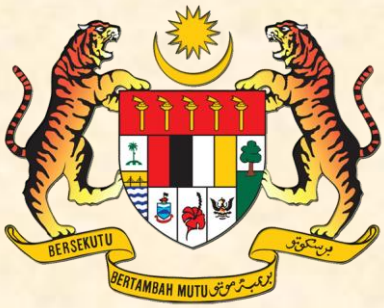

GUIDELINES ON GOOD DISTRIBUTION PRACTICE (GDP)

2nd Edition 2013

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INTRODUCTION

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. All manufacturers, importers and wholesalers of registered products / notified cosmetics and its related materials are required to adopt proper distribution and store management procedures appropriate for the distribution and storage of registered products / notified cosmetics 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 or cosmetic.

Good Distribution Practice or **GDP** is defined as:

"The measures that need to be considered in the storage, transportation and distribution of any registered product / notified cosmetic 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 or cosmetics classified as dangerous drugs, scheduled poisons and psychotropic substances, under the Dangerous Drugs Act 1952 (Revised 1980), Poison Act 1952 (Revised 1989), Poisons (Psychotropic Substances) Regulations 1989 and the Control of Drugs and Cosmetics Regulations 1984 (Revised 2009), are stored and distributed in accordance with the requirements of the respective Acts and Regulations.

GLOSSARY OF SOME TERMS USED

The terms below shall have the meanings described when they are used in the text:

Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances intended to be used in the manufacture of a drug product and that when used in the production of a drug becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effects in the diagnosis, cure, mitigation, treatment or prevention of diseases, or to affect the structure and function of the body.
Authorities	Refers to government bodies or agencies such as local authorities, state health department as well as Ministry of Natural Resources & Environment given lawful approval or recognition on particular responsibilities.
Counterfeit product or cosmetic	Product or cosmetic which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products/ cosmetics and may include products/ cosmetics with the correct ingredients or with wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.
Consignment	The delivery batch of materials and products or cosmetics 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.
Cosmetic	Any substance or preparation intended to be placed in contact with the various external parts of the human body (including epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfume them, changing their appearance or correcting body odours, protecting them or keeping them in good condition.
Cross - contamination	Contamination of a material or product or cosmetic with another material or product or cosmetic.

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 labelling.
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.
First In/ First Out (FIFO) principle concept	A distribution procedure that ensures the oldest approved stock is distributed and/ or utilized before a new approved and identical stock item is distributed and/ or utilized.
Intermediate (API Intermediate)	A material produced during the processing step of an API which must undergo further molecular change or purification before it becomes an API.
Labelling	The term "labelling" designates all labels and other written, printed, or graphic matter upon, or in, any package or wrapper in which it is enclosed, except any outer shipping container. A shipping container, unless such container is also essentially the immediate container or the outside of the consumer package, is exempt from labelling requirements.
License	Any license issued under Regulation 12 of the Control of Drugs and Cosmetics Regulations 1984 (Revised 2009).
Manufacturer	Includes: a) the making or assembling of the product / cosmetic; b) the enclosing or packing of the product in any container in a form suitable for administration or application, and the labelling 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 labelling materials.
Notified cosmetic	A cosmetic product currently notified in accordance with the provisions of the Sales of Drugs Act 1952 (Revised 1989) and the Control of Drugs and Cosmetics Regulations 1984 (Revised 2009).

Packaging material	Any material employed in the packaging of a material or product or cosmetic, 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.
Printed packaging material	Packaging material which is imprinted with text or numbers or a combination of both.
Product	Means: a) a drug in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for medicinal purpose; or b) a drug to be used as an ingredient of a preparation for medicinal purpose.
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 or cosmetics.
Registered product	A product currently registered in accordance with the provisions of the Control of Drugs and Cosmetics Regulations 1984 (Revised 2009).
Return material/ product/ cosmetic	Material or product or cosmetic sent back from the customer to the supplier.
Storage	A term used to describe the safe keeping of materials and products or cosmetic such as starting materials and finished products received from suppliers, semi-finished products or cosmetics in process and finished products awaiting dispatch and products or cosmetics awaiting distribution to retailers and products or cosmetics (rejected, recalled and damaged) awaiting disposal.
Supplier	A person providing products or materials or cosmetics on request. Supplier may be agents, brokers, distributors, manufacturers or traders.

CHAPTER 1: QUALITY MANAGEMENT

1.1 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.

1.2 Quality management should include an appropriate organizational structure, procedures, processes and resources; and systematic actions necessary to ensure adequate confidence that a material and/or product and/or cosmetic and documentation will satisfy given requirements for quality. Totality of these actions is termed "Quality System".

1.3 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 and/or cosmetics. Such materials and/or products and/or cosmetics have to be stored in a secure segregated area and have to be clearly identified to prevent further distribution or sale.

1.4 All parties involved in the distribution of materials and/or products and/or cosmetics should share responsibility for the quality and safety of materials and/or products and/or cosmetics 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 and/or cosmetics. 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.

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

1.6 Authorized procurement and release procedures for all administrative and technical operations performed should be in place, to ensure that appropriate materials and/or products and/or cosmetics 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/or cosmetics 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/or cosmetics and regions, pedigree record and/ track and trace technologies provide possible options to ensure traceability.

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

1.8 Inspection and 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.

1.9 To support the avoidance of penetration of counterfeit materials and/or products and/or cosmetics into the supply chain pedigree procedures and records should be developed in order to allow the tracking and tracing of material and/or product and/or cosmetic 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.

1.10 If seal control programmes 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 and/or cosmetics addressing a plausibility check, whether the materials and/or products and/or cosmetics might be counterfeit.

1.11 Quality system should also foster a safe, transparent and secure distribution system by establishing measures to ensure that materials and/or products and/or cosmetics have a form of documentation that can

be used to permit traceability of the materials and/or products and/or cosmetics throughout distribution channels from the manufacturer/importer to the retailer.

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

CHAPTER 2: PERSONNEL

2.1 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.

2.2 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.

2.3 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.

2.4 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.

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

2.6 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 programme should be available and approved. Training records should be kept.

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

CHAPTER 3: PREMISES AND FACILITIES

There should be defined and reserved areas or other control systems for the following activities:

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

3.1 Storage of materials and/or products and/or cosmetics should be carried out in buildings or parts of buildings that have been built for, or adapted to this purpose.

3.2 Buildings should protect materials and/or products and/or cosmetics from contamination and deterioration, including protection from excessive heat or undue exposure to direct sunlight. Adequate precautions should be taken against spillage or breakage.

3.3 The grounds should be established and maintained so as to minimize ingress into the buildings of dust, soil or other contaminants and should be maintained in an orderly manner.

3.4 The foundation should be as secure as possible against ground water and high enough to remain dry even under extreme rainfall and flood conditions.

3.5 Buildings should have sufficient security to prevent unauthorized access and misappropriation of the goods.

3.6 Premises must have a permanent address and be located at a site approved by the local authorities and/or other related Acts or Regulations which must be adhered to by the licensee.

3.7 Premises should be constructed, serviced and maintained regularly to protect stored materials and/or products and/or cosmetics, from all potentially harmful influences such as undue variations of temperature and humidity.

3.8 Storage facilities should be clean and free from accumulated waste and vermin. A written sanitation programme should be available indicating the frequency of cleaning and the methods used to clean the premises and storage areas. There should also 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/or products and/or cosmetics. There should be appropriate procedures for cleanup of any spillage to ensure complete removal of any risk of contamination.

3.9 The storage facilities should be sufficiently large, and if necessary, have physically separated zones for the orderly segregation of materials and/or products and/or cosmetics. The requirements under the regulations governing the storage of scheduled poisons, dangerous drugs and psychotropic substances must be taken into consideration.

3.10 Appropriate and suitable storage conditions should be provided for hazardous, sensitive and dangerous materials and/or products and/or cosmetics such as combustible liquids and solids, pressurized gases, highly toxic substances and radioactive materials / products.

3.11 Storage facilities should have sufficient lighting to allow store and warehouse operations to be carried out accurately and safely.

3.12 Materials and/or products and/or cosmetics requiring special storage conditions should be placed in separate areas constructed and equipped to provide the desired conditions.

3.13 Where controlled environmental storage conditions are required, these conditions should be continuously monitored and the appropriate action should be taken where necessary. Materials and/or products and/or cosmetics requiring dry or humidity controlled storage should be stored in areas where the relative humidity and temperature are maintained within prescribed limits by the use of proper equipment.

3.14 Bagged and boxed materials should be stored off the floor and suitably spaced to permit cleaning and inspection.

3.15 Materials and/or products and/or cosmetics should be stored in conditions which assure their quality, and appropriately rotated so that the oldest stock

is used first. The First In/First Out (FIFO) or First Expired/First Out (FEFO) principle should be followed.

3.16 Rejected materials and/or products and/or cosmetics should be identified and controlled under a quarantine system designed to prevent their unintended use and distribution.

3.17 Materials and/or products and/or cosmetics should be re-evaluated as necessary to determine their compliance with specifications and suitability for use e.g. after prolonged storage or exposure to temperature (heat) or humidity.

3.18 Precautions must be taken to prevent unauthorized persons entering controlled storage facilities.

3.19 Printed packaging materials are considered a critical conformity of the medicinal product and special attention should be paid to the safe and secure storage of these materials.

3.20 Receiving and dispatch bays should protect materials and/or products and/or cosmetics from the weather. Reception areas should be designed and equipped to allow containers of incoming materials to be cleaned where necessary before storage.

Uniform labelling recommendation

Depending on the results of stability studies, some special label statements are recommended:

- Store in well-closed container
- Store in an airtight container
- Store protected from light
- Store protected from light and humidity
- Store protected from heat
- Store protected from freezing or do not freeze
- Short-time storage at a temperature of Xº C to Yº C

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 labelled as follows:

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

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

Where temperature is not stated (in terms of range) on the labels of the materials and/or products and/or cosmetics 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
Cold place	The temperature does not exceed 8°C
Cool place	The temperature is between 8°C and 15°C
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

Where storage conditions stated on the label means the following: -

ON THE LABEL	MEANS
Dry place	No more than 75±5% relative humidity in normal storage conditions; to be provided to the user in a moisture-resistant container
Protect from light	To be provided to the user in a light resistant container

3.21 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.

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

3.23 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.

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

CHAPTER 4: STOCK HANDLING AND STOCK CONTROL

4.1 RECEIVING MATERIALS / PRODUCTS / COSMETICS

4.1.1 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.

4.1.2 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.

4.1.3 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. Where current regulations state a period for retention of records, this should be followed.

4.1.4 Security measures should be taken to ensure that rejected materials and/or products and/or cosmetics 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.

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

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

4.2 STOCK ROTATION AND CONTROL

Comprehensive records should be maintained showing all receipts and issues of materials and/or products and/or cosmetics according to batch number.

4.2.1 Periodic stock reconciliation should be performed comparing the actual and recorded materials and/or products and/or cosmetics quantity. All significant stock discrepancies should be subjected to investigation to check against inadvertent mix-ups and wrong issues.

4.2.2 Issues should normally observe the principle of stock rotation (first-in-first-out) especially where expiry dated materials and/or products and/or cosmetics are concerned.

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

4.2.4 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.

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

4.2.6 Partly used containers of materials and/or products and/or cosmetics 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.

4.2.7 Materials and/or products and/or cosmetics 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 and/or cosmetics in conditions which satisfy the requirements for the materials and/or products and/or cosmetics, so that shelf-life declaration may be maintained.

4.3 CONTROL OF EXPIRED STOCK

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

4.4 RETURNED AND REJECTED PRODUCTS

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

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

4.4.3 Provision should be made for the appropriate and safe transport and storage of returned or rejected materials and/or products and/or

cosmetics in accordance with the relevant storage and other requirements.

4.4.4 All action taken should be approved and recorded.

4.5 DISTRIBUTION

4.5.1 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/or cosmetics, and after taking into account any special precautions to be observed.

4.5.2 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.

4.5.3 In the event of materials and/or products and/or cosmetics 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 and/or cosmetics do not come into contact with the dry ice, as it may have adverse effect on the quality of the materials and/or products and/or cosmetics.

4.5.4 Distribution documents should comply to relevant national regulations, and at least includes:

a) Date of distribution
b) Customer's name and address
c) Product and/or cosmetic description, e.g. name, dosage form and strength (if appropriate), batch number and quantity.

CHAPTER 5: DISPOSAL OF MATERIALS / PRODUCTS / COSMETICS

5.1 Disposal of materials and/or products and/or cosmetics should be carried out, according to proper destruction procedures, approved by appropriate authorities such as States Enforcement Offices, National Pharmaceutical Control Bureau, the Ministry of Natural Resources and Environment and local authorities.

5.2 Disposal records should be maintained.

CHAPTER 6: DOCUMENTATION

Documentation should be made available at all times.

6.1 WRITTEN INSTRUCTIONS

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

- Receipt and checking of deliveries,
- Storage, cleaning and maintenance of the premises (including pest control),
- Recording of the storage conditions,
- Security of stocks on site and of consignments in transit,
- Withdrawal from saleable stock
- Records, including records of clients' orders,
- Returned materials and/or products and/or cosmetics, 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 and/or cosmetics should comply with the national requirements.

6.1.1 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.

6.1.2 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.

6.2 INVENTORY SYSTEM

(Applicable for all registered products and/or notified cosmetics)

These should include (e.g. see Appendix I):-

- ❖ Stock Card Serial No.
- ❖ Name of Materials or Products or Cosmetics
- ❖ Strength and Packing size of materials and products or cosmetics
- ❖ DCA Registration No. / Notification No. / Product Identification Number
- ❖ Date of Transaction
- ❖ Invoice No./ Delivery No.
- ❖ Quantity Received
- ❖ Quantity Supplied
- ❖ Batch No. (where applicable)
- ❖ Stock Balance
- ❖ Initial / Signature

Entries of incoming goods should be clearly identified and a separate stock card is required for each material and/or product and/or cosmetic as well as each strength of the same material and/or product and/or cosmetic.

6.3 LABELLING OF CONTAINERS / PACKAGING MATERIALS

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

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

6.3.3 For manufacturers/importers, each hologram label should be recorded according to its usage in a logbook. Any hologram labelling activity that is done by a third party, delivery/distribution record of the hologram should be recorded in a logbook for traceability purpose.

CHAPTER 7: VEHICLES AND EQUIPMENT

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

7.2 Vehicles and equipments 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 and/or cosmetics being distributed.

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

7.4 Where non-dedicated vehicles and equipment are used, procedures must be in place to ensure that the quality of the materials and/or products and/or cosmetics will not be compromised. Appropriate cleaning should be performed, checked and recorded.

7.5 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.

7.6 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.

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

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

7.9 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. All monitoring records should be kept as required by national requirements.

7.10 Equipment used for monitoring conditions within vehicles and containers, e.g. temperature and humidity, should be calibrated, at regular intervals.

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

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

7.13 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 8: TRANSPORTATION AND GOODS IN TRANSIT

8.1 Materials and/or products and/or cosmetics 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.

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

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

8.4 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.

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

8.6 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.

8.7 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.

8.8 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.

8.9 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/or cosmetics and suspected counterfeits. The materials and/or products and/or cosmetics should be appropriately identified, securely packaged, clearly labelled, and be accompanied by appropriate supporting documentation.

8.10 Materials and/or products and/or cosmetics 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.

8.11 Packaging materials and transportation containers should be of suitable design to prevent damage of materials and/or products and/or cosmetics 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).

8.12 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.

8.13 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.

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

CHAPTER 9: PRODUCT / COSMETIC COMPLAINTS

9.1 PRINCIPLE

9.1.1 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 and/or cosmetic defect or adverse reactions with any of the company's marketed materials or products or cosmetics. This is valid regardless of whether:

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

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

9.2 CLASSIFICATION OF COMPLAINTS

9.2.1 Complaints can be classified as:

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

9.3 PROCEDURE FOR COMPLAINTS

9.3.1 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

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

9.4 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
Name (as in Passport / IC):
Passport / IC No :
Position :
Home Address :
Telephone No:
- Office
- Residence

PERSON RESPONSIBLE II
Name (as in Passport / IC):
Passport / IC No :
Position :
Home Address :
Telephone No:
- Office
- Residence

9.5 REPORTING

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

9.5.2 All complaints reported should be recorded and properly documented.

9.6 INVESTIGATION

9.6.1 The persons responsible should initiate the investigation immediately.

9.6.2 The investigation shall be documented.

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

9.6.4 The investigation should also cover:

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

9.7 CORRECTIVE AND PREVENTIVE ACTION

9.7.1 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.

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

9.7.3 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.

9.8 RESPONSE TO COMPLAINANT

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

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

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

9.9 DOCUMENTATION

(e.g. Appendix II for Registered Products & Appendix III for Cosmetics)

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

9.9.2 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.

9.9.3 A **Complaint File** should contain:

- Written procedures describing the actions to be taken in the handling of all written and oral complaints regarding materials and products and/or cosmetics (procedures for dealing with complaints).

- ❖ A written record of each individual complaint and as well as the completed investigation report.

CHAPTER 10: PRODUCT / COSMETIC RECALL

10.1 PRINCIPLE

The Control of Drugs and Cosmetics Regulations 1984, requires every licensed manufacturer, importer and wholesaler to have a procedure (Product Recall Procedure), which sets out in a step-wise manner the various actions to be taken to ensure the prompt recall of defective products. Such procedures should be reviewed regularly and updated.

10.2 DEFINITION

Product recall is a process taken by the manufacturer, importer and wholesaler to remove or withdraw a particular material and/or product and/or cosmetic from all links of distribution.

The removal or withdrawal may be due to critical quality defects discovered or serious adverse drug reactions reported which might cause health risks to users of the materials and/or products and/or cosmetics.

10.3 DECISION FOR RECALL

The decision for recall shall be made when there is or may caused potential risk to the user of the materials and/or products and/or cosmetics by reason of faulty production or on medical grounds:

10.3.1 Voluntarily undertaken by the manufacturers and distributors.

10.3.2 As directed by the Director of Pharmaceutical Services, Ministry of Health.

10.4 DEGREE AND LEVEL OF RECALL

The following criteria are used to classify the degree and level of recall.

10.4.1 **DEGREE OF RECALL**

The degree of recall is classified according to the severity of quality defects and adverse reactions of the products and/or cosmetics.

Degree I	Materials and/or products and/or cosmetics with major health risks that might caused serious injuries or death. Should be under an embargo within 24 hours.
Degree II	Materials and/or products and/or cosmetics with minor health risks or are substandard. Should be under an embargo within 72 hours.
Degree III	Materials and/or products and/or cosmetics with other reasons for recall. Should be under an embargo within 30 days or as specified.

10.4.2 **LEVEL OF RECALL**

The level of recall depends on the nature of problem, extent of the material or product or cosmetic's distribution and degree of hazard involved.

Level A:	To all consumers (end users)
Level B:	To all points of sales (e.g. Hospitals, Pharmacies, Clinics, Specialists Centres)
Level C:	To all sub-distributors (wholesalers)

10.5 DECISION ON THE DEGREE AND LEVEL OF RECALL

Unless the Director of Pharmaceutical Services, Ministry of Health has already specified the degree and level of a particular materials and/or products and/or cosmetics recall, the degree and level will be decided by the Product Recall Committee based on risks involved.

The Product Recall Committee shall comprise of personnel who are responsible for the execution and coordination of recall. The persons responsible shall handle all aspects of the recalls with the appropriate degree of urgency.

10.6 ORGANISATION OF PRODUCT RECALL

Two persons responsible for the recall activities shall be appointed. Once a decision is made, the responsible persons appointed are to initiate and undertake the material and/or product and/or cosmetic recall as well as to follow-up on any matters arising from such recall. The distribution records should be maintained and made readily available to the persons responsible for recalls. They should also contain sufficient information on wholesalers and customers supplied directly. The required particulars for the persons responsible are as follows:

PERSON RESPONSIBLE I
Name (as in Passport / IC):
Passport / IC No :
Position :
Home Address :
Telephone No:
- Office
- Residence
- Mobile

PERSON RESPONSIBLE II
Name (as in Passport / IC):
Passport / IC No :
Position :
Home Address :
Telephone No:
- Office
- Residence
- Mobile

10.7 NOTIFICATION OF RECALL

Notification of recall should be extended to all parties involved.

The notification of recall should include:

- The name of the material and/or product and/or cosmetic, its strength (if necessary) and pack size
- The material(s) and/or product(s) and/or cosmetic(s) batch number The nature of the defect
- The action to be taken
- The urgency of the action (with reasons, indication of health risk, as appropriate)

10.8 DISSEMINATION OF PRODUCT RECALL NOTICES

10.8.1 Level A : To the consumers (end users)

This recall level is carried out when necessary as an attempt to stop all use of a material and/or product and/or cosmetic and to recover stock that has reached the end user.

When there is imminent danger, the public are warned by a media release which is meant to urgently alert the public by radio, television and the press.

10.8.2 Level B : To all points of sale

All wholesalers will be identified and required to provide a list of all points of sale. These points can be established through a distribution record.

Recall notices will be sent to all points of sales. At the same time, representatives from the company will be sent to these points of sale to retrieve the stocks.

10.8.3 Level C : To wholesalers and stockists

Consumers are not at any risk from administering the materials and/or products and/or cosmetics.

The wholesalers and stockists will be contacted by the company representatives so that arrangement can be made to retrieve all stocks concerned from the wholesalers and stockists.

10.9 ORGANIZING THE RETURN OF THE RECALLED PRODUCT

All affected stocks of the recalled materials and/or products and/or cosmetics will be stored separately and sealed appropriately in a different section of the warehouse to prevent any mix-up.

A centre which collects and stores all returned stocks of the recalled materials and/or products and/or cosmetics need to be named. Details such as date returned, name and address of customer, batch number, expiry date, quantity and nature of materials and/or products and/or cosmetics shall be noted down by this centre as records.

Depending on the degree of product recall, the most effective and appropriate mode of transportation of such recalled materials and/or products and/or cosmetics will be decided and agreed upon.

The storage conditions applicable to a material and/or product and/or cosmetic which is subjected to recall should be maintained during storage and transit until a decision has been made regarding the material and/or product and/or cosmetic.

10.10 FATE OF THE RECALLED MATERIAL AND/OR PRODUCT AND/OR COSMETIC

All available records and information on the returned stocks will be collected for evaluation of recall situation.

A report of the affected stocks will be presented to the product recall committee and the fate of the material and/or product and/or cosmetic shall be made.

The recalled material and/or product and/or cosmetic shall be destroyed if the conditions under which the material and/or product and/or cosmetic, its container, carton or labelling as a result of storage or transportation, casts doubt on its safety, identity and quality.

Upon approval from the relevant authorities, proper destruction with appropriate precautionary measures shall be taken to ensure total elimination of affected stock. The destruction should be carried out and witnessed by authorized personnel. Details, such as mode and place of material and/or product and/or cosmetic destruction, the date and quantity shall be noted down and retained.

10.11 FINAL REPORT OF RECALLED PRODUCT

A final report of the executed material and/or product and/or cosmetic recall will be prepared and forwarded to the National Pharmaceutical Control Bureau.

CHAPTER 11: SELF INSPECTION

11.1 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.

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

11.3 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 programme. Management should evaluate the inspection report, and corrective actions taken and recorded.

CHAPTER 12: COUNTERFEIT MATERIALS/ PRODUCTS/ COSMETICS

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

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

CHAPTER 13: CONTRACT ACTIVITIES

13.1 Any activities performed, referenced in the GDP guideline and delegated to another party, should be agreed upon in a contract.

13.2 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.

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

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

CHAPTER 14: LEGAL DOCUMENTS

All relevant legal records and documentations should comply to the current legislations referring to:

a) Poisons Act 1952 and its regulations
b) Sales of Drugs Act 1952
c) Control of Drugs and Cosmetics Regulations 1984
d) Dangerous Drugs Act 1952
e) Dangerous Drugs Regulations 1952

14.1 RECEIVING RECORDS FOR DANGEROUS DRUGS

Records of Transactions of Registered Products (Regulation 27),
Control of Drugs and Cosmetics Regulations 1984);
Second Schedule Dangerous Act 1952 (Revised 1980);
Form of Register Part I Regulations 15 (1) (a):

14.1.1 Entries to be made in the "Register" in case of drugs or preparation obtained.

14.1.2 These records should include:-

- ❖ The Class of Drugs and preparations to which the entries relate to be specified at the head of each page in the register INN Name
- ❖ Name, strength and packing size of product Date on which supply was received
- ❖ Name and address of person or firm from whom obtained Amount obtained
- ❖ Form in which obtained (Name, strength and packing size products)
- ❖ MAL Registration No.
- ❖ Invoice Number or Delivery Order Batch Number
- ❖ Total Stock

14.2 SUPPLY RECORDS FOR DANGEROUS DRUGS

Records of Transactions of Registered Products (Regulation 27),
Control of Drugs and Cosmetics Regulations 1984);
Second Schedule Dangerous Drug Act 1952 (Revised 1980);
Form of Register Part II Regulations 15 (1) (a):

14.2.1 Entries to be made in the "Register" in case of drugs or preparation obtained.

14.2.2 These records should include:-

- ❖ The Class of Drugs and preparations to which the entries relate to be specified at the head of each page in the register INN Name
- ❖ Name, strength and packing size of material / product Date on which the transaction was effected
- ❖ Name and address of person or firm from whom supplied Authority of person or firm supplied to be in possession Amount supplied
- ❖ Form in which supplied (Name, strength and packing size products)
- ❖ MAL Registration No.
- ❖ Invoice Number or Delivery Order Batch Number
- ❖ Total Stock

14.3 SUPPLY REGISTER FOR PSYCHOTROPIC SUBSTANCES

Regulation 20 & 22, Poisons (Psychotropic Substances) Regulations 1989;
Records of Transactions of Registered Products (Regulation 27),
Control of Drugs and Cosmetics Regulations 1984):

14.3.1 These records should include:-

- The INN Name
- Name, Strength and packing (quantity) of product
- Name and address of supplier / purchaser
- Date of Sale / Supply / Received
- Purpose for which required
- Quantity supplied/ received
- Total Stock
- MAL Registration No.
- Batch No.
- Invoice No / Import or Export Authorization
- No. Bill Landing No/Airway Bill No.
- Reference to purchaser's signed order

A SEPARATE REGISTER IS REQUIRED FOR EACH PRODUCT AND EACH STRENGTH OF THE SAME PRODUCT

14.3.2 Entries for incoming registered products should be clearly identified.

14.4 POISON WHOLESALE RECORD

Section 15(3), Poisons Act 1952 (Revised 1989);
Records of Transactions of Registered Products (Regulation 27),
Control of Drugs and Cosmetics Regulations 1984):

14.4.1 Entries to be made in "Poisons Wholesale Sales Book".

14.4.2 These records should include:-

- INN Name
- Name, strength and packing size of products
- Name of Purchaser
- Name and address of purchaser

- Date of Sale
- Name of Poison Sold
- Quantity Poison Sold
- Purpose for which required
- Signature of Purchaser or refer to signed order
- MAL Registration No
- Batch No
- Invoice No. / Bill Landing No. / Airway Bill No.
- Reference to purchaser's signed order

14.4.3 Entries for incoming registered products should be made clearly identified.

14.5 WHOLESALE RECORDS

Records of Transactions of Registered Products (Regulation 27), Control of Drugs and Cosmetics Regulations 1984):

14.5.1 Applicable for all registered products and/or cosmetics other than scheduled poisons, psychotropic substances and dangerous drugs.

14.5.2 Entries to be made in "Records of Transactions (For Licensed Wholesaler)".

14.5.3 These records should include:-

- Name, strength of products or cosmetics
- Date of Sale / Supply
- Name and address of supplier / purchaser
- Registration Reference of the product
- (MAL Registration No.) or cosmetic (Notification No.)
- Quantity Received / Sold
- Packing Size
- Batch No.
- Invoice No / Delivery Order No.

14.5.4 Entries for incoming registered products and/or notified cosmetic should be clearly identified.

14.6 IMPORTATION RECORDS

Records of Transactions of Registered Products (Regulation 27), Control of Drugs and Cosmetics Regulations 1984):

14.6.1 Applicable for all registered products and/or cosmetic other than scheduled poisons, psychotropic substances and dangerous drugs.

14.6.2 Entries to be made in "Records of Transactions (For Licensed Importer)".

14.6.3 These records should include:-

- INN Name (if applicable)
- Name, strength and packing size of products / cosmetics
- Date of Importation
- Name and address of supplier / purchaser
- Quantity imported / supplied
- Invoice No. / Bill Landing No. /Airway Bill No.
- Date of Sale / Supply
- Name and address of purchaser
- PBKD Registration No. / Notification No.
- Batch No.
- Packing Size
- Invoice No. / Delivery

14.6.4 Entries for incoming registered products and/or notified cosmetics should be clearly identified.

CHAPTER 15: MANAGEMENT OF COLD CHAIN PRODUCTS/ MATERIALS

15.1 List of products should be provided with cold chain storage temperature specifications for reference by personnel who handle the receipt of goods and related store personnel.

15.2 Written procedures should be available and appropriate training should be provided for all staff involved in the handling, receipt, storage, packing and delivery operations for cold chain products/materials to ensure the quality of cold chain products/materials is maintained.

15.3 Cold chain product storage facilities should be qualified prior to prevail that it is capable of storing the product in accordance with the specifications given situation. Qualification and validation records must be kept and cold chain products storage facilities must be able to operate at all time in accordance to the qualifying conditions.

15.4 Written procedures should be established to ensure that the cold chain products / materials received are distributed under storage conditions comply with the directions on the label of products based on product stability testing results. Companies can use the temperature 'data logger' or other temperature recording devices to verify that the desired temperature has been maintained during the delivery of each consignment received. In addition, simulation studies can be conducted to validate the delivery conditions, taking into account the possibility of the worst situation.

15.5 Cold chain products should be identified immediately after receipt and stored under the storage conditions that comply with the directions on the product label. Written procedures should be provided to ensure that the activities of receipt, storage, and distribution is done without compromising on the quality, efficacy and safety products / materials that should be stored under cold conditions.

15.6 Inspection upon receipt of products / materials should be done to prevent signs of aggression, destruction and non-conformance along the cold chain storage and distribution, as well as physical damage to the packaging materials, labels and quantity of the product compared to the information in the purchase order. These inspections shall be conducted under the recommended storage conditions as on the product label.

15.7 All cold chain products (e.g. removed, quarantined) must be stored under the storage conditions stated on the label other than the product which will be disposed off.

15.8 Temperature and humidity (if needed) for cold room or refrigerator must be monitored and recorded continuously using temperature and humidity sensors.

15.9 Maximum and minimum temperatures should be recorded, either electronically or manually at least once in the last 24 hours, with continuous review of records. Records must be kept for at least one year.

15.10 Suitability of locations for placing temperature sensors in a cold room used for storage of cold chain products should be subjected to temperature mapping study. Mapping studies should be conducted in accordance with written procedures and storage conditions determined before operation.

15.11 Periodic maintenance programmes for air conditioning systems in a cold room and freezer must be established and implemented.

15.12 Cold room or freezer must be fitted with an alarm system to alert staff if any occurrence of temperature beyond specifications. Action and warning limits should be established. Periodic testing programme on the alarm system should be established to ensure the alarm system is functioning.

15.13 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 programme 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.

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

15.15 Written procedures should be available to explain the packing materials required, packing configuration of transportation container for cold chain products / materials and labels to identify these products as products that require special storage /shipping conditions. Packaging operations for cold chain products should be recorded and should have the second person conformance to ensure that the packaging operations carried out in accordance following written procedures.

15.16 Outer packing / shipping containing cold chain products/ materials should be labelled:

- "Cold but not freezing" for medicines that require maintenance of temperature in the range of +2ºC to +8ºC, or
- "Refrigerate the contents of the package" for medicine transported in packaging that needs to be removed before the medicines be placed in the refrigerator, or
- "Keep frozen" for medicines that require maintenance in the range of temperatures below 0 º C.

15.17 Medicines labelled "Keep Frozen" should be transported in such a manner to ensure that it remains frozen.

15.18 Packing and handling of cold chain medicines should put a warning to acknowledge the recipient that it is a cold chain medicines and receiver must put the medicines in appropriate storage facilities as soon as possible.

15.19 Necessary precaution steps should be implemented when using dry ice during transportation in order to avoid a direct contact with the product and consequently caused coagulation of products / materials.

15.20 Refrigerated vehicles or containers to transport cold chain products should be mapped and monitored.

15.21 Delivery route planning for cold chain products should be created to prevent the risk of exposure to the cold chain products beyond the control of the ambient temperature. Cold chain medicines should be clearly identified from other items in the same distribution activities.

15.22 For each delivery, evaluation and validation of methods of delivery temperature control system to be used must consider the time required for delivery, weather conditions and any future risk exposure.

15.23 Procedures must be implemented to handle the returned products and also the products / materials that have been stored under out of the specified storage condition during the reception, storage and distribution of products / materials.

15.24 If the storage temperature is found to have deviated from the storage specifications, manufacturer for the products / materials should be contacted to confirm the suitability of the use of products / materials and the decision recorded.

Appendix I

STOCK CARD

STOCK CARD SERIAL NO. :

NAME OF MATERIAL/PRODUCT/ COSMETIC :

PACK SIZE OF MATERIAL/ PRODUCT/ COSMETIC :

PBKD REGISTRATION NO/ NOTIFICATION NO :

Date	Invoice No. / Delivery No.	Batch No.	Quantity Received	Quantity Supplied	Stock Balance	Initial/ Signature

[ENTRIES OF INCOMING GOODS SHOULD BE MADE CLEARLY IDENTIFIED AND A SEPARATE STOCK CARD IS REQUIRED FOR EACH MATERIAL/ PRODUCT/ COSMETIC AS WELL AS EACH STRENGTH OF THE SAME PRODUCT]

Appendix II

BORANG: BPFK 418.3

BORANG ADUAN PRODUK
BAGI PRODUK YANG BERDAFTAR DENGAN PIHAK BERKUASA KAWALAN DADAH
Product Complaint Form for Products Registered with the Drug Control Authority

SILA KEMUKAKAN SAMPEL ADUAN BERSAMA DENGAN BORANG INI
Please send complaint samples with this form.

i. BUTIRAN PRODUK
Particulars of Product

NAMA PRODUK:
Name of Product
NO. PENDAFTARAN: | **NO. KELOMPOK:**
Registration Number | Batch Number
TARIKH DIKILANGKAN: | **TARIKH LUPUT:**
Manufacturing Date | Expiry Date

ii. BUTIRAN ADUAN LENGKAP
Sila isikan butiran mengikut jenis aduan
Please fill in the details according to the nature of the complaint

ADUAN TENTANG KUALITI PRODUK:
Complaint on product quality
.....
.....
.....

ADUAN TENTANG KEBERKESANAN PRODUK:
Complaint on product efficacy
Sila berikan maklum balas objektif kepada kami seperti:
- *% pesakit yang menghadapi masalah yang sama*
- *Adakah masalah berlaku selepas menukar jenama*
- *Penemuan objektif seperti bacaan tekanan darah (BP), ujian gula dalam darah secara rawak (RBS) dan lain-lain yang boleh menyokong aduan tentang keberkesanan produk*

Kindly provide us with objective feedback such as:
- % patients having similar problems
- Did the problem occur after brand switching
- Objective findings such as BP reading, RBS etc to support complaint on efficacy of product

.....
.....
.....

iii. BUTIRAN PENGADU
Particulars of Complainant
Sila hantarkan kepada:

NAMA:
Name
JAWATAN/PEKERJAAN:
Designation/Occupation
ALAMAT:
Address
TELEFON: | **FAKS:**
Telephone | Fax
TARIKH TANDATANGAN: | **TARIKH:**
Signature | Date:

Sila hantar kepada:

SEKSYEN SURVEILANS & ADUAN PRODUK
PUSAT PASCA PENDAFTARAN PRODUK
BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN
KEMENTERIAN KESIHATAN MALAYSIA
JALAN UNIVERSITI, PETI SURAT 319
46730 PETALING JAYA

Faks: 603-79567151

Appendix III

COSMETIC PRODUCT [CONFIDENTIAL]

APPENDIX 1

To:
Name & Address of the Regulatory Authority
Department
Telephone no,
Fax no.
Email address

FOR OFFICIAL USE ONLY
Date received:
Product Notification No:

REPORT FORM FOR ADVERSE COSMETIC EVENT

I. Company Particulars

Name and address of Company		
Name & designation of person reporting		
Tel No.:	Fax No.:	Email:

II. Product Particulars

Product Name (as in product notification)	
Ingredient listing & pack size	(Please attach a separate list)
Product Type/Intended use	
Name of Manufacturer & country of manufacture	
Expiry or manufacturing date	
Batch No.	

III. Details of Adverse Event

Name/ Initials of person			
Identification or Passport no.			
Age		Sex	
Ethnic group / Nationality			
Date of onset of adverse event			
Description of adverse event (please use and attach a separate report if necessary) Delay between last application of the product and onset of symptoms: ___ min(s) ___hour(s)____day(s) How was the product used:			
Is the person hospitalised due to the adverse reaction?		□ Yes	□ No
Did person seek medical attention?		□ Yes	□ No
Outcome	□ Recovered (Date:_____) □ Not yet recovered	□ Death (Date: _____) □ Unknown	
Source of report	□ Healthcare professional	□ Consumer	□ Others (specify)

[Signature of person making report & date of report]

References

1. Guidelines on Good Storage Practice (GSP), 2nd Edition, 2004. National Pharmaceutical Control Bureau.
2. WHO Good Distribution Practices for Pharmaceutical Products, Annex 5. WHO Technical Report Series, No. 957, 2010.
3. Australian Code of Good Wholesaling Practice for Medicines in Schedule 2,3,4 and 8. National Coordinating Committee on Therapeutic Goods.
4. Guidance Notes on Good Distribution Practice. Health Sciences Authority. Regulatory Guidance.
5. Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use. European Commission, Health and Consumers Directorate-General. Brussels, SANCO/C8/AM/an D(2010) 380358.