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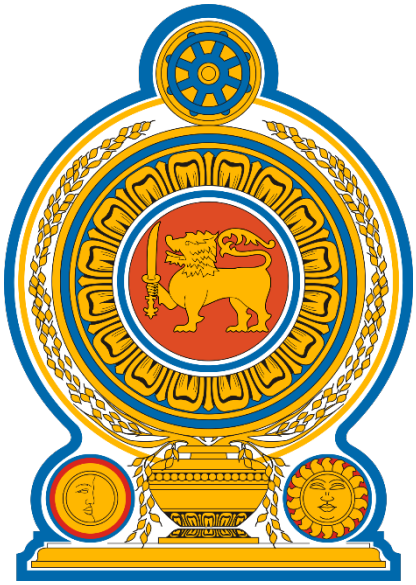
NATIONAL MEDICINES REGULATORY AUTHORITY



GUIDELINE ON GOOD STORAGE PRACTICES FOR PHARMACEUTICALS (GSP)

Pharmacy Regulatory Division

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GUIDELINE ON GOOD STORAGE PRACTICES FOR PHARMACEUTICALS (GSP)

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1. INTRODUCTION

The NMRA Act defines GSP as "Good Storage Practice" means good distribution practice guidelines issued by the Authority;

Storage and distribution are important activities in the supply chain management Therapeutic goods. Therapeutic goods may be subjected to various risks at different stages in the supply chain, i.e. during purchasing, storage, distribution, transportation, repackaging, and relabelling. It is essential to protect against the penetration of substandard and falsified products supply chains that pose a real threat to public health and safety.

All persons and outlets involved in any aspect of the storage and distribution of therapeutic goods from the premises of the manufacturer of the therapeutic goods and/or its related materials to the person dispensing or providing therapeutic good directly to a patient or his or her agent are required to adopt proper distribution and store management procedures appropriate for the distribution and storage of therapeutic goods and its related materials destined for the consumer.

This includes all parties involved in trade, storage and distribution of medical products, manufacturers and wholesalers, as well as other parties such as brokers, suppliers, distributors, logistics providers, traders, transport companies, forwarding agents and their employees.

The relevant sections of this guideline should also be considered for implementation by, amongst others, governments, regulatory bodies, international procurement organizations, donor agencies and certifying bodies, as well as all parties involved in any aspect of the trade and distribution of pharmaceutical products, including health care workers.

The GSP also requires that materials and products classified as dangerous drugs under the Poison, Opium and Dangerous Drugs Act 1984, are stored and distributed in accordance with the requirements of the respective Act and Regulations.

This guideline is used as a standard to justify status and as a basis for the inspection of facilities, such as manufacturers, importers and wholesalers.

This guide is intended for those involved in the storage, transportation and distribution of Therapeutic goods are required to adopt proper distribution and store management procedures appropriate for the distribution and storage of products and its related materials destined for the consumer.
These procedures should include the management of personnel, premises, facilities and adequate documentary procedures that preserve the safety and quality of the material or product.

2. SCOPE

- This document lays down guidelines for the storage of therapeutic Goods It is closely linked to other existing guidelines published by the NMRA. The guidelines thus cover products for which medicines, medical devices, Boarder line products, biological and vaccines.

3. GLOSSARY

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.

ALCOA

A commonly used acronym for "attributable, legible, contemporaneous, original and accurate".

Good storage practices (GSP)

That part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the storage thereof.

Contamination

The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a starting material, or intermediate or finished product during production, sampling, packaging or repackaging, storage or transport.

Cross-contamination

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

Excipient

A substance, other than the active ingredient, which has been appropriately evaluated for safety and is included in a drug delivery system to:

- aid in the processing of the drug delivery system during its manufacture;
- protect, support or enhance stability, bioavailability, or patient acceptability;
- assist in product identification; or
- Enhance any other attribute of the overall safety and effectiveness of the drug during storage or use.

Expiry date

The date given on the individual container (usually on the label) of a drug 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.

First expiry/First out (FEFO)

A distribution procedure that ensures that the stock with the earliest expiry date is distributed And/or used before an identical stock item with a later expiry date is distributed and/or used

Heating, ventilation and air conditioning systems (HVAC)

Heating, ventilation and air-conditioning, also referred to as environmental control system (ECS)

Labelling

The action involving the selection of the correct label, with the required information, followed by line clearance and application of the label.

Manufacture

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

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

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.

PDCA (plan–do–check–act or plan–do–check–adjust) is an iterative four-step management method used for the control and continuous improvement of processes and products.

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.

Production
All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labeling and relabeling, to completion of the finished product.

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

Storage
The storing of pharmaceutical products and materials up to their point of use.

Supplier
A person providing pharmaceutical products and materials on request. Suppliers may be agents, distributors, manufacturers or traders. The suppliers should be authorized by the NMRA.

4. GENERAL PRINCIPLES

- There should be collaboration between all parties, including governments, customs agencies, law enforcement agencies, regulatory authorities, manufacturers, distributors and entities responsible for the supply of therapeutics products to patients, to ensure the quality and safety of these products; to prevent the exposure of patients to substandard and falsified products and to ensure that the integrity of the storage is maintained.

5. QUALITY MANAGEMENT

5.1 Quality Systems

- Entities involved in the storage of therapeutic products must have a comprehensively designed and correctly implemented, documented, quality system that incorporates good storage practices, quality risk management and management review
- Senior management has the ultimate responsibility to ensure an effective quality system is established, is adequately resourced, implemented and maintained.

- The effectiveness, roles, responsibilities and authorities should be defined, communicated and implemented throughout the organization.
- The quality system should ensure that GSP is adopted and managed through satisfactory arrangements to ensure, as far as possible, that the therapeutics goods are stored, and subsequently handled ,so that quality is maintained throughout their shelf-life in the supply-chain, products are appropriately procured, stored, and delivered to the right recipients, operations are clearly specified in a written procedures, responsibilities are clearly specified in job descriptions, all risks are identified and necessary, effective controls are implemented; processes are in place to assure the management of outsourced activities; there is a procedure for self-inspection and/or quality audit; there is a system for quality risk management (QRM) there are systems for managing returns, complaints and recalls; systems are in place to manage changes, deviations and corrective and preventive actions (CAPAs).
- There should be an authorized, written quality policy describing the overall intentions and requirements regarding quality.
- This may be reflected in a quality manual. There should be an appropriate organizational structure.
- This should be presented in an authorized organizational chart.
- The responsibility, authority and interrelationships of all personnel should be clearly indicated.
- Duties and responsibilities should be clearly defined and understood by the individuals concerned and recorded as written job descriptions.
- The quality system should include appropriate procedures, processes and resources.

5.2 Self inspection

- The quality system should include self-inspections.
- These should be conducted to monitor implementation and compliance with the principles of regulations, GSP and other appropriate guidelines.
- Self-inspections should be conducted periodically according to an annual schedule.
- The team conducting the inspection should be free from bias and individual members should have appropriate knowledge and experience.
- Audits by independent third parties may be beneficial.
- The results of all self-inspections should be recorded.
- Reports should contain all observations made during the inspection and presented to the relevant personnel as well as management.
- Necessary CAPAs should be taken and the effectiveness of the CAPAs should be reviewed.

6. QUALITY RISK MANAGEMENT

- There should be a system to assess, control, communicate and review risks identified at all stages in the supply chain.
- The evaluation of the risk should be based on scientific knowledge and experience with the process and ultimately linked to the protection of the patient.
- Appropriate controls should be developed and implemented to address any risks identified.
- The effectiveness of the controls implemented should be evaluated at periodic intervals.

(*For further reading, see also WHO Guideline on Risk Management, ICH Q9 & ISO 31000*)

7. MANAGEMENT REVIEW

- There should be a system for periodic management review.

- The review should include senior management; review of the quality system and its effectiveness by using quality metrics and key performance indicators; identification of opportunities for continual improvement; and follow-up on recommendations from previous management review meetings.
- Records should be maintained.

8. PERSONNEL

- 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 to achieve pharmaceutical quality assurance objectives headed by a competent person. The competent person is responsible for activities related to quality assurance of product and materials stored in the storage site.
- Personnel should have the authority and resources needed to carry out their duties and to follow the quality systems, as well as to identify and correct deviations from the established procedures. There should be arrangements in place to ensure that management and personnel are not subject conflict of interest that may have an adverse effect on the quality of service provided or on the integrity of pharmaceutical products
- Personnel should receive initial and continued training in accordance with a written training programme. The training should cover the requirements of GSP, as well as on-the-job training. Other topics may include product security, product identification, and the detection of falsified products.
- Personnel dealing with hazardous pharmaceutical products (such as highly active materials, radioactive materials, narcotics, and other hazardous, environmentally sensitive and/or dangerous pharmaceutical products, as well as products presenting special risks of abuse, fire or explosion)should be given specific training
- There should be a training program and training schedule at the storage site and all training events should be recorded.
- The training records should be checked in the events of self-inspections and be available for regulatory inspections.
- Appropriate procedures relating to personnel hygiene, relevant to the activities to be carried out, should be established and observed. Such procedures should cover health, hygiene and clothing of personnel.
- Safety procedures relating to all relevant aspects including the safety of personnel and property, environmental protection and product integrity, should be in place. Personnel employed in storage areas should wear suitable protective or working garments appropriate for the activities they perform,
- Procedures and conditions of employment for employees, including contract and temporary staff, and other personnel having access to therapeutic goods, must be designed and administered to

assist in minimizing the possibility of such products coming into the possession of unauthorized persons or entities

9. PREMISES AND FACILITIES

9.1 General

- Premises should be suitably located, designed, constructed and maintained to ensure appropriate operations such as receiving, storage, picking, packing and dispatch of therapeutic goods
- There should be sufficient space, lighting and ventilation to ensure required segregation, appropriate storage conditions and cleanliness.
- Sufficient security should be provided and access should be controlled.
- Appropriate controls and segregation should be provided for products requiring specific handling or storage such as radio-active materials, products containing hazardous substances, and products to be stored under controlled temperature and relative humidity conditions.
- Receiving and dispatch bays should be separate and should protect products from weather conditions. Activities relating to receiving and dispatch such be done in accordance with authorized procedures. Areas should be suitably equipped for the operations.
- Premises should be kept clean. Cleaning equipment and cleaning agents should not become possible sources of contamination
- Premises should be protected from the entry of birds, rodents, insects and other animals. A rodent and pest control programme should be in place.
- Toilets, wash, rest and canteen facilities should be separate from other areas. Food, eating, drinking, and smoking should be prohibited in all areas where therapeutic goods are stored or handled.

- Receiving areas should be of sufficient size to allow cleaning of incoming containers.
- Measures should be taken to ensure that rejected materials and products cannot be used. They should be stored separately from other materials and products while awaiting destruction or return to the supplier.

9.2 Storage areas

- Precautions should be taken to prevent unauthorized persons from entering storage areas.
- Storage areas should be of sufficient capacity to allow the orderly storage of the various categories of materials and products, such as starting and packaging materials, intermediates, finished products, products in quarantine, and released, rejected, returned or recalled products.
- Storage areas should be appropriately designed, constructed, maintained or adapted.
- They should be kept clean and dry and there should be sufficient space and lighting.
- Storage areas should be maintained within acceptable temperature limits. Where special storage conditions are required on the label (e.g. temperature, relative humidity), these should be provided, controlled, monitored and recorded.
- Materials and products should be stored off the floor and suitably spaced to permit ventilation, cleaning and inspection. Suitable pallets should be used and kept in a good state of cleanliness and repair.
- A written sanitation programme should be available indicating the frequency of cleaning and the methods to be used to clean the premises and storage areas.
- There should be a written programme for pest control. The pest-control agents used should be safe and there should be no risk of contamination of the materials and products.
- There should be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination.

- Where the status is ensured by storage in separate areas, these areas must be clearly marked and their access restricted to authorized personnel.
- Any system replacing physical separation and labelling or demarcation should provide equivalent security. For example, computerized systems can be used provided that they are validated to demonstrate security of access.
- Where required, a separate sampling area should be in place. If sampling is performed in the storage area, it should be conducted in such a way that there is no risk of contamination or cross-contamination.
- Adequate cleaning procedures should be in place for the sampling areas.
- Certain materials and products such as highly active and radioactive materials, narcotics and other hazardous, sensitive and/or dangerous materials and products, as well as substances presenting special risks of abuse, fire or explosion (e.g. combustible liquids and solids and pressurized gases), should be stored in a dedicated area that is subject to appropriate additional safety and security measures.
- Materials and products should be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination.
- Materials and products should be stored in conditions which assure that their quality is maintained and stock should be appropriately rotated. The "first expired/first out" (FEFO) principle should be followed.

- Narcotic products should be stored in compliance with international conventions, and national laws and regulations on narcotics. Medicine registered as Schedule 111 medicines (Dangerous drugs or Narcotic drugs) should be stored in compliance with conditions stipulated in Poison Opium and Dangerous Drug Ordinance (PODDO).

9.3 Storage conditions

- The storage conditions for materials and therapeutic goods s should be in compliance with the labelling, which is based on the results of stability testing. Heating, ventilation and air conditioning systems (HVAC) should be appropriately designed, installed, qualified and maintained to ensure that the required storage conditions are maintained.
- Where required, mapping studies for temperature and relative humidity, as appropriate, should be done to show uniformity across the storage facility. This applies, for example, to areas, refrigerators and freezers.
- Temperature and relative humidity, as appropriate, should be controlled and monitored at regular intervals. Data should be recorded and the records should be reviewed. The equipment used for monitoring should be calibrated and be suitable for their intended use. All records pertaining to mapping and monitoring should be kept for a suitable period of time and as required by national legislation. .

Storage conditions for pharmaceutical products and materials should be in compliance with the labelling, which is based on the results of stability testing.

Defined storage instructions

The use of the following labelling instructions are recommended:

ON THE LABEL	MEANS
Freezer	The temperature is thermostatically controlled between -20°C and -10°C

Refrigerator	The temperature is thermostatically controlled between 2°C and 8°C
Protect from light	To be provided to the user in a light resistant container
Room temperature	The temperature is between 15°C and 30°C
Warm	The temperature is between 30°C and 40°C
Excessive heat	The temperature is above 40°C
Do not store over 30°C	The temperature is between 2°C and 30°C
Do not store over 25°C	The temperature is between 2°C and 25°C
Do not store over 15°C	The temperature is between 2°C and 15°C
Do not store over 8°C	The temperature is between 2°C and 8°C
Do not store below 8°C	The temperature is between 8°C and 25°C

"Protect from moisture"	no more than 60% relative humidity in normal storage conditions; To be provided to the patient in a moisture resistant container.
"Protect from light"	to be provided to the patient in a light-resistant container.

9.4 Monitoring of storage conditions

- Recorded temperature monitoring data should be available for review.
- The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained.
- All monitoring records should be kept for at least the shelf-life of the stored material or product plus 1 year.
- Temperature mapping should show uniformity of the temperature across the storage facility where applicable. It is recommended that temperature monitors be located in areas that are most likely to show fluctuations.
- Equipment used for monitoring should also be calibrated at defined intervals.

10. EQUIPMENT

- Equipment, including computerized systems should be suitable for their intended use. These should be appropriately designed, located, installed, qualified and maintained.
- If Computerized systems are used those should be capable of achieving the desired output and results. Where electronic commerce (e-commerce) is used, i.e. electronic means are used for any of the steps, defined procedures and adequate systems should be in place to ensure traceability and confidence in the supply chain and products concerned.
- Where GXP systems are used, these should meet the requirements of WHO guidelines on computerized systems. Procedures should be followed, and records maintained for the back-up and restoration of data.
- Data should meet ALCOA principles. Procedures should be followed, and records maintained for the back-up and restoration of data.

11. STORAGE REQUIREMENTS

Documentation: written instructions and records

- Written instructions and records should be available which document all activities in the storage areas including the handling of expired stock. These should adequately describe the storage procedures and define the route of materials and pharmaceutical products and information through the organization in the event of a product recall being required.
- Permanent information, written or electronic, should exist for each stored material or product indicating recommended storage conditions, any precautions to be observed and retest dates. Pharmacopoeia requirements and current national regulations concerning labels and containers should be respected at all times.
- Documentation should be prepared and maintained in accordance with principles of good documentation practices.

  For further info refer to: WHO Guidance on good data and record management practices.
- Records should be kept for each delivery. They should include the description of the goods quality, quantity, supplier, batch number, date of receipt, assigned batch number and the expiry date.
- All the records must be retained for a period of one year after the shelf-life of the incoming materials and products.
- Comprehensive records should be maintained showing all receipts and issues of materials and pharmaceutical products according to a specified system, e.g. by batch number.

Labelling and containers

- All materials and pharmaceutical products should be stored in containers which do not adversely affect the quality of the materials or products concerned, and which offer adequate protection from external influences. In some circumstances, this could include bacterial contamination.

- All containers should be clearly labelled with at least the name of the material, the batch number, the expiry date or retest date, the specified storage conditions and reference to the pharmacopoeia, where applicable. Unauthorized abbreviations, names or codes should not be used.

Receipt of incoming materials and pharmaceutical products

- On receipt, each incoming delivery should be checked against the relevant purchase order and each container physically verified, e.g. by the label description, batch number, type of material or pharmaceutical product and quantity.
- The consignment should be examined for uniformity of the containers and, if necessary, should be subdivided according to the supplier's batch number should the delivery comprise more than one batch.
- Each container should be carefully inspected for possible contamination, tampering and damage, and any suspect containers or, if necessary, the entire delivery should be quarantined for further investigation.
- When required, samples should be taken only by appropriately trained and qualified personnel and in strict accordance with written sampling instructions. Containers from which samples have been taken should be labelled accordingly.

- Following sampling, the goods should be subject to quarantine.
- Batch segregation should be maintained during quarantine and all subsequent storage.
- Materials and pharmaceutical products should remain in quarantine until an authorized release or rejection is obtained.
- Measures should be taken to ensure that rejected materials and pharmaceutical products cannot be used.
- Rejected materials and products should be identified and controlled under a quarantine system designed to prevent their use until a final decision is taken on their fate.
- Rejected materials should be stored separately from other materials and pharmaceutical products while awaiting destruction or return to the supplier.

Stock rotation and control

- Periodic stock reconciliation should be performed by comparing the actual and recorded stocks.
- All significant stock discrepancies should be investigated as a check against inadvertent mix-ups and/or incorrect issue.
- In manufacturing facilities, partly used containers of materials and pharmaceutical products should be securely reclosed and resealed to prevent spoilage and/or contamination during subsequent storage.
- Materials and pharmaceutical products from containers which have been opened or partly used should be used up before those in unopened containers.
- Damaged containers should not be issued unless the quality of the material has been shown to be unaffected. Where possible, this should be brought to the attention of the person responsible for quality control. Any action taken should be documented.

Control of obsolete and outdated materials and pharmaceutical products

- All stocks should be checked regularly for obsolete and outdated materials and pharmaceutical products.
- All due precautions should be observed to prevent the issue of outdated materials and pharmaceutical products.

12. THE COLD CHAIN MAINTENANCE OF VACCINES AND OTHER TEMPERATURE SENSITIVE PRODUCTS AND MATERIALS

- The purpose of the “cold chain” is to maintain product quality from the time of manufacture until the point of administration by ensuring that vaccines are stored and transported within recommended temperature ranges.

- The guidelines published by the WHO and the Department of Epidemiology, Ministry of Health on Cold Chain Maintenance of vaccines are accepted for all cold chain products and materials.

- Alternative power systems should be established for cold rooms to ensure cold room temperatures remain and the temperature /humidity detector will continue functioning in the event of power failure. Periodic testing program on alternative power systems should be established to ensure that it works. Alternative plan to provide alternative areas where storage temperature equivalent should be provided if no alternative power systems can be provided.

- Calibration and temperature monitoring functions of all equipment, including alarms and other related equipment, must be inspected at least annually.

13. DISPATCH AND TRANSPORT

- Materials and pharmaceutical products should be transported in such a way that their integrity is not impaired and that storage conditions are maintained.
- Special care should be exercised when using dry ice in cold chains. In addition observing to safety precautions, it must be ensured that the materials or product does not come in into contact with dry ice, as this may adversely affect the product quality, e.g. by freezing.
- Where appropriate, the use of devices to monitor conditions such as temperature during transportation is recommended. Monitoring records should be available for review.
- The dispatch and transport of materials and pharmaceutical products should be carried out only after receipt of a delivery order. The receipt of the delivery order and the dispatch of the goods must be documented.
- Dispatch procedures should be established and documented, taking into account the nature of the materials and pharmaceutical products concerned and any special precautions that might be required.
- The outside container should offer adequate protection from all external influences and should be indelibly and clearly labelled.
- Records for dispatch should be retained, stating at least:
    a) the date of dispatch;
    b) the customer's name and address;
    c) the product description, e.g. name, dosage form and strength (if appropriate), batch number and quantity;
    d) The transport and storage conditions.
- All records should be readily accessible and available on request.

14. DOCUMENTATION

- Documentation includes all procedures and records, whether in paper or electronic form.
- Documents should be appropriately designed, completed, reviewed, authorized, distributed and kept as required.
- Documents should be readily available.
- The contents of documents should be accurate, legible, traceable, attributable and unambiguous.
- Written procedures should be followed for the preparation, review, approval, use of and control of all documents relating to the policies and activities for storage of therapeutic goods
- Documents should be laid out in an orderly fashion and be easy to complete, review and check.
- The title, scope, objective and purpose of each document should be clear. . The contents of documents should be accurate, legible, traceable, attributable and unambiguous.
- All documents should be completed, signed and dated as required by authorized person(s) and should not be changed without the necessary authorization.
- Documentation should be prepared and maintained in accordance with the national legislation and principles of good storage practices

- Documents should be reviewed regularly and kept up-to-date. When a document has been revised, a system should be clearly documented.
- All records must be readily retrievable and be stored and retained using facilities that are safeguarded against unauthorized access, modification, damage, deterioration and/or loss of documentation.
- Records should contain at least the following information: date; name of the product; quantity received, or supplied; and name and address of the supplier.
- Comprehensive records should be maintained for all receipts, materials and products stored.
- All containers should be clearly labelled with at least the name of the material/product, the batch number, the expiry date or retest date, and the specified storage conditions. Unauthorized abbreviations, names or codes should not be used.

15. RETURNED GOODS

- Returned therapeutic goods should be handled in accordance with authorized procedures. All returned goods should be placed in quarantine upon receiving.
- The status of the goods should be clear.
- Precautions should be taken to prevent access and distribution until a decision has been taken with regard to their disposition.
- The particular storage conditions applicable to the products should be maintained.
- When handling returned goods, at least the following considerations should be taken•
- A risk-based process should be followed when deciding on the fate of the returned goods. This should include, but not be limited to, the nature of the product, storage conditions, condition of the product history, time-lapse since distribution, manner and condition of transport while being returned;
- The terms and conditions of the agreement between the parties; and examination of the returned goods, with decisions taken by suitably qualified, experienced and authorized persons.
- Where products are rejected, authorized procedures should be followed, including safe transport. Destruction of products should be done in accordance with international, national and local requirements regarding disposal of such products and with due consideration to the protection of the environment.
- Records of all returned, rejected and destroyed medical products should be kept for a defined period.

16. SUBSTANDARD AND FALSIFIED PRODUCTS

- The quality system should include procedures to assist in identifying and handling materials and products that are suspected to be substandard and or falsified. Where these materials and products are identified, the holder of the marketing authorization, the manufacturer and the appropriate national and/or international regulatory bodies, as well as other relevant competent authorities, should be informed.
- Such products should be stored in a secure, segregated area and clearly identified to prevent further distribution or sale.
- Access should be controlled.
- Records should be maintained reflecting the investigations and action taken, such as disposal of the material or products.
- Falsified materials and products should not re-enter the market

17. PRODUCT RECALL

- There should be a procedure to recall from the market, promptly and effectively, pharmaceutical products and materials known or suspected to be defective.
- This section is referred to "Recall Procedure Guidelines" published by NMRA

18. OUTSOURCED ACTIVITIES

- Any activity relating to the storage of a therapeutic goods which is delegated to another person or entity should be performed by parties appropriately authorized, in accordance with national legislation, and the terms of a written contract.
- . There should be a written contract between the parties. The contract should define the responsibilities of each party (contract giver and contract acceptor) and at least the following:
  -Compliance with this guideline and the principles of GSP
  -relevant warranty clauses;
  -responsibilities of the contractor for measures to avoid the entry of substandard and falsified products into the distribution chain training of personnel;
  -Conditions of subcontracting subject to the written approval of the contract giver; and periodic audits.
- The contract giver should assess the competence of the contract acceptor before entering into an agreement. The contract giver should provide all relevant information relating to the material/products to the contract acceptor.
- The contract acceptor should have adequate resources (e.g. premises, equipment, personnel, knowledge, experience, vehicles as appropriate) to carry out the work.
- The contract acceptor should refrain from performing any activity that may adversely affect the materials or products handled

19. REGULATORY INSPECTIONS BY NMRA

- Storage facilities should be inspected by Authorized inspection officers of the NMRA, in terms of national legislation.

- This should be done at determined periodic intervals. Authorized inspection officers should have appropriate educational qualifications, knowledge and experience.
- An inspection should normally be conducted by a team of Authorized inspection officers
- Authorized inspection officers should assess compliance with national legislation, GSP and related guidelines (GxP) as appropriate.
- Inspections should cover the premises, equipment, personnel, activities, quality system, qualification and validation, and other related aspects as contained in this guideline.
- An inspection report should be prepared and provided to the inspected entity within days from the last day of the inspection as per NMRA procedures.
- Observations may be categorized based on risk assessment. CAPA for observations listed as non-compliances in the inspection report, with the national legislation and guidelines, should be submitted for review by the Authorized inspection officers within the defined period as stated by the Authorized inspection officers
- Inspections should be closed with a conclusion after the review of the CAPAs.

20. REFERENCES

1. WHO guide to good storage practices for pharmaceuticals, World Health Organization - WHO Technical Report Series, No. 908, 2003
2. Draft WHO guide to good storage and distribution practices, World Health Organization.
3. WHO Guidance on good data and record management practices, WHO TRS 996 annex 5..
4. WHO Guideline on Quality Risk Management.
5. WHO Guideline on Cold Chain Maintenance of vaccines.
6. ICH guideline Q9 on quality risk management.

21. FEEDBACK

Staff and customers may provide feedback about this document by emailing info@nmra.gov.lk

22.APPROVAL AND REVIEW DETAILS

	Title	SIGNATURE	Date
Prepared by			
Reviewed By			
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Next Review Date	