GOOD DRUG STORAGE AND DISTRIBUTION

APPROVED CODE OF PRACTICE (ACOP) FOR HEALTHCARE OPERATORS

GSDP ACOP FOR HEALTHCARE OPERATORS

Table of Contents

Section 1: Introduction

The Good Drug Storage and Distribution (GDP & GSP) Approved Code of Practice (ACOP) for Healthcare Operators operating within Dubai Healthcare City (DHCC) has been developed to ensure compliance with international best practices, standards, United Arab Emirates Federal Laws and DHCC Codes of Practice. It is binding on all Retail Pharmacies, Hospital Pharmacies, Pharmaceutical Establishments, Drug stores, Clinics and Hospitals. Full compliance with this document will ensure that statutory and regulatory obligations are met. Non-compliance may result in breach of legal and regulatory requirements.

The DHCC Pharmacy Services Unit (PSU) shall make periodic inspections and/or audits of DHCC concerned facilities to ensure compliance with UAE Federal Laws, DHCC Rules and Regulations and DHCC GDP & GSP ACOP for Licensed Healthcare Operators. Identified non-conformities will be reported to DHCC and the tenant for corrective actions. It is the responsibility of each tenant to fully cooperate with the DHCC PSU to ensure compliance.

Section 2: Applicability

The GDP and GSP ACOP applies to Medical stores, stores that are part of Pharmaceutical and Medical Devices Manufacturing establishments, Nutrition & Health Dietary Supplements food stores, Herbal Pharmaceutical stores, Retail Pharmacies and Hospital Pharmacies, areas designated for storing Pharmaceuticals and Medical Products in a Licensed Healthcare Operator Healthcare operator like hospitals and clinics.

Section 3: Abbreviation and Definition

3.1: Abbreviation

DHCC	Dubai Healthcare City
PSU	Pharmacy Services Unit of DHCC
MOH	Ministry of Health
GDP	Good Distribution Practice
GSP	Good Storage Practice
GMP	Good Manufacturing Practice
HIRAS	Healthcare Information Reporting and Analysis System

3.2: Definition

Capitalized terms not defined in this ACOP shall have the meanings ascribed to them in the relevant Regulations and Rules. Unless it is specifically stated otherwise in another Rule or unless the context otherwise requires:

Batch	A defined quantity of starting material, packaging material or product processed in a single process or series of processes so that it is expected to be homogeneous.
Batch Number	A distinctive combination of numbers and/or letters which uniquely identifies a batch on the labels, its batch records and corresponding certificates of analysis, etc.
Bulk Product	Any product that has completed all processing stages up to, but not including, final packaging
Licensed Retail Pharmacy	A Retail Pharmacy holding a Clinical Operating Permit issued by the Licensing Board in accordance with the Healthcare Operators Regulation and the Retail Pharmacy Facility Rule.
Pharmacy Department	A Licensed Retail Pharmacy that is not free-standing but that is physically located within a Licensed Healthcare Facility.
Hospital Pharmacy	A Hospital Pharmacy holding a Clinical Operating Permit issued by the Licensing Board in accordance with the Healthcare Operators Regulation and the Hospital Pharmacy Facility Rule.

Drug Store	A Licensed Drug Store holding a Clinical Operating Permit issued by the Licensing Board in accordance with Healthcare Operators Regulation, Retail Pharmacy Facility Rule, GSDP ACOP and relevant Federal Regulations that allows the wholesale and distribution of Pharmaceutical Products and other medical supplies.
Pharmaceutical Product	A drug or medication that may be dispensed to an individual only if a prescription is provided by or for the benefit of such individual by a Prescribing Professional.
Prescribing Professional	A Licensed Physician, or a Physician duly licensed in another jurisdiction outside of DHCC, who is legally qualified to prescribe a Product for a patient that is to be Dispensed by a Licensed Retail or Hospital Pharmacy.
HIRAS	Healthcare Information Reporting and Analysis System" or "HIRAS" is the health information system maintained and used by CPQ to collect patient information from Licensed Healthcare Operators and Licensed Healthcare Professionals for quality, licensing, medical educational, research and other purposes that are related to implementing the provisions of the Regulations, these Rules and other applicable regulations and rules in effect from time to time in the DHCC;
Container	The material employed in the packaging of a Pharmaceutical Product. Containers include primary, secondary and transportation containers. Containers are referred to as primary if they are intended to be in direct contact with the Product. Secondary containers are not intended to be in direct contact with the Product.
Contamination	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a starting material, intermediate or Pharmaceutical Product during handling, production, sampling, packaging or repackaging, storage or transport.
Distribution	The division and movement of Pharmaceutical Products from the premises of the manufacturer of such Products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments.

Good Distribution Practices (GDP)	That part of quality assurance that ensures that the quality of Pharmaceutical Products is maintained through adequate control throughout the numerous activities which occur during the distribution process.
Good Storage Practices	Good Storage Practices are that part of quality assurance that ensures that the quality of Pharmaceutical Products is maintained through adequate control throughout the storage.
Labeling	Process of identifying a product, including the following information, as appropriate: name; active ingredient(s); type and amount; batch number; expiry date; special storage conditions or handling precautions; directions for use, warnings, and precautions; names and addresses of the manufacturer and/or the supplier.
Material	A general term used to denote starting materials (active pharmaceutical ingredients and excipients), reagents, solvents, process aids, and intermediates, packaging materials and labeling materials.
Product Recall	Product recall is a process for withdrawing or removing a Pharmaceutical Product from the pharmaceutical distribution chain because of defects in the Product or complaints of serious adverse reactions to the Product. The recall might be initiated by the manufacturer/importer/distributor or a responsible agency.
Quality Assurance	Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a Pharmaceutical Product. It is the totality of the arrangements made with the object of ensuring that Pharmaceutical Products are of the quality required for their intended use.
Quarantine	The status of starting or packaging materials, intermediates, or bulk or finished Products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.
Sampling	Operations designed to obtain a representative portion of a Pharmaceutical Product, based on an appropriate statistical procedure, for a defined purpose (e.g. acceptance of consignments, batch release, etc.).
Storage	The storing of Pharmaceutical Products up to the point of use.
Transit	Going, conveying, being conveyed, across, or over or through; passage, route

Validation	A documented program that provides a high degree of assurance that a specific process, method or system will consistently produce a result that meets pre-determined acceptance criteria.
Vehicle	Vehicle refers to trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means of transportation that are used to convey Pharmaceutical Products.

Section 4: Qualified Personnel

(1) All Pharmacists and Pharmacy Technicians working under the jurisdiction of DHCC have to be licensed by both the Center for Healthcare Planning and Quality and by the UAE Ministry of Health.
(2) An adequate organizational structure shall be defined with the aid of an organizational chart. The responsibility, authority and interrelationships of all personnel shall be clearly defined and documented through clear job descriptions.
(3) At each storage site (e.g. that of a manufacturer, distributor, wholesaler, retail pharmacy, hospital pharmacy, and an in-house pharmacy used to store medications to be used at a day surgery unit and compounding pharmacy) there shall be an adequate number of qualified personnel available during all working hours to achieve pharmaceutical quality assurance objectives.
(4) For Drugstore establishments, a designated person shall be appointed at each distribution point who should have defined authority and responsibility for ensuring that a quality management system is implemented and maintained.
(5) All personnel (Licensed Pharmacists and other licensed personnel) working in the storage, dispensing and distribution area shall be provided with proper initial and continuous training related to Good Distribution and Storage Practice, related rules and regulations, and safety procedures, in order to be capable of meeting these requirements. The training records shall be kept for review, if needed.
(6) All staff members shall be trained in and observe high levels of personal hygiene and sanitation. Clear instructions for personal hygiene shall be distributed and observed.
(7) Personnel employed in the storage, dispensing and distribution areas shall wear suitable protective or working garments appropriate for the activities they perform.
(8) First-aid procedures and equipment for dealing with emergencies involving personnel should be available.
(9) There shall be arrangements in place to ensure that management and personnel are not subject to commercial, financial, and other pressures or conflicts of interest that may have an adverse effect on the quality of service provided.

(10) Codes of practice and disciplinary procedures shall be in place to prevent and address situations where persons involved in the distribution of Pharmaceutical Products are suspected of, or found to be implicated in, the misappropriation and/or theft thereof.

Section 5: Healthcare operator, Warehousing and Storage

5.1: Minimum Facility Requirements

To obtain and maintain a Clinical Operating Permit, each Licensed Healthcare Operator Facility shall meet and comply with the:

a) CPQ approved design submission;
b) American Institute of Architects/Academy of Architecture for Health (AIA/AAH) Guidelines for Design and Construction of Health Care Facilities;
c) DHCC Medical Equipment Management Manual;
d) Pre-Operating/Post-Operating assessment survey checklists; and
e) Any other applicable DHCC Healthcare operator Standards and Policies.

5.2: Security

a) All facilities shall be secure from unauthorized entry.
b) Access from outside the premises shall be kept to a minimum and shall be well controlled.
c) The outer perimeter of the premises shall be well lit.
d) Entry into areas where Pharmaceutical Products are held shall be limited to authorized personnel.
e) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion.
f) When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

5.3: Storage

a) Storage areas shall be of sufficient capacity to allow the orderly storage of the various categories of Products, namely bulk and finished Products, products in quarantine, and released, rejected, returned or recalled Products.
b) Storage areas shall be designed or adapted to ensure good storage conditions. In particular, they shall be clean and dry and maintained within acceptable temperature limits. Where special storage conditions are required on the label (e.g. temperature, relative humidity), these must be provided, checked, monitored and recorded.
c) Storage areas shall have construction materials that include solid masonry, secure glazing and sealed ceilings.
d) Pharmaceutical Products must be stored off the floor and suitably spaced to permit cleaning and inspection. Pallets shall be kept in a good state of cleanliness and repair.

e) Storage areas must be clean and free from accumulated waste and vermin. A written sanitation program shall be available indicating the frequency of cleaning and the methods to be used to clean the premises and storage areas. There shall also be a written program for pest control. The pest-control agents used must be safe, and there shall be no risk of contamination of the materials and Pharmaceutical Products. There shall be appropriate procedures for the cleanup of any spillage to ensure complete removal of any risk of contamination.
f) For Drug store organization, receiving and dispatch bays shall protect Products from the weather. Reception areas should be designed and equipped to allow containers of incoming Pharmaceutical Products to be cleaned, if necessary, before storage.
g) Radioactive materials, chemotherapeutics, narcotics and other hazardous, sensitive and/or dangerous Pharmaceutical Products, as well as Products presenting special risks of abuse, fire or explosion (e.g. combustible liquids and solids and pressurized gases) shall be stored in a dedicated area that is subject to appropriate additional safety and security measures and shall be consistent with the requirements listed in the DHCC Occupational Healthcare Safety and environment Policies, Regulations and Guidelines.
h) Pharmaceutical Products that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened shall be stored in a quarantined, physically separate, clearly labeled portion of any storage area.
i) All Pharmaceutical Products shall be stored at appropriate temperatures and under appropriate conditions in accordance with manufacturer

i. If no storage requirements are established for a Pharmaceutical Product, it must be stored at "controlled" temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
ii. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of medications.
iii. DHCC and MOH record-keeping requirements shall be followed for all stored Pharmaceutical Products.

5.4: Examination of materials

a) Upon receiving Pharmaceutical Products , each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated Pharmaceutical Product or Pharmaceutical Product that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

b) Each outgoing shipment shall be carefully inspected for the identification of the Pharmaceutical Products and to ensure that there is no delivery of any Product that have been damaged in storage or held under improper conditions.
c) The record keeping requirements shall be followed for all incoming and outgoing Pharmaceutical Product.

5.5: Returned, damaged, and outdated Pharmaceutical Products

a) Pharmaceutical Products that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other medications until they are destroyed or returned to their supplier.
b) Any Pharmaceutical Product whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other drugs until they are either destroyed at a dedicated area at the storage site or returned to the supplier.
c) If the conditions under which a Pharmaceutical Product has been returned cast doubt on the safety, identity, strength, quality, or purity of the Product, then the Product shall be destroyed, or returned to the supplier, unless examination, testing or other investigation proves that the Product meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a Pharmaceutical Product has been returned cast doubt on the safety, identity, strength, quality, or purity of the drug, the drug's distributor shall consider, among other things, the conditions under which it has been held, stored, or shipped before and/or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.
d) The record-keeping requirements shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated medications.
e) Unused outdated or damaged narcotics and fully controlled Pharmaceutical Products that are supplied by MOH only shall be returned to MOH stores to be destroyed by MOH authorized personnel. In case of incidence of broken, damage or missing Narcotic Products, an incidence report shall be filled out and sent to the MOH Drug Control Department.
f) Unused, outdated or damaged radioactive materials, chemotherapeutics and other hazardous, sensitive and/or dangerous Pharmaceutical Products, as well as Products

presenting special risks of fire or explosion (e.g. combustible liquids and solids and pressurized gases) shall be subjected to appropriate additional safety measures and shall be disposed according to the requirements listed in the DHCC Occupational Healthcare Safety and Environment SE Policies, Regulations and Guidelines.

Section 6: Vehicles and Equipment

(1) Vehicles and equipment used to distribute, store, or handle Pharmaceutical Products shall be suitable for their use and appropriately protective of the Products to prevent exposure to conditions that could affect their stability and packaging integrity, and prevent contamination of any kind.

(2) The design and use of vehicles and equipment must aim to minimize the risk of distribution errors and permit effective cleaning and/or maintenance, in order to avoid contamination, build-up of dust or dirt and/or any adverse effect on the quality of Pharmaceutical Products(?) being distributed.

(3) Dedicated vehicles and equipment should be used, where possible, when handling Pharmaceutical Products.

(4) Where non-dedicated vehicles and equipment are used, procedures must be in place to ensure that the quality of the Pharmaceutical Products will not be negatively influenced.

(5) Defective vehicles and equipment shall not be used, and shall either be removed or labeled as such.

(6) There shall be procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions.

(7) Vehicles, containers and equipment shall be kept clean, dry and free from accumulated waste. A written cleaning program shall be available, indicating the frequency of cleaning and the methods to be used.

(8) Vehicles, containers and equipment must be kept free from rodents, vermin, birds and other pests. There also shall be written programs for such pest control. Cleaning and fumigation agents must not have an adverse effect on Product quality.

(9) Special attention must be given to the design, use, cleaning and maintenance of all equipment used for the handling of Pharmaceutical Product which is not in a protective shipping carton or case.

(10) Where special storage conditions (e.g. temperature and/or relative humidity), different from or limiting the expected environmental conditions, are required during transit, such storage conditions shall be provided, checked, monitored and recorded. All monitoring records shall be kept for a minimum of the shelf-life of the Product distributed plus one year, or as required by national legislation. Monitoring records shall be reviewed on receipt of Pharmaceutical Products to assess whether required storage conditions have been met.

(11) Equipment used for monitoring conditions within vehicles and containers (e.g. temperature and humidity) must be calibrated on regular basis.

(12) Vehicles and containers should be of sufficient capacity to allow orderly storage of the various categories of Pharmaceutical Products during transportation. Where possible mechanisms should be available to allow for the segregation during transit of rejected, recalled and returned goods as well as suspected to be counterfeits. Such goods must be securely packaged, clearly labeled, and be accompanied by appropriate supporting documentation.

(13) Measures shall be in place to prevent unauthorized persons from entering and/or tampering with vehicles and/or equipment, as well as to prevent the theft or misappropriation thereof.

Section 7: Containers and Container Labeling

(1) All Pharmaceutical Products must be stored and distributed in containers that do not have an adverse effect on the quality of the Products, and that offer adequate protection from external influences, including microbial contamination.

(2) Labels applied to containers must be clear, unambiguous, permanently fixed to the container and be indelible. Information on the label must comply with applicable national legislation with regard to the labeling of containers. The labeling should be written in at least one language which is understood by persons involved in the distribution chain.

(3) Shipping containers may not need not to bear labels with full description of the identity of the container's content (in order to prevent theft), but shall nonetheless provide sufficient information on handling and storage conditions and precautions to ensure the Product is properly handled at all times.

(4) Special transport and/or storage conditions shall be stated on the label. If a Product is intended for transfer outside the control of the manufacturer’s products management system, the name and address of the manufacturer, special transport conditions and any special legal requirements, including safety symbols, Shall also be included on the label.

(5) Only internationally and/or nationally accepted abbreviations, names or codes shall be used in the labeling of containers.

(6) Special care shall be used when using dry ice in containers. In addition to safety issues, it must be ensured that the Pharmaceutical Product(s) does not come into contact with the dry ice, as it may have an adverse effect on the quality of the Product.

(7) Written procedures shall be available for the handling of damaged and/or broken containers. Particular attention shall be paid to potentially toxic and hazardous Products.

Section 8: Dispatch

(1) Pharmaceutical Products shall only be sold and/or distributed to or by persons or entities that are entitled to acquire such Products as dictated by applicable national, regional and international legislation. Written proof of such authority must be obtained prior to the dispatch of Products to such person or entities.

(2) No Pharmaceutical Products, Non-Pharmaceutical Products or medical samples shall be sold to patients by a clinic or a day surgery unit within the jurisdiction of DHCC.

(3) The supplier of Pharmaceutical Products shall, prior to the dispatch of such Products, ensure that the person or entity (e.g. the delivery agent for transportation of the Products) is aware of and follows the appropriate storage and transport conditions.

(4) The dispatch and transport of Pharmaceutical Products shall be commenced only after the receipt of a valid delivery order or material replenishment plan which should be documented.

(5) Written procedures for the dispatch of Pharmaceutical Products shall be established. Such procedures should take into account the nature of the Product, as well as any special precautions to be observed.

(6) Records for the dispatch of Pharmaceutical Products must be prepared and shall include at least the following information:

a) date of dispatch;
b) name and address of the entity responsible for the transportation;
c) name, address and status of the addressee (e.g. retail pharmacy, hospital, clinic);
d) a description of the Products, including name, dosage form and strength;
e) quantity of the Products, i.e. number of containers and quantity per container;
f) assigned batch number and *expiry* date;
g) applicable transport and storage conditions; and
h) a unique number to allow identification of the delivery order.

(7) Records of dispatch shall contain enough information to enable traceability of the Pharmaceutical Product(s). Such records shall facilitate the recall of a batch of a Product as necessary. Each party involved in the distribution chain has a responsibility to ensure traceability.

(8) Methods of transportation, including vehicles to be used, should be selected with care, and local conditions should be considered, including the climate of the region and any seasonal variations experienced. Delivery of Products requiring controlled temperatures should be done in accordance with the storage and transport conditions.

(9) Delivery schedules should be established and route planning performed where needed, taking local needs and conditions into account. Such schedules and plans should be realistic and systematic. Care should be taken that the volume of Pharmaceutical Products ordered should not exceed the capacity of storage facilities at the destination.

(10) Where applicable vehicles and containers shall be loaded carefully and systematically on a first out/last-in basis in order to save time when unloading and to prevent physical

damage. Extra care should be taken during loading and unloading of cartons to avoid breakage.

(11) Pharmaceutical Products shall not be supplied or received after their *expiry* date, or so close (3 to 6 months) to the *expiry* date that this date is likely to occur before the Products are used by the consumer.

Section 9: Record Keeping

(1) Records must contain the specific data elements required by the Healthcare Information Reporting and Analysis System (HIRAS) which are detailed in the DHCC Minimum Data Requirement Rule _____/2008.

(2) There shall be an established and maintained process for inventorying and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records shall include the following information:

a) The source of the Pharmaceutical Products, including the name and principal address of the seller or transferor, and the address of the location from which the Products were shipped;
b) The identity and quantity of the Pharmaceutical Products received and distributed or disposed; and
c) The dates of receipt and distribution or other disposition of the Pharmaceutical Products.

(3) Inventories and records shall be made available for inspection and photocopying by any official authorized by the Dubai Healthcare City for a period of three (3) years following disposition of the Pharmaceutical Product.

(4) Records described in this document that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by any official authorized by Dubai Healthcare City.

(5) Each Licensed Healthcare operator must comply with MOH Rules and Regulations regarding dispensing, registering and keeping records regarding controlled Pharmaceutical Products.

(6) The Licensed Professional in Charge is responsible for complying with MOH record-keeping requirements with respect to controlled Pharmaceutical Products, referencing the following MOH Register Books:

a) Psychotropic Drug Register (also known as the “Registered Prescription”, “R.P.“or “Group 4” Medicines. The Register is obtained from the MOH after payment of the specified fees, and it shall be labeled “CD-A”/”R.P.”/Group 4;

b) Semi-Controlled Drug Register, also known as “Controlled Prescription”, “C.P.”, or “Group 5” medicines. For each item, the Register should record the data and quantity Dispensed. It must be labeled “CD-B”/“C.P.”/Group 5.

(7) A prescription filing system shall be developed for controlled medications. The filing system for these medications shall separate the Group 4 from the Group 5 prescriptions. The prescriptions should be arranged by prescribing doctor and by date.

(8) Controlled drug prescriptions must be kept for five (5) years, including a minimum of two (2) years at the Licensed Healthcare operator, and the remaining three (3) years within secure storage.

Section 10: Quality Management

There shall be a documented Quality Policy describing the overall intentions and policies of the Licensed Healthcare operator regarding quality, as formally expressed and authorized by upper management.
Quality management shall include:

(1) Appropriate infrastructure or "quality system", encompassing the organizational structure, procedures, processes and resources;
(2) Systematic actions necessary to ensure adequate confidence that a product (or service) and documentation will satisfy given requirements for quality. The totality of these actions is termed "Quality Assurance";
(3) Where electronic commerce (e-commerce) is used, defined procedures and adequate systems shall be in place to ensure traceability and confidence in the quality of materials and Pharmaceutical Products;
(4) Authorized procurement and release procedures shall be in place to ensure that appropriate Pharmaceutical Products are sourced from approved suppliers and distributed by approved entities;
(5) All entities in the supply chain shall be traceable, depending on the type of product and on the applicable Federal and DHCC Rules and Regulations. There shall be written procedures and records to ensure traceability of the products distributed.
(6) Inspection and certification of compliance with a quality system shall be done (such as the applicable International Standardization Organization (ISO) series or national or international guidelines) by external bodies). Such certification shall not, however, be seen as a substitute for compliance with DHCC guidelines and the applicable principles of GMP relating to Pharmaceutical Products.
(7) The system of Quality Assurance shall include self-inspections. These shall be conducted in order to monitor the implementation and compliance with the applicable MOH and DHCC Rules and Regulations and to trigger necessary corrective and preventive measures.
(8) All self-inspections shall be recorded. Reports shall contain all observations made during the inspection and, where applicable, proposals for corrective measures. Follow up corrective actions taken shall be documented and recorded.

Section 11: Policies and Procedures

There shall be an established, maintained and documented process to ensure adherence to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of Pharmaceutical Products, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. The following shall be included in the written policies and procedures:

(1) An operational policy for the day to day management of the healthcare operator shall be available which includes provision for standard operation procedures that are linked to education, orientation, training and integration with other healthcare operator policies;
(2) A procedure whereby the oldest approved stock of a Pharmaceutical Product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate;
(3) A procedure to be followed for handling recalls and withdrawals of a Pharmaceutical Product. Such procedure shall be adequate to deal with recalls and withdrawals due to:
    a) Any action initiated at the request of DHCC or Federal Law Enforcement;
    b) Any voluntary action by the manufacturer to remove defective or potentially defective Products from the market; and
    c) Any action undertaken to promote public health and safety by replacement of existing
    d) Products with an improved Product or new package design.
(4) A procedure to ensure readiness for, protect against, and handle any crisis that affects security or operation of any healthcare operator in the event of strike, fire, flood, or other natural disaster, or other situations of local, or national emergency;
(5) A procedure to be followed for handling spills;
(6) A procedure to ensure that any outdated Pharmaceutical Product shall be segregated from other Products and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated Pharmaceutical Products. This documentation shall be maintained for three (3) years after disposition of the outdated Product.
(7) Written policies and procedures shall be in place that complies with the required Quality Standards and Policies.
(8) The policies and procedures shall include provision for annual review and revision as necessary as well as for provision of training of all staff involved in handling Pharmaceutical Products, both prior to and subsequent to its becoming a Licensed Healthcare operator, on the content of the policies and procedures.

Section 12: Complaints handling and product recall

12.1: Complaints Handling

(1) There shall be a written procedure in place for the handling of complaints. A distinction should be made between complaints about a Product or its packaging and those relating to distribution. In the case of a complaint about the quality of a Product or its packaging, the

original manufacturer and/or marketing authorization holder shall be informed as soon as possible.

(2) All complaints and other information concerning potentially defective and potentially counterfeit Pharmaceutical Products should be evaluated carefully according to written procedures describing the action to be taken, including the need to consider a recall where appropriate.

(3) Any complaint concerning a material defect shall be recorded and thoroughly investigated to identify the origin or reason for the complaint (e.g. repackaging procedure, original manufacturing process, etc.).

(4) If a defect relating to a Pharmaceutical Product is discovered or suspected, consideration should be given as to whether other batches of the product should also be checked.

(5) Where necessary, appropriate follow-up action shall be taken after investigation and evaluation of the complaint.

12.2: Recalled products

(1) Recalled Products shall be handled according to approved and documented procedures that ensure the prompt and effective recall of all Pharmaceutical Products that are known or suspected to be defective. The procedures shall be checked and updated regularly.

(2) A qualified person shall be appointed to be in charge of recall or “pull out” procedures.

(3) All records that document the procedures that were followed, actions taken and quantities recalled, including required data, shall be readily available. These records shall contain sufficient information on the Pharmaceutical Products recalled (brand name, strength, batch number, entities that the Product was recalled from) signed by persons in charge for each entity involved. All recalls must be reported to the MOH Drug Controlled Department and to the DHCC Pharmacy Services Unit.

Section 13: Environmental Management, Infection Control & Safety

(1) Each Licensed Healthcare operator shall comply with all applicable environment management rules, policies and procedures, including those contained in the DHCC Occupational Health, Safety and Environment Approved Code of Practice.

(2) Each Licensed Healthcare operator shall comply with the infection control requirements of the DHCC Outpatient Clinic Quality Standards and Policies.

(3) Each Licensed Healthcare operator shall have a back-up communication system to communicate with the emergency management agency or other local and regional emergency medical resources in the event communications are disabled.