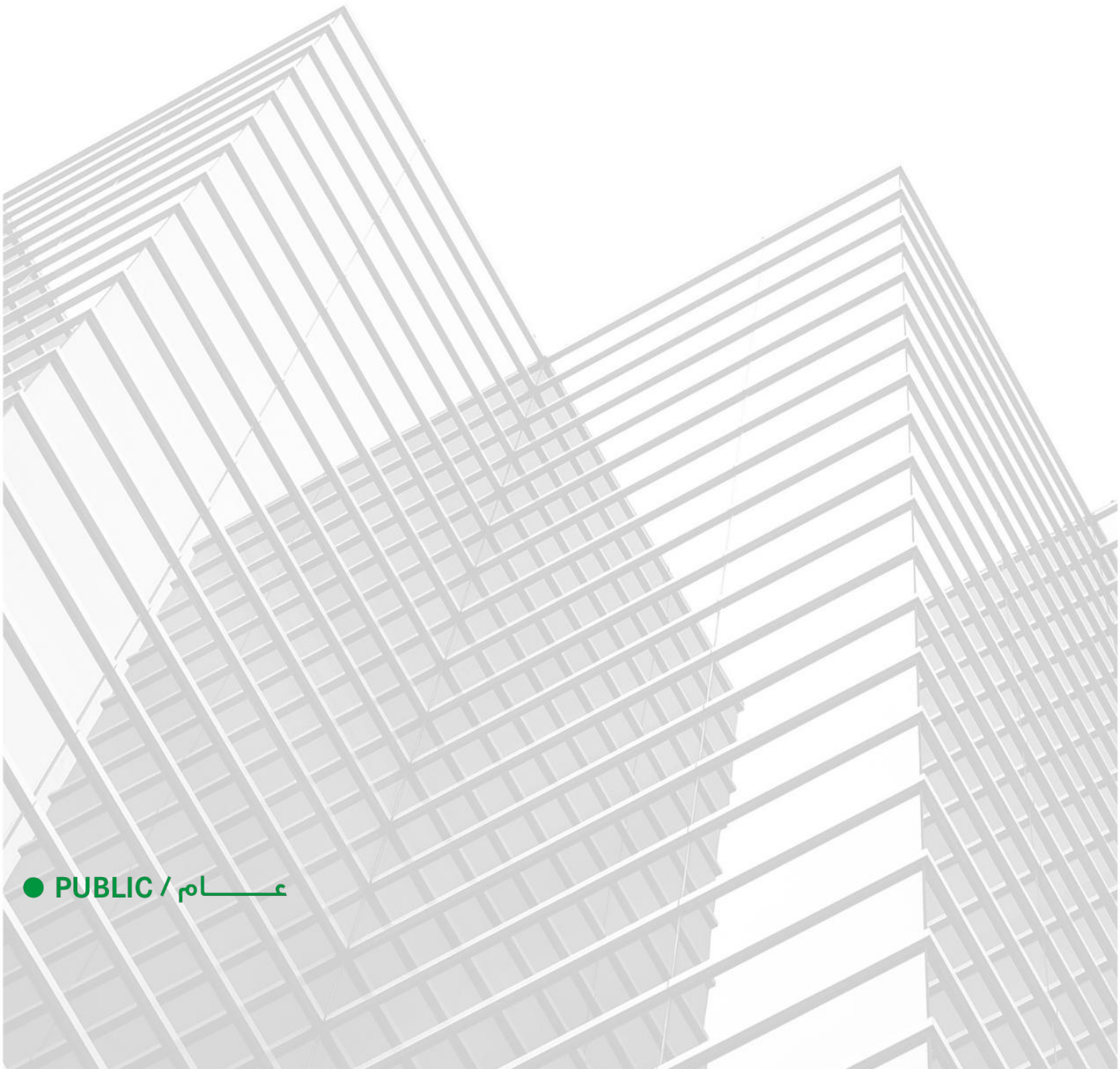
دائـــــرة الـصـــحـــة
DEPARTMENT OF HEALTH

Standard for Ensuring Continuous Drug Supply, Storage, Distribution and Therapeutic Governance



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1.Standard Scope

This standard applies to all pharmacists, supply chain personnel, and organizations involved in supply, storage, and distribution of medicines.
The purpose of this standard is to ensure the safe, effective, and continuous supply of medicines for better practices and to reflect global standards, including but not limited to: automated dispensing system and real time tracking and through establishing a dynamic, evidence-based drug formulary managed by the Pharmacy and Therapeutics (P&T) Committee, enforcing robust storage and distribution practices in line with GSDP standards, and integrating advanced technologies such as automated dispensing systems and real-time inventory tracking.

The standards shall be read and implemented along with all other relevant DoH policies, standards, guidelines and circulars that include but are not limited to:
-Delivery of Pharmacy Medication Standard,
-Pharmacist and Pharmacy Technician Scope of Practice,
-Policy for Quarantine and Recall of Medical Products,
-Standard on Managing Drug Shortages,
-Standard for Non-registered Drugs,
-DoH Standard on Administration of Vaccines in Outpatient Pharmacies,
-Health Information Exchange Standards,
-Pharmaceutical Waste Management,
and in accordance with the Federal Decree-Law No. (38) of 2024 Governing Medical Products, Pharmacists and Pharmaceutical Establishments.

Except for Drug Stores, all healthcare facilities shall also comply with the requirements of Abu Dhabi Healthcare Information Security Program and shall be AAMEN Certified, and all related healthcare professionals shall have completed the Information and Cyber Security Awareness courses that are assigned by DoH.

2. Definitions and Abbreviations

No.	Term / Abbreviation	Definition
2.1	Barcode Scanning	Using barcodes to verify medication information.
2.2	Cold Chain	Is a system of storing and transporting vaccines and medicines at recommended temperatures from the point of manufacture to the point of use.
2.3	Corrective & Preventive Action (CAPA)	In the context of this standard, it is a structured quality management process used to identify, investigate, and resolve issues related to compliance, deviations or risks in the storage and distribution of medicines or medical products.
2.4	Compounded Medicines	Are medical preparations that are prepared based on medical prescriptions (i.e., tailored for individual patients), or formulated to meet the needs of health establishments with synthetic products that are not otherwise commercially available.
2.5	Contingency Planning and Supply Chain Resilience	The ability of a supply chain to anticipate, prepare for, respond to, and recover from disruptions to ensure continuous medicine availability.

2.6	Days of Cover (DOC)	refers to the number of days a given inventory of drugs or pharmaceutical products will last based on the current rate of consumption or sales, assuming no additional stock is received. It's a key metric used to assess inventory management efficiency, ensure supply continuity, and avoid stockouts or overstocking in the pharmaceutical supply chain.
2.7	Drug Formulary System Management	Managing a list of approved medications by the hospital Pharmacy & Therapeutics Committee for use within a healthcare facility.
2.8	Department of Health (DoH)	The regulative body of the Healthcare Sector in the Emirate of Abu Dhabi, Established based on law No. (10) of 2018.
2.9	Expiry Date	The date after which the safety, efficacy and quality of the medicine cannot be guaranteed. It can be written as dd/mm/yy or as mm/yy form with the latter expiring on the last day of the specified month.
2.10	First Expiry, First Out (FEFO)	In managing the expiry dates, it is a method to ensure older stock is used before newer stock.
2.11	Good Storage & Distribution Practice (GSDP)	The World Health Organization (WHO) defines Good Storage and Distribution Practices (GSDP) as a set of guidelines ensuring that medicinal products and other health-related products are stored, transported, and distributed under conditions that maintain their quality, safety, and efficacy throughout the supply chain. These practices are part of the broader framework of Good Manufacturing Practices (GMP) and are critical for ensuring that products reach the end user in a safe and effective condition.
2.12	Humidity Conditions	Medicines shall be kept in a dry environment, protected from excessive humidity. In the context of this standard Below 60% Relative Humidity (RH) is recommended.
2.13	Inventory Management	Keeping an accurate and up-to-date record of available medicines' quantities, expiry dates, consumption rate and replenishing schedule.
2.14	Labeling Medicines	The act of placing information on medication packaging. This includes details such as dosage, administration instructions, and warnings to ensure proper use.
2.15	Management of Expired Medications	Measures to ensure patient safety and compliance with regulations regarding expired medications.
2.16	Near Expiry Medicines	In the context of this standard, it is the medicines that have three months remaining before their expiry dates and shall be isolated on a special shelf prepared for this purpose.

2.17	Pharmacy and Therapeutics (P&T) Committee	A group of healthcare professionals responsible for managing the formulary system and promoting rational drug use.
2.18	Storage Temperature	Medicines are highly sensitive to temperature. Stability and potency depend on storing them within specified ranges as stated by the manufacturers and regulated by the authority: Room temperature (Controlled Room Temp): 15–25°C. Refrigerated storage: 2–8°C. Frozen storage: –15 to –25 °C . Ultra-low temperature: –60°C to –90°C.
2.19	Temperature excursions	When medicines are exposed outside the defined storage temperature range as defined by the manufacturers and the regulator based on the stability testing.

3.Standard Requirements and Specifications

3.1. Drug Formulary System Management: for enhanced patient access to evidence-based treatments.

3.1.1. The healthcare facility (Hospitals-Only) shall establish and maintain a comprehensive drug formulary system that is evidence-based, regularly reviewed, at least every 3 months, and tailored to the services offered.

3.1.2. Formulary Development and Maintenance

3.1.2.1. The facility must maintain a current, evidence-based formulary that includes medications essential for the facility's scope of clinical services.

3.1.2.2. All formulary medications must comply with national drug regulations including controlled drugs regulations.

3.1.2.3. Non-formulary requests should be addressed promptly through a defined evaluation process.

3.1.2.4. The standard prioritizes medications registered with the Emirates Drug Establishment (EDE), ensuring they are used over non-registered products to maintain safety and compliance.

3.1.3. Pharmacy and Therapeutics (P&T) Committee

3.1.3.1. The facility shall establish a multidisciplinary P&T Committee consisting of pharmacists, physicians, nurses, and other relevant professionals, who should all disclose conflict of interest (COI), if exists.

3.1.3.2. The committee shall have a clear written term of reference that defines the committee's authority, roles, quorum, decision-making process, documentation and reporting the decisions.

3.1.3.3. The committee shall meet regularly (at least quarterly) to evaluate and update the formulary based on safety, efficacy, availability, pharmacoeconomic evaluation, and emerging clinical evidence.

3.1.3.4. shall manage the formulary system to promote rational drug use, optimize therapeutic outcomes, ensure cost-effectiveness, and enhance timely access to essential medications for all patients.

3.1.3.5. The committee is responsible for policy formulation on drug use, antimicrobial stewardship, pharmacovigilance monitoring (i.e. adverse drug reaction, medication error & adverse event following immunization) , and formulary decisions.

3.1.3.6. Shall establish a robust collaboration with the Health Technology Assessment (HTA) of the Department of Health to actively integrate cutting-edge, innovative technologies that significantly improve patient outcomes and transform lives.

3.1.4. Access and Availability

3.1.4.1. The facility shall ensure formulary drugs are readily available and stocked according to usage patterns and critical care needs.

3.1.4.2. Processes must be placed to prevent and mitigate drug shortages, including approved substitutions or therapeutic alternatives.

3.1.5. Information and Education

3.1.5.1. The formulary should be easily accessible to all prescribers and healthcare professionals through electronic platforms.

3.1.5.2. Hospital should have ongoing training, and communication should be provided to clinical staff on formulary updates and rational prescribing.

3.1.6. Monitoring and Evaluation

3.1.6.1. The effectiveness of the formulary system shall be regularly assessed through audits, utilization reviews, and feedback mechanisms.

3.1.6.2. Key performance indicators such as formulary adherence, patient satisfaction, and medication error rates should be monitored and reported as per the *Standard on Reporting Medication Errors & Suspected Quality Problems Related to Medicinal Products and Dietary Supplements*.

3.1.6.3. All corrective actions and performance improvement plans based on audit results shall be documented.

3.2. Continuous Supply: Maintain an uninterrupted supply of medicines.

3.2.1. Inventory Management

3.2.1.1. Healthcare facilities should maintain an accurate and up-to-date inventory of medicines.

3.2.1.2. Shall ensure that medicines and medicinal products are procured from appropriately registered/authorized suppliers/distributors to avoid substandard and counterfeit drugs.

3.2.1.3. Use inventory management software to track stock levels and expiration dates.

3.2.1.4. For outpatient pharmacies, the software shall be compatible and aligned with digital health initiatives such as malaffi and e-prescription.

3.2.1.5. Implement a first expiry-first-out (FEFO) system to minimize waste.

3.2.1.6. Establish Early Shortage Notification (ESN) with measurable Days of Cover (DOC) triggers.

3.2.2. Procurement

3.2.2.1. Obtain medicines from approved, reliable suppliers to ensure quality and authenticity

3.2.2.2. Adhere to regulatory requirements and unified procurement standards during the procurement process.

3.2.2.3. Maintain a buffer stock of essential medicines, accounting for seasonal consumption trends and potential demand fluctuations, to prevent shortages and ensure consistent availability.

3.2.3. Storage and Handling

3.2.3.1. Store medicines under appropriate conditions (e.g., temperature, humidity, light).

3.2.3.2. Monitor and document storage conditions regularly.

3.2.3.3. Ensure cold chain integrity for temperature-sensitive medicines, such as vaccines, insulin, or biologics, to preserve their potency and safety.

3.2.3.4. Maintain consistent storage conditions (typically 2–8°C) in calibrated refrigeration units, monitor temperatures with data loggers, and use validated cold chain logistics during transport to prevent exposure to heat or freezing.

3.2.3.5. Comply with DoH guidelines, including regular equipment checks and staff training, ensures these medicines remain effective until their expiration or disposal.

3.2.3.6. Follow the special requirements for storage and handling of controlled drugs as listed in the DoH Standard for The Management of Narcotics, Psychotropic, and Semi-Controlled Medicinal Products.

3.2.4. Contingency Planning

3.2.4.1. Develop and maintain a contingency plan for medicine shortages.

3.2.4.2. Identify alternative suppliers and therapeutic alternatives for critical medicines.

3.2.4.3. Communicate shortages to DoH promptly for essential medicines and monthly for other medications, refer to the *Standard on Managing Drug Shortage*

3.2.4.4. Implement a contingency plan for cold chain breaches, including:

3.2.4.4.1. immediate quarantine of affected medicines, assessment of temperature excursion impact using stability data or manufacturer guidance, and reporting to DoH Monitoring and Compliance Department as per the DoH Standard for Pharmacovigilance Reporting at DoH Portal.

3.2.4.4.2. Ensure backup power sources and secondary storage units are available to mitigate risks during equipment failure or power outages.

3.2.4.4.3. Immediate transfer procedures for medicines to alternative storage units when early detection of temperature deviates from the acceptable range.

3.2.4.4.4. Documentation of excursions, corrective actions taken, and notification to DoH Monitoring and Compliance Department.

3.2.4.4.5. Regular testing of backup systems to ensure readiness.

3.3. Transportation of medical products: Implement the best practices of transporting medical products to maintain the integrity and quality of the medical products and medications.

3.3.1. Develop written procedures for shipping products that include the following:

3.3.1.1. A documented risk assessment and route planning procedure shall be implemented prior to transportation of medical products to ensure product integrity by identifying potential hazards, evaluating environmental and logistical risks, and selecting the safest and most suitable transport routes.

3.3.1.2. Consider the change in local conditions or any seasonal variations.

3.3.1.3. Ensure necessary controls are in place for temperature and relative humidity.

3.3.1.4. Ensure using calibrated data loggers.

3.3.1.5. Refrigerated vehicles/transportation containers should be validated and monitored periodically.

3.3.1.6. Keep all records of data loggers, validation, and the performed maintenances for one year, and any discrepancies should have a follow up.

3.3.1.7. Records of deliveries must include:

3.3.1.7.1. Description of products

3.3.1.7.2. Quantity of products

3.3.1.7.3. Suppliers' name.

3.3.1.7.4. Batch number

3.3.1.7.5. Date of receipt.

3.3.1.7.6. Expiration date of the product.

3.3.1.8. Should implement corrective action in case the medicinal products have been transported at a temperature outside of those specified for them.

3.3.1.9. In such cases, a proper investigation should be carried out, and the disposition of stock should be evidence based.

3.3.2. All the shipping containers should have a clear and adhesive label, which must have the following information

3.3.2.1. Name and description of the product

3.3.2.2. Batch number

3.3.2.3. Expiration date.

3.3.2.4. Specific storage conditions if any.

3.3.2.5. Any special handling precautions.

3.4. Management of expired medications: the following measures should be implemented to ensure patient safety and compliance with regulations.

3.4.1. Where the expiry date is written as: dd/mm/yy: the product is considered expired on that specified date. Where the expiry date is written as: mm/yy: the product shall be deemed expired on the last day of the specified month.

3.4.2. All compounded medicines should be labeled “to use before” and specify the expiry date as dd/mm/yy.

3.4.3. Regular Inventory Checks

3.4.3.1. Use the "First Expiry, First Out" (FEFO) method to ensure older stock is used before newer stock.

3.4.3.2. Inventory and dispensing software shall implement alerts in electronic dispensing systems for near-expiry medications.

3.4.3.3. Conduct routine checks of all medications to identify those nearing their expiry dates.

3.4.3.4. Isolate medicines that have three months remaining before their expiry dates in special shelve that should be labeled “Near Expiry Medicines”.

3.4.4. Documentation:

3.4.4.1. Maintain accurate records of all medications, including their expiry dates.

3.4.4.2. Use inventory management systems to track and alert staff about upcoming expiries.

3.4.5. Disposal of Expired Medications:

3.4.5.1. Remove expired medications from shelves immediately.

3.4.5.2. Follow regulations and guidelines for the safe disposal of expired drugs and medical waste management

3.4.5.3. For controlled and narcotic medicines follow the special requirements as listed in *DOH Standard for The Management of Narcotics, Psychotropic and Semi-Controlled Medicinal Products*.

3.4.6. Staff Training:

3.4.6.1. All pharmacy staff shall receive training on the importance of checking expiry dates and the procedures for handling expired medications.

3.4.6.2. Regularly update training to include any changes in regulations or best practices.

3.4.6.3. Document the training sessions in the competency checklist for all staff.

3.4.7. Patient Safety Measures with Expired Medicines:

3.4.7.1. Ensure that no expired medications are dispensed to patients.

3.4.7.2. Outline procedures for proper storage to minimize the risk of medicines expiring prematurely & dispensing errors.

3.4.7.3. Stickers for the patient’s details or instructions for use should never conceal the expiry dates that are printed or engraved on the medications’ outer box.

3.4.7.4. Educate patients on the importance of checking expiry dates on their medications.

3.4.7.5. Educate the patients on Post-Opening Expiry for certain medications that have a shorter shelf life once they are opened. Such as eye drops, antibiotic suspensions, nitroglycerine tablets and some oral liquids that need to be discarded within a specific period after opening.

3.4.7.6. In case of dispensing from the near expiry medicines

3.4.7.6.1. Dispense the right amount of the near expiry medicine, so that the patient will not have any remaining of expired medicines when reaching the expiry date.

3.4.7.6.2. Inform the patient to use before the expiry dates.

3.4.7.6.3. Write the expiry date clearly on the medicine’s outer box or label it, in case of eye drops, oral syrups and suspensions that have Post-Opening Expiry.

3.4.7.6.4. Guide the patient to the safe disposal of expired or unused medicine as described in “Safe disposal of unused medicines at home” published on DoH website

Medications and Supplements awareness brochures | Department of Health Abu Dhabi

3.5. Training and Education

3.5.1. Educate patients on the proper use, storage, and disposal of expired and unused medicines.

3.5.2. Conduct simulations and drills to prepare for medicine shortages or emergencies.

3.6. Documentation and Reporting

3.6.1. Pharmacy shall have a Pharmacy Management System (inventory management, dispensing prescription)

3.6.2. Maintain accurate records of all medication-related activities.

3.6.3. Report drug shortages to the DoH Drug and Medical Products Department at dmp@DoH.gov.ae.

3.6.4. Report medication errors, adverse drug reactions, and near misses through the established system for Pharmacovigilance in DoH.

4.Key stakeholder Roles and Responsibilities

4.1. Hospital / Healthcare Facility Management

4.1.1. Ensure adequate stock levels of essential medicines.

4.1.2. Establish Pharmacy and Therapeutics Committees (PTC).

4.1.3. Approve formularies and monitor prescribing compliance.

4.1.4. Collaborate with the HTA of the DOH for the inclusion of new technologies in the healthcare facility.

4.1.5. Ensure compliance with all information security requirements as defined by the prevailing applicable laws and regulations.

4.2. Pharmacists

4.2.1. Ensure good storage conditions and valid expiry date for all medicines at the pharmacy.

4.2.2. Maintain the correct storage conditions (e.g., cold chain).

4.2.3. Communicate effectively with supply chain and procurement to ensure product availability

4.2.4. Patient education on administration, storage of medicines at homes and how to dispose unused and expired medications.

4.3. Supply- Chain and Procurement Managers:

4.3.1. Vendor/Supplier Management, Select and manage approved suppliers.

4.3.2. Maintain procurement schedules and supplier relationships.

4.3.3. Forecast demand that is data- driven using consumption trends, and seasonal disease patterns, place orders, and track deliveries.

4.3.4. Stock Control.

4.3.5. Ensure timely replenishment and minimize stockouts or wastage.

4.3.6. Establish Early Shortage Notification (ESN) with measurable Days of Cover (DOC) triggers.

4.4. Suppliers

4.4.1. Ensure product quality during transportation and storage.

4.4.2. Fulfill orders reliably and maintain communication during delays.

4.4.3. Report constraints and anticipated drug shortage to Drug & Medical Products department in DoH at least:

4.4.3.1 ≥90-day advance notice of foreseeable constraints,

4.4.3.2 48-hour notice of emergent constraints,

4.4.3.3 and monthly status updates.

5. Monitoring and Evaluation

5.1. DoH's monitoring and evaluation framework is designed to evaluate the effectiveness, quality outcomes, and overall impact of this Standard.
5.2. Auditors will focus on the following key performance indicators:
5.2.1. Routine audits of procurement records, storage logs, and distribution practices.
5.2.1.1. Assess compliance with Good Storage & Distribution Practice (GSDP) **Appendix 1**
5.3. KPIs will be measured as follows:
5.3.1.1. Drug Supply: Availability, procurement cycles, stock levels (% of essential medicines in stock), (% of depleted stock below 3 months (minimum stock level) for DoH-designated Essential Medicines.
5.3.1.2. Storage Conditions: Temperature control, expiry management, cleanliness (% of facilities meeting GSP standards, % of expired stock)
5.3.1.3. Distribution: Delivery timeliness, cold chain integrity (% of on-time deliveries, % of temperature excursions)
5.3.1.4. Therapeutic Governance: Formulary adherence, ADR reporting (% of prescriptions aligned with DOH guidelines, ADR reporting rate, % of compliance with the HTA of the DoH to incorporate cutting edge technologies that have positive impact on public health.
5.3.1.5. Stock Management: Inventory accuracy, wastage, loss/theft (% stock discrepancies, % of medicines lost/damaged)

6. Enforcement and Sanction

6.1. The Department of Health – Abu Dhabi (DoH) upholds the highest regulatory standards to ensure the continuous availability, safe storage, proper distribution, and rational use of pharmaceutical products across the emirate.

7. Relevant Reference Documents

No.	Reference Date	Reference Name	Relation Explanation / Coding / Publication Links
1.	2017	Chase, K. A. (2017). "Chapter 4: Medication Management". In *Introduction to Acute & Ambulatory Care Pharmacy Practice*. Bethesda MD, USA: American Society of Health-System Pharmacists. Retrieved Apr 2, 2025	https://doi.org/10.37573/9781585285464.004
2.	2021	Ciccarello C, Leber MB, Leonard MC, Nesbit T, Petrovskis MG, Pherson E, Pillen HA, Proctor C, Reddan J. ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System. Am J Health Syst Pharm. 2021 May 6;78(10):907-918. doi: 10.1093/ajhp/zxab080. PMID: 33954417.	https://doi. 10.1093/ajhp/zxab080 PMID: 33954417.
3.	2006	GOOD Pharmaceutical Storage & Distribution Practices (GS&DP)	https://mohap.gov.ae/en/w/mohap-uae-good-storage-practices-english?

4.	2020	World Health Organization (WHO) guidelines on (Good Storage and Distribution Practices for medical products) are outlined in Annex 7 of WHO Technical Report Series No. 1025 (2020)	TRS 1025 - Annex 7: Good storage and distribution practices for medical products
5.	2024	Pharmacist and Pharmacy Technician Scope of Practice. (DOH/SOP/PPTSOP/V1/2024)	https://www.doh.gov.ae/-/media/E160783B819C479D90E4DF8BAA108737.ashx
6.	2003	Guidelines and minimum standards for Good Pharmacy Practice GPP in UAE Pharmacies.	Ministry of Health and Prevention Guideline and minimum standards for good pharmacy practice (GPP) Version 1, 2003 | Ministry of Health and Prevention - UAE
7.	2013	EU Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01)	Good distribution practice | European Medicines Agency (EMA)
8.	2025	Federal Decree-Law No. (38) of 2024 Governing Medical Products, Pharmacists and Pharmaceutical Establishments.	https://uaelegislation.gov.ae/en/legislations/2751
9.	2011	Model guidance for the storage and transport of time and temperature sensitive pharmaceutical products	https://www.who.int/publications/i/item/9789241209618
10.	2022	Circular USO/29/2022 Abu Dhabi Healthcare Sector Cyberlearning Program	https://www.doh.gov.ae/en/resources/Circulars
11.	2024	Abu Dhabi Healthcare Information and Cyber Security [ADHICS] Standard	https://www.doh.gov.ae/en/resources/standards
12.	2022	DOH STANDARD ON ADMINISTRATION OF VACCINES IN OUTPATIENT PHARMACIES	https://www.doh.gov.ae/-/media/FBA46167008C4CA4AD4C2C29D11B5E4B.ashx
13.	2024	Department of Health Chairman Decision No. 97/2024 Amending Some Provisions of Decision No. 36/2019 Regarding the Disciplinary Regulations for the Health Sector in the Emirate of Abu Dhabi	LINK

8. Appendices

Appendix 1. Good Storage and Distribution Practices (GSDP) Checklist for Pharmaceutical and Medical Products

This checklist is designed to ensure the quality, safety, and integrity of pharmaceutical and medical products throughout storage and distribution. It is compiled based on key guidelines from authoritative sources such as European Union Good Distribution Practice (EU GDP) and the World Health Organization (WHO) guidelines on (Good Storage and Distribution Practices for medical products). It covers essential areas such as quality systems, personnel, facilities, operations, and risk handling.

Supply Chain Managers & Drug Suppliers shall adopt this checklist to comply with DoH regulations and conduct regular audits.

1. Quality Management

Establish, document, and implement a comprehensive quality system incorporating good storage practices (GSP), good distribution practices (GDP), quality risk management, and management review	☑
Ensure senior management is responsible for resourcing, implementing, and maintaining the quality system	☑
Adopt GSP and GDP to maintain product quality throughout the supply chain and shelf life	☑
Specify all operations in written procedures and define responsibilities in job descriptions	☑
Identify and control risks with effective measures, including processes for outsourced activities	☑
Include procedures for self-inspection, quality audits, returns, complaints, recalls, changes, deviations, and corrective/preventive actions (CAPAs)	☑
Develop an authorized quality policy, possibly in a quality manual, with an organizational chart showing responsibilities and authority	☑
Ensure roles are clearly defined, understood, and recorded	☑

2. Management Review

Conduct periodic reviews to evaluate quality system effectiveness using metrics and key performance indicators	☑
Identify opportunities for improvement and follow up on previous recommendations	☑
Maintain minutes and documentation from reviews	☑

3. Personnel

Ensure adequate staffing with appropriate qualifications, experience, and training for roles.	☑
Implement safety procedures for personnel, products, and the environment.	☑
Deliver initial and ongoing training on GSP/GDP, product security, falsified product detection (checking for GTIN, appropriate barcode), and personal hygiene.	☑
Provide specialized training for handling hazardous products (e.g., Chemotherapy and narcotics).	☑
Maintain training records and assessments.	☑
Require suitable garments and protective clothing; enforce hygiene procedures.	☑
Implement codes of practice and measures to prevent misappropriation or falsification by staff.	☑

4. Sanitation and Hygiene

Keep premises clean; ensure cleaning equipment and agents do not contaminate products	☑
Implement a pest control program to prevent entry of animals, insects, etc	☑
Prohibit eating, drinking, smoking, and food in storage/handling areas, separate facilities for rest and toilets	☑
Have procedures for spillage cleanup to remove contamination risks	☑

5. Premises and Equipment

Design, locate, construct, and maintain premises for receiving, storage, picking, packing, and dispatch, with sufficient space, lighting, and ventilation	☑
Implement security measures and controlled access to prevent unauthorized entry	☑
Provide segregation for products needing special conditions (hazardous, temperature-controlled)	☑
Separate receiving and dispatch areas; protect from weather	☑
Install, qualify, and maintain HVAC systems; conduct mapping studies for temperature/humidity	☑
Monitor and record environmental conditions with calibrated equipment; retain records as required	☑
Store products off the floor on clean pallets; allow space for cleaning and inspection	☑
Have a written sanitation program with cleaning frequency and methods	☑
Mark and restrict areas for specific product status (quarantine); use validated systems	☑
Dedicate secure areas for highly alert, narcotic, or hazardous materials per regulations	☑
Ensure equipment is suitable, installed, qualified, maintained, and calibrated; prevent quality impact	☑

6. Materials and Medical Products

Procure from authorized suppliers; verify deliveries against documentation (batch, expiry, quantity)	☑
Inspect consignments for tampering, damage, or contamination, quarantine suspects	☑
Maintain batch segregation	☑
Prioritize products with special storage conditions (vaccines, insulin; release only after authorization	☑
Segregate and securely store rejected products pending destruction or return	☑

7. Storage Operations

Maintain specified temperature/humidity; follow FEFO (first expired/first out) for stock rotation	☑
Prevent contamination, mix-ups, and cross-contamination	☑
Handle narcotics by EDE&DOH laws and regulations	☑
Withdraw damaged items from stock	☑

8. Distribution

Distribute per label conditions, maintaining identity and label legibility	☑
Keep detailed records for recalls	☑
Use dedicated vehicles/equipment where possible; have procedures for non-dedicated use	☑
Maintain operation and maintenance procedures for vehicles/equipment	☑
Monitor and record environmental conditions during distribution; calibrate instruments	☑
Securely package and label rejected/recalled products with documentation	☑
Prevent unauthorized access, tampering, or theft	☑

9. Transportation

Select transportation methods/routes to maintain product quality and prevent exposure to adverse conditions	☑
Use vehicles/equipment that protect against contamination, weather, and tampering	☑
Monitor temperature/humidity if required; use calibrated devices	☑
Have contingency plans for breakdowns or delays	☑
Ensure secure, traceable transport; avoid unauthorized subcontractors without assessment	☑

10. Dispatch and Receipt

Dispatch only after quality release; verify recipient authorization	☑
Use secure packaging to protect from damage And /OR contamination; label with handling instructions	☑
Record dispatch details (batch, quantity, destination)	☑
At receipt, inspect for integrity; quarantine until verified	☑
Handle urgent deliveries with maintained conditions	☑

11. Complaints

Have written procedures for handling; inform manufacturer/holder promptly for quality issues.	☑
Record, investigate root causes, assess impacts, and implement CAPAs.	☑
Share with DoH; initiate quarantine if needed	☑

12. Returned Medical Products

Quarantine returns upon receipt; maintain conditions and prevent distribution	☑
Assess quality via risk-based process considering history, storage, etc; destroy if doubtful	☑
Decisions by qualified personnel; record actions	☑
Handle rejected products securely; destroy by environmental regulations set by DOH regarding medical waste management	☑
Retain records for required period	☑

13. Recalls

Have written procedures handling recalls	☑
Inform manufacturer, holder, and authorities	☑
Segregate and label recalled products; maintain conditions	☑
Notify customers and DOH promptly; use distribution records	☑
Record progress; issue final report with reconciliation	☑

14. Counterfeit/Substandard/Falsified Products.

Include procedures to identify and handle suspects	☑
Inform manufacturer, report to DoH promptly	☑
Store in secure, segregated areas to prevent distribution	☑
Maintain investigation records; ensure no re-entry to market	☑

15. Importation.

Procure from authorized sources; examine for tampering/labeling at receipt	☑
Quarantine non-compliant consignments; investigate suspects	☑

16. Contract Activities

Select contractors based on assessments; have written agreements defining responsibilities	☑
Ensure contractors comply with GSP/GDP; monitor performance	☑

17. Self-Inspection

Include in quality system to monitor SOP compliance and regulations	☑
Schedule annually; use unbiased, knowledgeable teams	☑
Record results, report to management, implement CAPAs, and review effectiveness	☑

18. Qualification and Validation

Use risk management to determine scope for premises, equipment, processes, etc	☑
Conduct per procedures/protocols; record results and deviations	☑
Approve completion; re-qualify after changes. For example, moving the refrigerator to a new location should have the following re-qualification: Check the new setup; test under normal conditions; simulate challenges; document the results.	☑