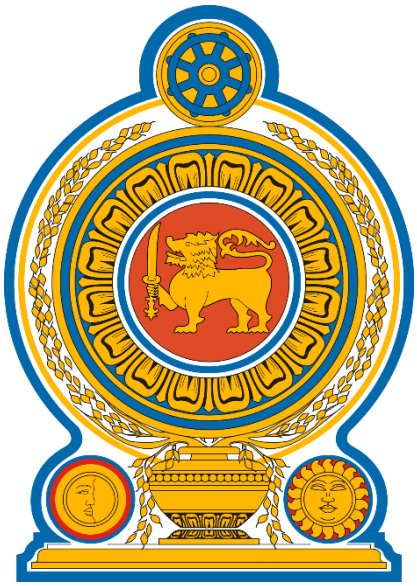

GUIDELINE ON GOOD DISTRIBUTION PRACTICES (GDP)

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NATIONAL MEDICINE REGULATORY AUTHORITY
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GUIDELINE ON GOOD DISTRIBUTION PRACTICES (GDP)

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1 INTRODUCTION

The National Medicines Regulatory Authority Act (NMRA Act) requires that "No person shall import or distribute any medicine without adhering to Good Distribution Practices (GDP) and any other prescribed guidelines and conditions. Section 49 (3) & "No person shall import or distribute any medical device without adhering to Good Distribution Practices (GDP) and any other prescribed guidelines or conditions." Section 75 (2).

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

All manufacturers, importers and wholesalers of products registered with the NMRA its related materials are required to adopt proper distribution and store management procedures appropriate for the distribution and storage of registered 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.

Good Distribution Practice or GDP is defined by this guideline as: "The measures that need to be considered in the storage, transportation and distribution of any registered product and its related materials such that the nature and quality intended is preserved when it reaches the consumer"

The GDP 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.

2 PURPOSE

In order to ensure the maintaining of high standards of quality assurance and the integrity of the distribution processes of products regulated under NMRA Act, to promote uniformity in licensing of wholesaling of medicinal products and to further facilitate the removal of barriers to trade in medicinal products, the following Guide to Good Distribution Practice (GDP) for products regulated under NMRA Act has been adopted.

3 SCOPE

The standards set out herein apply products regulated under NMRA Act intended for human use. It is recommended. This guideline can also be applicable for Investigational Medicinal Products (IMP). At the time of issue, this document reflected the current state of the art. It is not intended to be a barrier to technical innovation or the pursuit of excellence or to place any restraint upon the development of new concepts or new technologies, which have been validated and provide a level of Quality Assurance and integrity of the distribution processes at least equivalent to those set out in this Guide.

4 RELATED LEGISLATION AND DOCUMENTS

The National Medicines Regulatory Authority Act (NMRA Act); Section 49 (3)

"No person shall import or distribute any products regulated under NMRA Act without adhering to Good Distribution Practices (GDP) and any other prescribed guidelines or conditions.

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

5 DEFINITIONS of some terms used in this guideline

Consignment	The delivery batch of materials and products supplied at one time in response to a particular request or order.
Contamination	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter during manufacturing, sampling, packaging or repackaging, storage or transport.
Cross -contamination	Contamination of a material or product with another material or product.
Excipient	Any substances in the drug product other than the API
Finished product	A product that has undergone all stages of production, including packaging in its final container and labeling.
First Expired/ First Out (FEFO) principle concept	A distribution procedure that ensures the approved stock that has a nearer expiry date is distributed and / or utilized before an approved and identical stock item with later expiry is distributed and/ or utilized.
License	Any license issued under Regulation 12 of the NMRA Act or CDD Act
Manufacturer	Includes: a) The making or assembling of the product; b) The enclosing or packing of the product in any container in a form suitable for administration or application, and the labeling of the container; and c) The carrying out of any process in the course of any or the foregoing activities.
Material	A general term used to denote raw materials, starting materials, intermediates, excipients and packaging materials and labeling materials.
Packaging material	Any material employed in the packaging of a material including any other 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.
Product	Any product registered under NMRA Act 2015

Raw material	A general term used to denote starting materials, reagents, intermediates, process aids and solvents intended for used in the production of APIs or products.
Return material/ product	Material or product sent back from the customer to the supplier.
Storage	A term used to describe the safe keeping of materials and products such as starting materials and finished products received from suppliers, semi-finished products in process and finished products awaiting dispatch and products awaiting distribution to retailers and products (rejected, recalled and damaged) awaiting disposal.
Supplier	A person providing products or materials on request. Supplier may be agents, brokers, distributors, manufacturers or traders.

6. QUALITY MANAGEMENT

Quality Management System should be implemented and maintain with an appropriate organizational structure, procedures, and resources, setting out responsibilities, processes and risk management principles in relation to their activities; and systematic actions necessary to ensure adequate confidence that a material and/or product and documentation will satisfy given requirements for quality and integrity and remains within the legal supply chain during storage and/or transportation. Totality of these actions is termed "Quality System".

The quality system should be fully documented and its effectiveness monitored.
Within an organization, quality assurance serves as a management tool. In contractual situations quality assurance also serves to generate confidence in the supplier. There should be a documented quality policy describing the overall intentions and policies of the distributor regarding quality, as formally expressed and authorized by management.

The quality system should include provisions that the holder of the marketing authorization labelled entity (if different from manufacturer) the appropriate national and/or international regulatory bodies, as well as other relevant competent authorities, should be informed immediately in case of confirmed or suspected counterfeit products. Such materials and/or products have to be stored in a secure segregated area and have to be clearly identified to prevent further distribution or sale.

All parties involved in the distribution of materials and/or products should share responsibility for the quality and safety of materials and/or products to ensure that they are fit for their intended use. There should be a procedure in place that describes pedigree documentation as well as the visual and/or analytical identification of potential counterfeit materials and/or products. The procedure should include provisions for notification, as appropriate for the holder of the marketing authorization labelled entity (if different from manufacturer) the appropriate national and/or international regulatory bodies, as well as other relevant competent authorities, when a potential counterfeit drug is identified.

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/or products. The provisions should guarantee the same degree of materials and/or products safety as it can be achieved in non-e-commerce.

Authorized procurement and release procedures for all administrative and technical operations performed should be in place, to ensure that appropriate materials and/or products are sourced from approved suppliers and distributed by approved entities. The approval should come from the competent authority of the individual country where the legal entity is registered. There should be a written procedure in place to ensure and document traceability of materials and/or products and received and distributed based on batch numbers. While it is understood that a differentiated approach may be necessary for different materials and/or products and regions, pedigree record and/ track and trace technologies provide possible options to ensure traceability.

All entities in the supply chain should be traceable as applicable, depending on the type of materials and/or products, and on the national policies and legislation. There should be written procedures and records to ensure traceability of the materials and/or products distributed.

Self-inspections should be conducted in order to monitor implementation and compliance with GDP principles and to propose necessary corrective measures.
Certification of compliance with a quality system (such as the applicable International Organization for Standardization (ISO) series, or national or international guidelines) by external bodies is recommended. Such certification should not, however, be seen as a substitute for compliance with this guideline.

To support the avoidance of penetration of counterfeit materials and/or products into the supply chain pedigree procedures and records should be developed in order to allow the tracking and tracing of material and/or product in the supply chain. Each supplier should maintain and provide such pedigree records to the next recipient in the supply chain ending with the final recipient before purchase/use by end-user which is usually the patient or consumer.

If seal control programs for transit shipment are in place, they should be managed properly (seals are issued in a tracked and sequential manner, seals are intact and numbers verified during transit and open receipt). There should be written procedures to the control of incoming materials and/or products addressing a plausibility check, whether the materials and/or products might be counterfeit.

Quality system should also foster a safe, transparent and secure distribution system by establishing measures to ensure that materials and/or products have a form of documentation that can Guidelines on Good Distribution Practice (GDP) be used to permit traceability of the materials and/or products throughout distribution channels from the manufacturer/importer to the retailer.

An ISO audit is not a substitute for any national, federal or state regulation unless specifically stated by such regulatory agencies.

A responsible person should be appointed by the management, who should have clearly specified authority and responsibility for ensuring that a quality system is implemented and maintained.

The management of the distributor should ensure that all parts of the quality system are adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities.

The quality system should include an emergency plan which ensures effective recall of medicinal products from the market ordered by the manufacturer or the competent authorities or carried out in cooperation with the manufacturer or marketing authorization holder for the medicinal product concerned. The competent authorities must be immediately informed of any suspected falsified medicines offered in the supply chain.

7. PERSONNEL

The company should designate a person as "responsible person". A registered pharmacist is desirable. The responsible person should have appropriate competence and experience as well as knowledge of and training in GDP.

The responsible person should carry out their duties in such a way as to ensure that can demonstrate GDP compliance.

The company should have an adequate number of personnel with the necessary qualifications and/or practical experience. The responsibilities placed on any individual should not be so extensive as to present any risk to quality.

Key personnel who perform supervisory and/or controlling store or warehouse functions should possess the necessary competency, knowledge and experience. They should also where necessary be in possession of the required professional and technical qualifications suitable for the tasks assigned to them.

The company must have an organization chart. Personnel in responsible positions should have specific duties recorded in written job descriptions and adequate authority to carry out their responsibilities. Their duties may be delegated to designated deputies of a satisfactory qualification level. There should be no gaps or unexplained overlaps in the responsibilities of those personnel concerned with the application of GDP.

Personnel employed in storage facilities should be certified healthy and fit for their assigned responsibilities. They should receive medical examination upon recruitment. After the first medical examination, examinations should be carried out periodically.

Personnel employed in storage facilities should wear suitable protective or working garments, if necessary.

Besides the basic training on the theory and practice of GDP, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given,

and its practical effectiveness should be periodically assessed. Training program should be available and approved. Training records should be kept.

Visitors or untrained personnel should, preferably, not be taken into storage areas. If this is unavoidable, they should be closely supervised.

Personnel dealing with any products which require more stringent handling conditions should receive specific training. Examples of such products include hazardous products, radioactive materials, products presenting special risks of abuse (including narcotic and psychotropic substances), and temperature-sensitive products.

A record of all training should be kept, and the effectiveness of training should be periodically assessed and documented.

Appropriate procedures relating to personnel hygiene, relevant to the activities being carried out, should be established and observed. Such procedures should cover health, hygiene and clothing.

8. PREMISES AND FACILITIES

The company must have suitable and adequate premises, installations and equipment, so as to ensure proper storage and distribution of products regulated under NMRA Act. In particular, the premises should be clean, dry and maintained within acceptable temperature limits.

- Receipt, identification, storage and withholding from use of materials and/or products and pending release;
- Sampling of incoming materials, if necessary;
- Holding rejected materials and/or products before disposal;
- Storage of released materials and/or products.

If other labelling statements are made appropriate storage conditions should be provided and justified by supportive stability data. In certain cases a storage time at a higher temperature can be accepted provided it is justified and supported by suitable data generated under the proposed conditions. Special storage directions (e.g. shipping and transportation) need to be requested from the manufacturer or supplier.

In general, storage instructions should be labeled as follows:

- Related to the container, e.g. store in a well-closed container
- Related to light and/or temperature, e.g. store protected from light
- Related to temperature, e.g. store at a temperature not exceeding X º C

The storage conditions for materials and/or products should follow the required storage specification of the materials and/or products.

Where temperature is not stated (in terms of range) on the labels of the materials or products the following definitions should be followed: -

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

Records of temperature of the storage facilities must be measured at suitable predetermined intervals to show the maximum and minimum temperatures for the day. Where necessary humidity measurements should be performed.

The instruments used for measuring and monitoring temperature and humidity should be calibrated and calibration record or calibration certificate should be recorded and retained.

Materials and/or products and/or cosmetics requiring dry or humidity-controlled storage should be stored in areas where the relative humidity and temperature is maintained within prescribed limits.

It is recommended that temperature monitors be located in areas that are most likely to show fluctuations.

Medicinal products should be stored separately from other products likely to alter them and should be protected from the harmful effects of light, temperature, moisture and other external factors. Particular attention should be paid to products requiring specific storage conditions.
Incoming containers of medicinal products should be cleaned, if necessary, before storage

9. STOCK HANDLING AND STOCK CONTROL

All actions taken should ensure that the identity of the medicinal product is not lost and that the distribution of medicinal products is performed according to the information on the outer packaging. The company should use all means available to minimize the risk of falsified medicinal products entering the legal supply chain.

The company must obtain their supplies of medicinal products only from persons who are themselves in possession of a distribution authorization, or who are in possession of a manufacturing authorization which covers the product in question

a) RECEIVING MATERIALS / PRODUCTS

Upon receipt, each incoming delivery should be checked against the relevant documentation and physically verified by label description, type and quantity, against the relevant purchase order information. The consignment should be examined for uniformity and if necessary should be subdivided according to the supplier's lot numbers should the delivery comprise of more than one batch.

All containers should be carefully inspected for tampering, contamination and damage and if necessary the suspected container or the entire delivery should be quarantined or set aside for further investigation. Records should be retained for each delivery.

They should include the description of the goods, quality (if applicable), quantity, supplier details, supplier's batch number, the date of receipt and assigned batch number.

Security measures should be taken to ensure that rejected materials and/or products cannot be used and they should be stored separately from other products while awaiting destruction or return to the supplier. The method adopted should possess adequate safeguards to prevent uncontrolled or unsatisfactory materials from being used or released. Relevant records should be maintained.

Quarantine status can be achieved either through the use of separate storage areas or by means of documentary or electronic data processing systems.

Materials and/or products should remain in quarantine status until a given written release or is rejected by an authorized personnel.

b) Stock rotation and control

Comprehensive records should be maintained showing all receipts and issues of materials and/or products according to batch number.
Periodic stock reconciliation should be performed comparing the actual and recorded materials and/or products quantity. All significant stock discrepancies should be subjected to investigation to check against inadvertent mix-ups and wrong issues.

Issues should normally observe the principle of stock rotation (FEFO) especially where expiry dated materials and/or products are concerned.

Materials and/or products with broken seals, damaged packaging or suspected of possible contamination must not be sold or supplied.

Goods bearing an expiry date must not be received or supplied after their expiry date or too close to their expiry date that this date is likely to occur before the goods are used by the consumer.

All labels and containers of materials and/or products should not be altered, tampered or changed. Acts and regulations relating to labels and containers should be adhered to at all times.

Partly used containers of materials and/or products should be securely re-closed to prevent spoilage and/or contamination during subsequent storage. Damaged containers should not be issued but should be brought to the attention of the authorized personnel.

Materials and/or products should be protected from excessive climatic conditions during storage and transit, such as heat, moisture and direct sunlight. They should be stored separately from other materials and/or products in conditions which satisfy the requirements for the materials and/or products, so that shelf-life declaration may be maintained.

c) Control of expired stock

All stocks should be checked regularly for expired and degraded materials and/or products. All due precautions should be observed to preclude issue of expired materials and/or products.

d) Returned and rejected products

Returned products must be handled according to a written, risk-based process taking into account the product concerned, any specific storage requirements and the time elapsed since the medicinal product was originally dispatched. Returns should be conducted in accordance with national law and contractual arrangements between the parties.

All returned and rejected materials and/or products should be placed in quarantine and be clearly marked as such. They should be stored separately in restricted area.

The fate of returned and rejected materials and/or products should be determined after sufficient evaluation by authorized person.

Provision should be made for the appropriate and safe transport and storage of returned or rejected materials and/or products in accordance with the relevant storage and other requirements.

All action taken should be approved and recorded.

e) Distribution

The allocation of shipping materials should be carried out only after receipt of a sales order. Rules for distribution procedures should be established depending on the nature of the materials and/or products, and after taking into account any special precautions to be observed.

The shipping container should offer adequate protection from all external influences and should be indelibly and clearly labeled. When necessary, devices which allow monitoring during transportation should be used.

In the event of materials and/or products shipment, special care should be used when using dry ice in containers. In addition to safety issues, it must be ensured that the materials and/or products do not come into contact with the dry ice, as it may have adverse effect on the quality of the materials and/or products.

Distribution documents should comply with relevant regulations, and at least includes:

1. Date of dispatch
2. Customer's name and address
3. Product description, e.g. name, dosage form and strength, Date of Expiry, batch number and quantity.

10. DISPOSAL OF MATERIALS / PRODUCTS

Products regulated under NMRA Act intended for destruction should be appropriately identified, held separately and handled in accordance with a written procedure.

Disposal of materials and/or products should be carried out, according to proper destruction procedures, approved by appropriate authorities such as NMRA, the Ministry of Environment and local authorities.

Disposal records should be maintained and be retained for a period of five-year period from the date of disposal.

11. DOCUMENTATION

Good documentation constitutes an essential part of the quality system. Written documentation should prevent errors from spoken communication and permits the tracking of relevant operations during the distribution of medicinal products.

a. written instructions

Written instructions should describe the different operations which may affect the quality of the materials and/or products or of the distribution activity:

Receipt and checking of deliveries,

a) Storage, cleaning and maintenance of the premises (including pest control),
b) Recording of the storage conditions,
c) Security of stocks on site and of consignments in transit,
d) Withdrawal from saleable stock
e) Records, including records of clients' orders,
f) Returned materials and/or products, recall plans, etc.

These procedures should be approved, signed and dated by the authorized person.

Records should be made at the time each operation is taken and in such a way that all significant activities or events are traceable. Records should be clear and readily available. The retention of documentation relating to the distribution of materials and/or products should comply with the national requirements.

If records are computerized, only authorized persons should be able to enter or modify data in the computer. Access should be restricted by passwords or other means. User should have a unique identifier (User ID) for their personal and sole use so that activities can subsequently be traced to the responsible individual.

Records electronically stored should be protected by back-up transfer on paper or other means, at regular intervals. It is particularly important that the data, including audit trail, are readily available throughout the period of retention. Back-up data should be stored as long as necessary at a separate and secure location.

b. Inventory system

These should include;

1. Name of Materials or Products
2. Strength and Packing size of materials and products
3. Product Identification Number
4. Date of Transaction
5. Invoice No. / Delivery No.
6. Quantity Received
7. Quantity Supplied
8. Batch No. (where applicable)
9. Stock Balance
10. Initial / Signature

Entries of incoming goods should be clearly identified and inventory entry is required for each material and/or product as well as each strength of the same material and/or product.

c. Labeling of containers / packaging materials

All containers or packaging materials should be clearly and indelibly labeled with at least the name and/or of the material and/or product, and the lot number of the batch.

Written information should exist for each stored material and/or product indicating recommended storage conditions, along with any precautions to be observed. Pharmacopoeia requirements and other current national regulations concerning labels and containers should be respected at all times.

12. EQUIPMENT AND VEHICLES

All equipment impacting on storage and distribution of medicinal products should be designed, located and maintained to a standard which suits its intended purpose. Planned maintenance should be in place for key equipment vital to the functionality of the operation.

Equipment used to control or to monitor the environment where the medicinal products are stored should be calibrated at defined intervals based on a risk and reliability assessment.
Calibration of equipment should be traceable to a national or international measurement standard.

Appropriate alert systems should be in place to provide alerts when there are excursions from pre-defined storage conditions. Alert levels should be appropriately set and should be regularly tested to ensure adequate functionality.
Equipment repair, maintenance and calibration operations should be carried out in such a way that the integrity of the medicinal products is not compromised.
Equipment and processes should be respectively qualified and/or validated before commencing use and after any significant changes, e.g. repair or maintenance.

Vehicles and equipment used to distribute or transport materials and/or products should be suitable for their use and appropriately equipped to prevent exposure of the materials and/or products to conditions that could affect their stability and packaging integrity, and prevent contamination of any kind.

Vehicles and equipment used must aim to minimize the risk of errors and permit effective cleaning and/or maintenance, to avoid contamination, accumulation of dust or dirt and/or any adverse effect on the quality of materials and/or products being distributed.

Dedicated vehicles and equipment should be used, where possible, when handling materials and/or products.

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

Vehicles, containers and equipment should be kept clean, dry and free from accumulated waste. Organizations in charge of the distribution must ensure that vehicles are cleared up on regular basis.

Vehicles, containers and equipment should be kept free from rodents, vermin, birds and other pests. There should also be written program for such pest control. Cleaning and fumigation agents should not have an adverse effect on material and/or product quality.

Special attention should be given to the design, use, cleaning and maintenance of all equipment used for the handling of materials and/or products which are not in a protective shipping carton or case.

Where special storage conditions (e.g. temperature and/or relative humidity), different from or limiting, the expected environmental conditions, are required during transit these should be provided, checked, monitored and recorded.
Equipment used for monitoring conditions within vehicles and containers, e.g. temperature and humidity, should be calibrated, at regular intervals.

Vehicles and containers should be of sufficient capacity to allow orderly storage of the various categories of materials and/or products during transportation.

Where possible, mechanisms should be available to allow for the segregation during transit of rejected, recalled and returned materials and/or products as well as those suspected to be counterfeits. Where feasible, such goods must be securely packaged, clearly labeled, and be accompanied by appropriate supporting documentation.

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.

13 . TRANSPORTATION AND GOODS IN TRANSIT

Materials and products should be secured in such a manner to prevent or provide evidence of unauthorized access.

Shipments should be secured and include the appropriate documentation to ensure that identification and verification of compliance with regulatory requirements is facilitated at ocean ports, truck borders, airports, custom warehouses and third party logistic providers.

Materials and/or products should be stored and transported in accordance with procedures in such a way that: the identity of the materials and/or products is not lost; the materials and/or products does not contaminate and is not contaminated by other materials and/or products; adequate precautions are taken against spillage, breakage, misappropriation and theft; and temperature and relative humidity conditions are maintained accordingly.

Measures should be established to ensure that materials and/or products have a form of documentation that can be used to permit traceability of the materials and/or products throughout the distribution activity.

Where special conditions are required during transportation that are different from or limited by the given environmental conditions (e.g. temperature, humidity) these should be provided, monitored and recorded.

Written procedures should be in place for investigating and dealing with any violations of storage requirements, e.g. temperature violations.

Transportation and storage of materials and/or products comprising highly active and radioactive materials, other dangerous drugs and substances presenting special risks of abuse, fire or explosion (e.g. combustible liquids, solids and pressurized gases) should be stored in safe, dedicated and secure areas and transported in safe, dedicated and secure containers and vehicles. In addition, applicable international agreements and national legislation should be complied with.

Materials and/or products containing narcotics and other dependence producing substances should be transported in safe and secure containers and vehicles and be stored in safe and secure areas, and where it is a mandatory requirement transported in safe and secure containers and vehicles. In addition, applicable international agreements and national legislation should be complied with.

Spillages should be cleaned as soon as possible to prevent possible contamination, cross-contamination and hazards. Written procedures should be in place for the handling of such occurrences.

Physical or other equivalent (e.g. electronic) segregation should be provided for the storage and distribution during transit of rejected, expired, recalled or returned materials and/or products and suspected counterfeits. The materials and/or products should be appropriately identified, securely packaged, clearly labelled, and be accompanied by appropriate supporting documentation.

Materials and/or products containing toxic and/or flammable substances should be stored and transported in suitably designed, separate and closed containers, taking into account national legislation and international agreements.

Packaging materials and transportation containers should be of suitable design to prevent damage of materials and/or products during transport. If there are seal control programs, such programs should be in place and managed properly (e.g. seals are issued and tracked in a sequential manner, seals are intact and numbers verified during transit and upon receipt). Third party drivers should be segregated from the warehouse and only allowed in the shipping/receiving area. They should also identify themselves and present paperwork to identify that they are authorized for the load. Subcontracting carriers is not recommended. If subcontracting occurs, they must uphold the same standards as the contracted carrier.

Damage to containers and any other event or problem that occurs during transit must be recorded and reported to the relevant department, entity or authority and investigated.

Materials and/or products in transit must be accompanied by the appropriate documentation. For each importation, the Certificate of Analysis (CoA) for each batch of product must be kept by the importer.

14. PRODUCT COMPLAINTS

Complaints should be recorded with all the original details. A distinction should be made between complaints related to the quality of a medicinal product and those related to distribution. In the event of a complaint about the quality of a medicinal product and a potential product defect, the manufacturer and/or marketing authorization holder should be informed without delay. Any product distribution complaint should be thoroughly investigated to identify the origin of or reason for the complaint.

A person should be appointed to handle complaints and allocated sufficient support personnel.

a) Principle

A complaint is defined as a situation whereby when a customer or any other (outside party) has reported a material (e.g. active pharmaceutical ingredients) or product defect or adverse reactions with any of the company's marketed materials or products. This is valid regardless of whether:

- The report is written or verbal.
- The sample of affected product is attached.

A report on a product and defect which has been identified within the company on a marketed product batch is also considered a complaint.

b. Classification of complaints

Complaints can be classified as:

1. Medical (e.g. adverse reactions)
2. Pharmaceutical (e.g. precipitation, lack of efficacy)
3. Technical (e.g. damaged packaging or labelling defects)

c. Procedure for complaints

The procedure for dealing with complaints shall ensure that:

- That complaints received are given proper due attention and promptness that measures are taken to prevent repeated complaints
- That, when adequate information is available, a decision is made whether to make a recall and if so, the degree to which a recall is to be made

Follow-up of complaints will contribute to a higher and more uniform product quality and as well as prevent further defects, improve quality and client satisfaction.

d. Persons responsible

Within each company, 2 persons responsible with adequate knowledge shall be assigned the task of dealing with complaints. The persons responsible must also have the authority to decide on measures to be taken. The required particulars for the responsible persons are as follows:

PERSON RESPONSIBLE I	PERSON RESPONSIBLE II
• Name • NIC / Passport No • Position • Home Address • Telephone No	• Name • NIC / Passport No • Position • Home Address • Telephone No

e.Reporting

Procedures shall be developed within the company for the receipt of reports on complaints at any time. It is important that complaints reach the persons responsible

All complaints reported should be recorded and properly documented.

f. Investigation

The persons responsible should initiate the investigation immediately.

The investigation shall be documented.

If a material and/or product defect is discovered or suspected in a batch, consideration should be given to determine whether other batches are also affected.

The investigation should also cover:

- Distribution condition
- Condition under which the material and/or product is used

g. Corrective and preventive action

The persons responsible shall ensure that all the corrective and preventive actions are taken following the outcome of the investigation. All corrective and preventive actions should be recorded, reported and implemented.

If a recall has been decided, some of the procedures stated in the Product Recall Procedure shall be applied.

The company's management shall discuss possible steps to prevent future defects and take over any responsibility for further handling of the complaint from the persons responsible.

h. Response to complainant

The persons responsible should acknowledge the complainant within 24 hours after receipt of complaint(s).

The persons responsible shall provide response to the complainant within an agreed timeframe after completion of the investigation.

If the person who complains is informed of the outcome of the investigation over the telephone, the date and information provided shall be noted.

i, Documentation

Each individual complaint and its relevant attached documents shall be filed.

A final report shall be prepared and kept in the Complaint File. One copy of the final report shall be forwarded to the relevant parties.

A Complaint File should contain:

1. Written procedures describing the actions to be taken in the handling of all written and oral complaints regarding materials and products (procedures for dealing with complaints).
2. A written record of each individual complaint and as well as the completed investigation report.

15. PRODUCT RECALL

This section is referred to the "Guidelines on Recall procedure" published by the NMRA.

16. SELF INSPECTION

The quality assurance system should include self-inspections. These should be conducted in order to monitor implementation and compliance with the principles of GDP and to trigger necessary corrective and preventive measures.

Self-inspections should be conducted in an independent and detailed way by a designated, competent person, according to an approved written procedure.

The results of all self-inspection should be recorded. Reports should contain all observations made during the inspection and, where applicable, proposals for corrective measures. There should be an effective follow-up program. Management should evaluate the inspection report, and corrective actions taken and recorded.

17.COUNTERFEIT MATERIALS/ PRODUCTS

Any counterfeit materials and/or products found in the distribution network should be physically segregated from other materials and/or products to avoid any confusion. They should be clearly labelled.

The regulatory authority and the holder of the marketing authorization of the original materials and/or products should be informed immediately

18. CONTRACT ACTIVITIES

Any activity covered by the GDP guide that is outsourced should be correctly defined, agreed and controlled in order to avoid misunderstandings which could affect the integrity of the product.

Any activities performed, referenced in the GDP guideline and delegated to another party, should be agreed upon in a contract which clearly establishes the duties of each party.

There should be a written and approved contract or formal agreements between the Contract Giver and Contract Acceptor that addresses and defines in detail the responsibilities and GDP requirements for each party.

The contract should permit the Contract Giver to visit the facilities of the Contract Acceptor.

Depending on the nature of activities performed, the Contract Acceptor should understand that he might be subject to inspection by the regulatory authority.

19. LEGAL DOCUMENTS

1. NMRA Act 2015 and its regulations
2. All the published regulations on Cosmetic Devices and Drugs Act until new regulations are published under NMRA Act.
3. Poison Opium and Dangerous Drugs Act (PODDA) as amended in 1984

a. Records on Dangerous Drugs

Records must be in accordance with the conditions given in Poison Opium and Dangerous Drugs Act (PODDA) as amended in 1984 where applicable.

b. Wholesale records

Applicable for all registered products under NMRA Act 2015.

A register under the name of "Register of Transactions for Wholesale" should be maintained and the following entries should be made;

1. Name, strength of products
2. Date of Sale / Supply
3. Name and address of supplier / purchaser
4. Quantity Received / Sold

5. Packing Size
6. Batch No.
7. Invoice No / Delivery Order No.

The register should be preserved for 02 years after the last entry of a register.

c. Importation records

Applicable for all registered products under NMRA Act 2015.

A register under the name of "Register of Transactions for imported Products" should be maintained and the following entries should be made;

1. Name, strength and packing size of products / cosmetics
2. Date of Importation
3. Name and address of supplier / purchaser
4. Quantity imported / supplied
5. Invoice No. / Bill Landing No. /Airway Bill No.
6. Batch No.
7. Packing Size
8. Invoice No. / Delivery

20. MANAGEMENT OF COLD CHAIN PRODUCTS/ MATERIALS

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

21.REFERENCES

- PIC/S GUIDE TO GOOD DISTRIBUTION PRACTICE FOR MEDICINAL PRODUCTS
- WHO good distribution practices for pharmaceutical products

22.FEEDBACK

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

23.APPROVAL AND REVIEW DETAILS

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