United Arab Emirates
Ministry Of Health
Drug Control Department

GOOD PHARMACEUTICAL STORAGE & DISTRIBUTION PRACTICES (GS&DP)

2006

GOOD PHARMACEUTICAL
STORAGE & DISTRIBUTION PRACTICES

INTRODUCTION

Good Pharmaceutical Storage and Distribution Practices (GS&DP) are that part of Quality Management System that guarantees the quality of the pharmaceutical or medical product through controlling various activities related to storage and distribution operations procedures.

The Drug Control Department at Ministry of Health, is issuing Good Pharmaceutical Storage and Distribution Guidelines as the assigned regulatory body for licensing and controlling pharmaceutical establishments, to insure their adherence with the essential technical and commercial standards. In this regards the Drug Control Department reiterate on all concerned establishments which deals with pharmaceutical and medical products to consider application of the concerned guidelines as a serious commitment and as vital part of their core activities.

The given instructions and criteria mentioned in the issued guidelines considered a main objective which is to guarantee that the consumer is getting the pharmaceutical or medical product with the best quality and efficacy status, and through the legitimate reliable channels. In addition to the mentioned objective these guidelines aim at ensuring the traceability of the product from the manufacturing point to the point where it reaches the consumer. This traceability is a vital tool employed at its best in complaints cases or any other case which requires any voluntary or compulsory recall for any pharmaceutical or medical products in timely and effective manner.

The above objectives are considered as shared responsibility of the concerned establishment's management, the pharmacist in charge and the Drug Control Dept, all working together as one team putting the consumer's health and welfare as first priority.

The guidelines and instructions mentioned as Good Pharmaceutical Storage and Distribution Practices (GS&DP) comply with the previously issued guidelines by Drug Control Department (DCD) at Ministry of Health (MOH) in regard to:

- Good Manufacturing Practices published by the department in the year 2000.
- Good Laboratory Practices published by DCD in the year 2002.
- Good Pharmacy Practices published by DCD in the year 2003.
- Code of ethics for pharmacy practice issued by DCD .
- Registration guidelines for pharmaceutical products (of all classes) issued by the department.

These guidelines are meant to act as a comprehensive guide in the pharmaceutical storage and logistic field as it took in consideration the global progress in the pharmaceutical field with a broader scope by including pharmaceutical products in addition to Healthcare products, Medical Devices and in vitro Diagnostics.

The Drug control Dept Thanks Ph. Nadia A. Malik Younis for her efforts to accomplish this achievement with the supervision of Dr. Easa Ahmed. Bin Jakka Al Mansoori.

Definitions and technical terms

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- ***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.

- ***Consignment (or delivery)***

The quantity of a pharmaceutical(s), made by one manufacturer and supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include material belonging to more than one batch.

- ***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 on to a starting material, intermediate or pharmaceutical product during handling, production, sampling, packaging or repackaging, storage or transport.

- ***Counterfeit***

À counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products and may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.

- ***Cross-contamination***

Contamination of a starting material, intermediate product or finished product, with another starting material or product during production.

- ***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.

- ***Expiry date***

The date given on the individual container (usually on the label) of a product up to and including which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture.

- ***Labeling***

Process of identifying a product, by choosing and attaching the primary and secondary packaging (container) with the right label which includes all needed information regarding the product or material.

- ***Manufacture***

All operations of purchase of materials and products, production, quality control, release, storage and distribution of pharmaceutical products, and the related controls.

- ***Material***

A general term used to denote starting materials (active pharmaceutical ingredients and excipients), reagents, solvents, process aids, intermediates, packaging materials and labeling materials.

- ***Active pharmaceutical ingredient (API)***

Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when used in the production of a drug, becomes an active ingredient of that drug. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure and function of the body.

- ***Pharmaceutical product***

Any medicine intended for human use or veterinary product administered to food producing animals, presented in its finished dosage form or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.

- ***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 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.

- ***Quality control***

Quality control covers all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that starting materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.

- ***Quality system***

An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality.

- ***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.

- ***Shelf-life***

The period of time during which a finished pharmaceutical product, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches of the product. The shelf-life is used to establish the expiry date of each batch.

- ***Standard operating procedure (SOP)***

An authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection).

- ***Storage***

The storing of pharmaceutical products up to the point of use.

- ***Validation***

A documented program that provides a high degree of assurance that a specific process, method or system will consistently produce a result meeting pre-determined acceptance criteria.

- ***Vehicle***

Vehicle refers to trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means which are used to convey pharmaceutical products.

- ***Supplier***:

A person or party which provide the concerned establishment, pharmaceutical products and materials on request. Suppliers may be agents, brokers, distributors, manufacturers or traders. Suppliers should be authorized by a competent authority.

- ***Retest date:***

The date when a material should be re-examined to ensure that it is still suitable for use.

- ***Normal Storage Conditions***

Means to practice storage under environmental conditions described as dry with a good ventilation within temperature degrees range between 15 to 25 degrees Celsius that could extend to 30 degrees Celsius as marginal limit. The storage environment should be protected from any external vapors or smells, contamination factors and extensive direct light.

- *Packaging material*

Any material, including printed material, employed in the packaging of a pharmaceutical product, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

- ***Specific Storage conditions:***

Some pharmaceutical products require specific conditions to be stored within, and needs special instructions for storage handling and methods.

- *Interpretation of instructions included on the product label:*

- **Not to exceed 30 Degree Celsius: means to store within the range from +2 to +30 Degrees Celsius.**
- **Not to exceed 25 Degree Celsius: means to store within the range from +2 to +25 Degrees Celsius**
- **Not to exceed 15 Degree Celsius: means to store within the range from +2 to +15 Degrees Celsius.**
- **Not to exceed 8 Degree Celsius: means to store within the range from +2 to +8 Degrees Celsius.**
- **Do not store below 8 Degree Celsius: means to store within the range from +8 to +25 Degrees Celsius.**
- **The product should be protected from humidity: means to protect it from conditions where humidity exceeds 60%, and should be kept in a humidity resistant container.**
- **Keep away from light: means that should be stored in places not exposed to light. It should be kept in light proof containers.**

Chapter One
Concerned establishments and Scope

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A) Establishments concerned

Any pharmaceutical or health establishment which deals in handling, storing or distributing pharmaceutical or healthcare products has to be concerned by the guidelines and instructions mentioned in this issue. These establishments could be:

- Medical stores.
- Stores as part of pharmaceutical and medical devices manufacturing establishments.
- Nutrition & Health Dietary Supplements food stores.
- Herbal pharmaceutical stores.
- Private pharmacies and hospital pharmacies.
- Stores designated for storing pharmaceuticals and medical products at health establishments like hospitals and Public Healthcare institutions.

B) Management and Personnel:

1- There should be an adequate organizational structure defined with the aid of an organizational chart. The responsibility, authority and interrelationships of all personnel should be clearly defined and documented through clear job descriptions.

2- At each storage site (e.g. that of a manufacturer, distributor, wholesaler, and community or hospital pharmacy) there should be an adequate number of qualified personnel available at all working hours to achieve pharmaceutical quality assurance objectives.

3- A designated person should be appointed at each distribution point who should have defined authority and responsibility for ensuring that a quality management system is implemented and maintained. This person should be qualified according to the set requirements mentioned in the relevant administrative decision (circular).

4- All personnel (pharmacists and others) in the storage area should be provided by proper initial and continuous training related to the Good Distribution and Storage Practice, related rules and regulations, and safety regulations, in addition to be capable of meeting these requirements. The training records should be kept for review if needed.

5- All members of staff should be trained in, and observe high levels of, personal hygiene and sanitation. Clear instructions for personal Hygiene should be distributed and observed.
6- Personnel employed in storage areas should wear suitable protective or working garments appropriate for the activities they perform.
7- First-aid procedures and equipment for dealing with emergencies involving personnel should be available.
8- There should 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.
9- Codes of practice and disciplinary procedures should 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.

B- Contracting with third party:

1- Contracting (outsourcing) of certain storing or distribution services or activities is acceptable, given that these are outsourced from qualified and legitimate parties.
2- Any activity relating to the distribution of a pharmaceutical product which is delegated to another person or entity should be performed in terms of a written contract which is agreed upon by the contract giver and the contract accepter. The contract should define the responsibilities of each party including observance of the principles of GS &DP.

Chapter Two
Premises, Instruments and vehicles

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A- Premises:

1- Design and Layout of the storage site:

1-1 Storage areas should be designed or adapted to ensure the following good storage conditions:

- Proper cleanliness & Hygiene.
- Dry (relative humidity not more than 60%)
- Temperature should be within acceptable limits (8-25 degrees Celsius).
- Stored Goods and Materials should be stored off the floor
- Suitably spaced to permit cleaning and inspection.
- Pallets should be kept in a good state of cleanliness and repair.

1-2 Storing area should be sufficient to allow the storage of different items in orderly and separated avoiding jam packing. In this regards it is essential to designate separate areas for each of the following:

- Raw materials.
- Packaging material.
- Intermediate material.
- Finished product.
- Quarantined substances.
- Approved products.
- Rejected products.
- Recalled products.
- Returned products.
- Dangerous material.
- Inflammable substances.

1-3 Resting areas and areas for having food should be isolated from storing area.
1-4 Toilets and hand washing areas should be made available.
1-5 Toilets should not be opened directly into the storing area.

2- Specifications of the storage area

2-1 Precautionary physical arrangements and measurements should be taken in order to give access for those only authorized personnel to enter the storage area.
2-2 Storing area should have sufficient light to perform tasks in a correct, safe and accurate manner.

2-3 In case of windows presence in the storage area, arrangements should be made to block Sunlight away from the stored items.

2-4 All surfaces, shelves, cupboards used should be covered with an impermeable and easy to clean smooth layer.

3- **Receiving and dispatching area**:

- Receiving and dispatch bays should 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.

4- Quarantine area:

Quarantined material and Pharmaceutical products should be kept in specified quarantine areas until approved. This area should be:

- Well isolated, separated and clearly labeled.
- Restricted only for authorized personnel.
- Any system replacing physical quarantine should provide equivalent security, isolation and prevention of mixing up, provided that it is validated to demonstrate its effectiveness and security of access.

5- Sampling area:

There should be a designated area for sampling of primary material provided that it is:

- Isolated and of controlled and monitored environment.
- Sampling should be done in a certain manner to avoid contamination and cross contamination and according to a documented procedure.
- There should be a written cleaning procedure for cleaning of the sampling area effectively.

6- Rejected product area:

There should be a physical separation for defected products, rejected products, expired or recalled products so that it should be:

- Well controlled and prevent their use until a final decision is taken on their fate.
- It should be clearly labeled.
- Locked and restricted only to authorized personnel.

B- Instruments:

- Equipment available in the storage area should only be used for its intended purpose only and to be used only in those licensed activities compliant with its license issued by Drug Control dept.
- All equipment should be calibrated and validated periodically including temperature monitoring devices, humidity monitoring devices and scales.

C-Vehicles:

- Vehicles and equipment used to distribute, store, or handle concerned materials and products should be properly designed and equipped to insure protection from different environmental and weather conditions that it is operating in. proper policies and written procedures should be in hand to insure the above objective.
- The design and use of vehicles and equipment must aim to minimize the risk of 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. To make available clear and detailed written procedures and documenting records for the cleaning methods with specified frequency for each vehicle in use.
- The use of any vehicle other than of those designated should be avoided under any circumstance, and in case this has to happen there should be a written standard procedure for the vehicle's cleaning instructions along with other instructions that specifies the acceptable type of items or materials that could be transported within the same vehicle. In this regard it is reminded that this choice is not recommended and should be kept only for unavoidable and limited cases.
- The use of vehicles with defects that could affect the quality of the product or transferred materials should be avoided. Defected vehicle if any should be fixed while being clearly labeled with its condition until defect removal is accomplished.
- Written standard procedures should be made available for operating and maintenance of transporting vehicles clarifying the frequency of each maintenance measure. Records signed by a qualified party contracted for maintenance should be made available and used to provide maintenance history evidence of the concerned vehicle.
- Special protective precautions should be followed for transporting products or materials which not provided with any protective packaging.
- Storage conditions (e.g. temperature and/or relative humidity) required for maintaining the quality of transported products or material (as mentioned on their label) should be provided, checked, monitored and recorded. All monitoring records should be kept and made available for review at any time. Recorded

monitoring data should be reviewed on receipt of pharmaceutical products to assess whether required storage conditions have been met.

- 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 pharmaceutical products as well as suspected to be counterfeits.
- Effective measures should 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.

Chapter Three

Storage area Organizing and handling of stored items

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A- Handling of material at storage area

1- Stored material should be isolated according to its specified storage conditions mentioned on the label and in line with the risks in case personnel could be subjected to on handling. Inflammable materials should be kept in suitable room, or in a fire resistant safe lock, dangerous substances should be clearly identified and labeled ,this also applies on radioactive , narcotic substances and any substances that can impose a hazard when used improperly.

2- Narcotic ,psychotropic drugs and radioactive substances should be stored in a manner that complies with international regulations and U.A.E laws(federal law number 4 for year 1983 ,federal law 14 for year 1995 for narcotics and federal law No 20 for products derived from natural resources) and the relevant MOH instructions.

3- All procedures involving the dealing with and distribution of pharmaceuticals should comply with the GMP regulations issued by the drug control department in the year 2000.

4- Starting material and products should be isolated and be properly labeled in a way which prevents mix-up and cross contamination.

5- Stored materials and products should be stored (kept within containers) that:

- Don't affect the quality of products negatively.
- Provide the proper protection from the surrounding environmental factors as well microbial contamination.

6- A system should be in place to ensure that pharmaceutical products due to expire first are sold and/or distributed first (FEFO). Adequate controls should be in place to prevent the distribution of expired products.

7- Broken or damaged items should be withdrawn from usable stock, separated and labeled clearly.

8- Items that require refrigeration should be kept in fridges a way that prevents cross contamination, fridges' temperature should be recorded periodically to ensure its consistency within the required limits. The location of the storing fridges should be properly chosen.

9- Storage conditions for products and materials should be in compliance with the labeling, which is based on the results of stability testing approved by Drug Control department on the product's registration.

B- Monitoring and control of storage conditions during storing and transportation

1- It is recommended that temperature monitors be located in areas that are most likely to show fluctuations according to a validated plan.

2- All recorded temperature and humidity monitoring data recorded out of continuous monitoring should be:

- Available for review.
- Comprise all the results of the regular checks made at suitable predetermined intervals recorded and retained from equipment designated for monitoring temperature degrees.
- Kept for at least the shelf-life of the stored material or product plus one year.
- Temperature mapping should show uniformity of the temperature across the storage facility or transporting vehicle.

C- Hygiene

1- Storage areas should be clean, and free from accumulated waste and vermin. A written validated sanitation program should be available indicating:

- Frequency of cleaning
- Methods to be used to clean the premises and storage areas.
- Written program for pest control. The pest-control agents used should be safe, and there should be no risk of contamination of the stored materials and products. There should be appropriate procedures.
- Written program for disinfection methods mentioning the periodic exchange of used disinfectants in a way prevents microbial resistance.
- Written program for maintaining used cleaning tools (utensils) clean.
- Procedures for the clean up of any spillage to ensure complete removal of any risk of contamination.

2- Training should be provided for cleaning personnel in a way that ensures their understanding of the importance of the cleaning procedures followed.
3- Washing station in the storing area should not be used for washing hands.
4- An instructions sign should be displayed stating the need for washing hands and the use of hot air and tissues for drying.
5- Toilets should not be used for storage purposes.

Chapter Four
Quality Management and documentation

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1- Quality Management:

1-1 There should be a documented quality policy describing the overall intentions and policies of the establishment regarding quality, as formally expressed and authorized by upper management.

1-2 Quality management should include:

- Appropriate infrastructure or "quality system", encompassing the organizational structure, procedures, processes and resources; and
- 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".

1-3 Where electronic commerce (e-commerce) is used, defined procedures and adequate systems should be in place to ensure traceability and confidence in the quality of Materials and pharmaceutical products.

2- Documentation: instructions, written SOPs and records:

2-1 Good documentation is essential part of Good Distribution and storage practice. Documenting working actions main objectives are to avoid errors or misjudgments, to be sure that the same (consistent) methods are used at each time, to make sure that the used instruments are working properly according to set standards and to ensure recording of all steps (actions) followed on receiving and storing of the materials and products.

2-2 written standardized work procedures (SOP), instructions and records should be:

- Available for review
- To clearly explain work procedures.
- To include and document all activities and procedures followed in the storage premises.
- To clearly identify the distribution channels for materials and products.

2-3 among others, written standardized operation procedures (SOP) should be in place for the following:

- Dealing with expired stock
- Procedures to be followed in case of RECALL of any products.
- Authorized procurement and release procedures should be in place, to ensure that appropriate pharmaceutical products are sourced from approved, legitimate and licensed suppliers and distributed by approved legitimate entities.

2-4 there should be written procedures and records to ensure traceability of the products distributed from the point of production by the manufacturer covering all entities in the supply chain as they should be traceable as applicable until it reaches the final user. All information and details in this regard should be recorded and documented in a meaningful manner for concerned official authorities (Customs, Drug Control Dept…) as well as for other parties within distribution channels and final user.

2-5 A data Sheet of permanent information, written or electronic, should exist for each stored material or product indicating:

- Brand name, International Non-Proprietary Name (INN) name/s
- recommended storage conditions,
- any precautions to be observed
- retest dates
- Pharmacopoeial requirements
- Art work of labels and containers.
- Safety and first aid instructions.

2-6 Records should be kept for each delivery and must be retained for a period equal to the shelf-life of the incoming materials and products, where applicable, plus 1 year). They should include the following:

- description of the received goods (Pharmaceutical Dosage form, size and presentation of pack unit, number of units per pack, and any other important detail like supplementary accessories and so)
- quality
- quantity
- supplier
- supplier's batch number
- the date of receipt
- assigned batch number
- Expiry date.

2-7 Comprehensive records should be maintained showing all receipts and relevant invoices, including purchase orders and issues of materials and pharmaceutical products according to a specified system, e.g. by batch number, stock cards…

3- Labeling

1- Labels applied to containers should be clear, unambiguous, permanently fixed to the container and be indelible. The labeling should be written in a language which is understood by persons involved in the distribution chain as well for relevant official authorities.
2- All containers and packaged stored material or products should be labeled clearly.

3- Labels on secondary packaging should include at least the following:

- Material or product name (Brand name if applicable and the INN name in addition to pharmacopeias if applicable)
- Quantity (weight, size, unit number)
- Batch number
- Expiry date or retest date for active ingredients.
- Receiving date
- Production date
- Quality Control section approval and release date with signature of person in charge.
- Storage conditions (clear and specific)
- Transportation conditions and precautions.
- Handling precautions
- Manufacturer name with its trade mark.
- Supplier's name (in case it is a wholesaler or so) with contact details.
- When used, only internationally and/or nationally accepted abbreviations, names or codes should be used in the labeling of containers. Use of abbreviations or symbols should be avoided.

4- Self inspection

1- The system of quality assurance should include self-inspections. These should be conducted in order to monitor the implementation and compliance with the principles of GD &SP mentioned in this issue and to trigger necessary corrective and preventive measures.
2- Self-inspections should be conducted in an independent and detailed way by a designated, competent person.
3- All self-inspections should be recorded. Reports should contain all observations made during the inspection and, where applicable, proposals for corrective measures. Follow-up corrective actions taken should be documented and recorded.

Chapter five
Handling stored items

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1- Instructions for receiving supplied materials or products :

1- On receipt each incoming consignment and their invoices should be checked to match against the relevant purchase order made by the establishment in regard with all specifications (quantities, batch numbers etc.). Each container should be physically verified to ensure its compliance with all legal and regulations given as label description, expiry date , batch numbers quantities , etc…)
2- Each container received should be carefully inspected for uniformity of containers, any clear defects, for possible, tampering and damage. In case of any suspect containers or, if necessary, the entire delivery should be quarantined for further investigation.
3- Received Items or goods should be subdivided according to brand, the supplier's batch number should the delivery comprise more than one batch in all the storage areas (Quarantine and final storage area).
4- In warehouses where samples of the received goods should be drawn (Manufacturing sites warehouses and similar establishments), the sampling should be carried out by competent and trained personnel.
5- Received consignments should be kept at the quarantine area until ensuring its compliance with all technical specifications required based on either quality control lab reports, an authorized official legal release or rejection is obtained.
6-Effective measures should be in place to ensure that rejected; defected or expired materials and pharmaceutical products cannot be used or bypassed. They should be stored separately from other materials and pharmaceutical products while awaiting their disposal either by destruction or return to the supplier.

2- Stock Rotation and control.

1- Periodic stock reconciliation should be performed by comparing the actual and recorded stocks.
2- All significant stock discrepancies should be investigated as a check against inadvertent mix-ups and/or incorrect issue.

3- In case of partly used containers , should be securely re-closed and resealed to prevent spoilage and/or contamination during subsequent storage. Care should be taken to use first Containers which have been opened or partly used before those in unopened containers.
4- Damaged containers should not be issued unless the quality of the material has been shown to be unaffected.
5- Regular checks should be carried out for all stocks to identify and remove obsolete and outdated materials or products.

3- Stock Dispatch procedures and instructions:

1- The concerned management should establish and endorse written standardized procedures for dispatching and handling of stock taking into account the nature of the materials and products for any special precautions might be required.
2- Care should be taken on selling or distributing pharmaceutical products only to parties or entities that are legally licensed and entitled to acquire such products. Written proof of such entitlement must be obtained prior to the dispatch of products to any party.
3- Measures should be taken to only dispatch those batches of a valid quality certificate available. This certificate based on approved quality control testing should ensure the compliance of the batch with pre-set specifications according to recognized scientific references. If such a proof doesn't exist or the batch is out of specifications then the establishment should refrain from its selling or distribution. In such a case the establishment should transfer all quantities of that batch to quarantine and apply the quarantined stock procedures in hand.
4- The establishment should refrain from selling, distribution or dealing with any material or product after their expiry date or so close to the expiry date that this date is likely to occur before the products are used by the receiving party.
5- The dispatch of pharmaceutical products should be commenced only after the receipt of a valid and documented delivery order.
6- Records for the dispatch of material and products should be prepared and should include at least the following information:

- date of dispatch
- name, address and status of the intermediate (if applicable) and final receiver (e.g. retail pharmacy, hospital, community clinic)
- A description of the products including, e.g. brand name, INN name, dosage form, strength (if applicable), packing and presentation of pack units size of pack unit and number of units per pack.
- Quantity of the products, i.e. number of containers and quantity and size per container.
- assigned batch number and expiry date or retest date for starting materials
- required transport and storage conditions
- Unique serial number to allow identification and traceability of the delivery order.

7- Records of dispatch should contain enough information to enable traceability of the pharmaceutical product from the point of its dispatch by the manufacturer until reach of the final user. Such records should facilitate the recall of a batch of a product from markets or users if necessary. The records and documents of the received and dispatched consignments should be available and kept in a way that enables its quick review on need or on the request of relevant official authorities.
8- Each party involved in the distribution chain has a responsibility to ensure traceability for dispatched materials or products.
9- Transportation and delivery of consignments to the receiving party should only be carried out only after taking in and checking receiving orders to be matched against dispatch orders which should be kept as part of documentation.
10- The dispatching party should ensure that the receiving party owns the required resources and is capable of storing the received consignment in a manner that preserves its quality. Delivered quantities should be proportionate to the storage area size provided by the receiving party.

4- TRANSPORTATION AND PRODUCTS IN TRANSIT

1. Materials and pharmaceutical products should be transported in such a manner that doesn't allow:
   - The loss of their identity.
   - Its contamination by weather, surrounding environment r by other products.
   - Its spillage, breakage or spoilage.
   - Misappropriation and theft.
   - Exceeding of appropriate temperature and relative humidity conditions in the case of pharmaceutical products, as appropriate which could negatively affect the quality.

2. Packaging materials and transportation containers should be of certain specifications and organized throughout shipping process in manner which provides protection for the shipped goods from external factors and prevent damage of pharmaceutical products during transport.
3. To ensure communicating all relevant conditions and precautions for storage and transportation to the entity(-ies) responsible for the transportation of pharmaceutical products.
4. Transportation for material and pharmaceutical products should be carried carefully in a manner that corresponds to the special storage precautions for each product's nature:
   - Care should be given for products that require special precautions such as radioactive, flammable or internationally controlled substances. Security and safety should be provided through validated procedures.

- In case of shipping rejected, counterfeit or expired products, transported items should be clearly labeled to how its status and should be secured against tampering or theft.

5. transported consignment components should be labeled and documented with their storage requirements to be followed during transportation.
6. Proper and identifying documents should be accompanied during transportation available for review by authorities or similar entities.
7. The transporting vehicle or containers should be effectively cleaned according to the approved and validated written standard operation procedures prior to its loading Extra care should be taken when designing delivery schedules, loading and unloading in order to prevent possible physical damage (Ex: to organize bigger containers and those to be delivered later in the back and so on).
8. Storage conditions as temperature degrees should be recorded periodically. Such records should be available for review on request.
9. Special care should be used when using dry ice in containers. It must be ensured that the pharmaceutical product does not come into contact with the dry ice, as it may have an adverse effect on the quality of the product due to freezing.
10. Any case of spoilage or breakage should be reported by a documented report to the receiving party and to the dispatching party. use it can effect the stability of some them due to freezing

Chapter six

Complaints handling and product recall

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1- Complaints handling:

1- The establishment's management should be put in a place a written procedure for the handling of complaints which clarify procedures to be followed for information collection, investigating facts and follow up corrective actions. A distinction should be made between complaints about a product or its packaging and those relating to distribution.
2- In the case of a complaint about the quality of a product or its packaging the original manufacturer and/or marketing authorization holder should be informed as soon as possible and not wait until full investigation is performed.
3- Any received complaint, investigation carried out and their results should be documented.
4- To consider the possibility of recurrence of the same defect at other batches for the same when investigating any quality complaint.
5- There should be a written documented procedure in place for procedures to be followed in case of possible investigation results reached and actions to be taken through classifying type of results according to level of hazards that could be caused.

2-Recalled products:

1- Recalled products for quality reasons should be handled according to approved and documented procedures.
2- A qualified person should be appointed to be in charge of recall or pull out procedures.
3- Set procedures and arrangements should guarantee prompt and effective actions in case that a suspected quality defect which requires recall and suspension of batch/es is proven to be true.
4- All records that document the followed procedures, taken actions and recalled quantities with the required data should be readily available. These records should contain sufficient information on pharmaceutical products recalled (brand name, INN name, strength, batch number, entities that product was recalled from)signed by persons in charge for each entity involved.
5- All recalled pharmaceutical products and materials should be kept in quarantine area, and care should be given not to be restored with the stock approved for sale. Its release and reselling could be done only after being approved by a qualified person in charged based on proper evaluation and quality control testing. In case a quality defect is proven the recalled stock should be labeled as rejected and segregated in the rejected items area.

6- Any disposal for any rejected items by any means (destruction or re-export, etc..) should be done only after taking the permission of Drug Control Department at MOH. This requires submitting a documented proves and relevant certificates including the quantities, specifications of the concerned rejected goods signed by persons which approved the rejection.

3- Goods' Return from distribution points:

1- In case that any quantity of products or materials were returned for reasons related to any quality defect and it was proven that this defect is related to the quality of the products or its packaging then the case should be dealt with as mentioned in the second paragraph of the current chapter.
2- In case that any quantity of a product or materials were returned for a reason related to distribution operations, a full investigation should be carried out. If the investigations realized that returned goods are considered not suitable for reissue or reuse, the second paragraph of the current chapter should be applicable.
3- In case products are returned for pure commercial reason of no relation to the product's quality the following instructions should be followed:
    a- All returned products or materials should be kept in quarantine area. Its release and reselling could be done only after being approved by a qualified person in charged based on proper evaluation and quality control testing.
    b- Any reissued stock should be labeled and to add its data within stock records.
    c- Any products directly returned by patients (end users) through retail pharmacies should not be reissued to be stored with the approved for sale stock. Such products should be kept within rejected items area ready for disposal.

4- Handling of counterfeit products

1- Any counterfeit or suspected counterfeit medicines found in the pharmaceutical supply chain should be confiscated and segregated immediately in the rejected items area from other pharmaceutical products and recorded. Such products should be clearly labeled in order to prevent further distribution or sale. All confiscated quantities should be secured in a manner that prevents misappropriation and theft, were these items will be considered as a responsibility of the designated person in charge, this requires his signing for all relevant data records.
2- The holder of the marketing authorization, relevant official authorities and Drug Control Department, should be informed immediately. A full detailed report of the case in hand, attached with photos for the inner and outside packaging and the dosage form

unit along with representative samples should be submitted to be checked and analyzed by the Drug control Dept.

3- Upon confirmation of the product being counterfeit a formal decision should be taken on the disposal of counterfeit pharmaceutical products and the decision recorded under the supervision and control of the relevant authorities.

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