

MEDICINES CONTROL AGENCY



Guideline for Repackaging and Labelling of Medicines

MCA-GL-101, Version 1.0, 13 December 2017

FORWARD

The Medicines Control Agency (MCA) established by an Act of Parliament and assented to on 24th December 2014 is mandated to regulate the manufacture, import, wholesale, storage, distribution and supply of medicines and related products, and to ensure that all medicines and related products sold and used in the country conform to the required standards of quality, safety and efficacy throughout the product lifecycle in The Gambia.

In pursuance of the Medicines and Related Products Act 2014, Part VIII, MISCELLANEOUS, Section 64 Guidelines herein quoted "the Agency may publish guidelines in connection with matters provided for under this Act for the purpose of giving guidance", the MCA deems it very essential to develop written Guidelines and Standard Operating Procedures (SOPs) to guide the implementation of the various regulatory functions of MCA in ensuring the safety, efficacy and quality of medicines and related products available to the population.

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Gratitude is extended to key stakeholders including the Directorate of National Pharmaceutical Services, Pharmacy Council, Medical and Dental Association, Pharmaceutical Society of The Gambia, Nurses and Midwives Council, Regional Health Directorates, National Aids and TB Control Programs, National Public Health Laboratory Services and Gambia Standards Bureau for their valuable contributions and participation in the validation of the Quality Assurance Plan, which will ensure that all medicines and related products are of the required quality for their intended use.

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1. LIST OF ABBREVIATIONS AND ACRONYMS

| | |
|-------|-------------------------------------|
| BUD | Beyond-use-date |
| GMP | Good Manufacturing Practice |
| MCA | Medicines Control Agency |
| MoHSW | Ministry of Health & Social Welfare |
| MVTR | Moisture Vapour Transmission Rate |
| NGO | Nongovernmental Organisation |
| PIL | Patient Information Leaflet |
| WHO | World Health Organization |

2. INTRODUCTION

- 2.1. The main purpose of medicines packaging and labelling is for the unambiguous identification of the medicines and the conditions for their safe use by the patients, caregivers and consumers. Inappropriate packaging can lead to product mix-up, loss of product identity, contamination, cross-contamination and lack of stability data to support expiry dates.
- 2.2. The format and style of the information on the label are essential for minimising medication errors, enabling patients, caregivers and health professionals to select the correct medicine and use it safely.
- 2.3. Usually medicines are distributed in their original package provided and labelled by the manufacturer. In some instances, the manufacturer supplies medicines as bulk product and the medicines need to be repackaged for distribution. Other reasons may also necessitate the need for repackaging and/or labelling such as
 - for convenience for the practitioner;
 - to reduce waste and conserve drug supplies;
 - and in some cases to reduce costs.
- 2.4. The Medicine Control Agency (MCA) is mandated to prescribe standards of quality in respect of medicines and related products.
- 2.5. This guideline is based on the Medicines and Related Products Act, 2014, Part II, Section 4 (a) and (b).

3. PURPOSE AND SCOPE

- 3.1. This guideline applies to persons or entities engaged in repackaging and/or labelling of medicines registered at MCA for marketing nationally.
- 3.2. It provides information to any person who removes medicines from their original manufacturer's container-closure system and repacks them in a different container-closure system for resale or distribution.
- 3.3. This guideline does not apply to repackaging of any radioactive medicines.
- 3.4. A re-packager referred to in this guideline may also be a contract re-packager.

4. PREREQUISITES

- 4.1.1. Repackaging and labelling of medicines are manufacturing processes which must be conducted in accordance with applicable Good Manufacturing Practice (GMP) requirements.
- 4.1.2. Repackaging and labelling are beyond the regular practices of a pharmacist. A person or entity conducting repackaging (re-packager) is required to register with the MCA to receive a license for repackaging.
- 4.1.3. All packaging/repackaging operations should comply with GMP guidelines and are subject to the holding of a valid licence issued by MCA.
- 4.1.4. The facility in which the repackaging of medicines is practiced should be operated in conformity with current GMP. The environmental conditions during the packaging operation and storage should comply with the storage requirements as directed by the manufacturer, especially if the medicine requires storage at special temperature and/or humid conditions (see *MCA Guideline for Storage and Distribution of Medicines and Related Products*)
- 4.1.5. In all circumstances, repackaging must not have an adverse effect on the original conditions of the product.
- 4.1.6. The re-packager is responsible for ensuring the quality and stability of the repackaged medicine.
- 4.1.7. The re-packager has to ensure that an adequate control system is in place.
- 4.1.8. The re-packager is expected to ensure that appropriate analytical testing for all pertinent specifications, such as identity and strength of each active ingredient and the finished product tests were done and to maintain those records on a batch by batch basis for the repackaged product.
- 4.1.9. If the re-packager does not use a container–closure system equivalent to the manufacturer’s approved package system, the re-packager must generate stability data for the medicine in the new container–closure system to justify the expiry date assigned (see Section 5.4).
- 4.1.10. If the re-packager performs stability tests for the repackaged product records of such analysis on a batch by batch basis must be maintained.
- 4.1.11. Any alteration or manipulation of the repackaging process should be documented.
- 4.1.12. The concept of adverse effects on the original condition of the product as stated in Section 4.1.5 refers to the condition of the product inside the packaging. It is accepted that the condition of the product is not adversely affected when repackaging affects only the secondary packaging, leaving the primary packaging intact. On the other hand the original condition of the product inside the packaging might be indirectly affected where, for example:
 - The secondary packaging of the repackaged product, or a new set of user instructions or information, omits certain important information or gives inaccurate information concerning the nature, composition, effect, use or storage of the product, or

- An extra article is inserted into the packaging by the re-packager designed for the ingestion and dosage of the product that does not comply with the method of use and the doses envisaged by the manufacturer.
- 4.1.13. Since it is in the trade mark owner's interest that the consumer should not be led to believe that the owner is responsible for the repackaging, an indication must be clearly and legibly shown on the secondary packaging of who repackaged the product.

5. REPACKAGING

5.1 Packaging material

- 5.1.1. In accordance with the methods of use and administration of medicines, packaging materials, closures and containers vary a great deal and have to meet a wide variety of different requirements.
- 5.1.2. The manufacturer should include in the product information supplied to the re-packager specifications about the packaging materials as approved in the original application including its oxygen and light transmission characteristics in order to enable the re-packager to properly select an equivalent container-closure system.
- 5.1.3. A re-packager may or may not use the same container-closure system as the manufacturer.
- 5.1.4. If the container-closure system is different, the re-packager should use a container-closure system that is at least as protective as, or more protective than, the original container-closure system in terms of moisture vapour transmission rate (MVTR), oxygen transmission, light transmission, and compatibility of the container-closure system with the medicine (equivalent container-closure system).
- 5.1.5. System equivalency extends to any special protective materials, such as for light transmission, seals, or desiccants associated with the original container-closure system.
- 5.1.6. These values may be determined by the re-packager, or they may be obtained from the container-closure vendor for the specific container-closure system under consideration.

5.2 Bulk products

The following criteria should be considered by the re-packager upon receipt of bulk prior to repackaging:

- 5.2.1. The bulk product should be distributed to the re-packager by the manufacturer in accordance with MCA regulatory requirements and accompanied by appropriate labelling, batch numbers and valid expiry date. The re-packager should also receive Material Safety Datasheet, Certificate of Analysis, and sample market labelling including product information inserts from the medicine manufacturer.
- 5.2.2. The bulk product should be received intact and undamaged and in appropriately labelled containers.

- 5.2.3. The bulk product should undergo definitive organoleptic evaluations to confirm its identity (e.g. physical appearance, marking/s, colour, and odour) to confirm the labelling as described by the manufacturer.
- 5.2.4. Records should be maintained to verify the identity and quantity of each shipment received and to verify the batch number and bar coded information for each article shipment received. These records should also include the name of the manufacturer or supplier and the date of receipt.
- 5.2.5. The re-packager should store and maintain the bulk under storage conditions specified by the manufacturer.

5.3 Repackaging process

The following criteria should be observed:

- 5.3.1. The re-packager operations should be conducted under specified storage conditions as instructed by manufacturer and that includes maintenance of required temperature in areas where repackaging is conducted.
- 5.3.2. It is acceptable to remove blister packs, flasks, vials, ampoules or inhalers from their original secondary packaging and place them into a new secondary packaging without affecting the original condition of the product inside the primary packaging.
- 5.3.3. The new secondary packaging must be fully compliant with the MCA requirements.
- 5.3.4. The re-packager must ensure that all information provided by the manufacturer has been affixed on the secondary packaging.
- 5.3.5. Written procedures should be in place and maintained to ensure that correct packaging materials are used for the repacked medicines and required conditions are met.

5.4 Establishing an expiry date

- 5.4.1. To establish the expiry date stability studies are performed on the medicine in the original manufacturer's package system. When a medicine is repackaged into a different container, the product's expiry date may be altered or interrupted.
- 5.4.2. The re-packager may perform stability studies on the repacked products to establish an expiry date for the repackaged product based on scientific evaluation of the medicine in the equivalent container-closure system and complies with criteria established for equivalency.

Establish equivalence means

- 5.4.3. The requirements stated in this guideline are met.
- 5.4.4. Specifications such as light transmission, seals or desiccants associated with the original container-closure system, or special protective materials in which the medicine is marketed, are the same. Comparison of container-closure systems may be done through stress testing of the product after storage under exaggerated conditions of temperature and humidity.
- 5.4.5. A re-packager should not use the equivalent container-closure system criteria to repackage medicines where such products have been identified by the manufacturer to have stability problems or if the manufacturer

specifically states that the product should not be repackaged using the equivalency container closure-system criteria. For e.g. the medicine is labile (moisture sensitive) and therefore should be dispensed only in the original manufacturer's container. In this case, a re-packer needs to demonstrate the stability of the medicine in the re-packer's container closure system.

5.4.6. Establishing the expiry date in the case listed in 5.4.5 is applicable to unit dose containers and multiple unit dose containers.

5.5 Assigning beyond-use-date (BUD)

5.5.1. In the absence of stability data, where a re-packer repackages a product into a unit dose or multiple-unit container without conducting appropriate stability studies to support expiry dates used, the period of use of the product is limited by the Beyond-Use Date for the repackaged product, which must be less than expiry date.

5.5.2. For **unit-dose** packaging the following criteria should be considered:

- The original bulk container of the medicine to be used for repackaging has not been previously opened.
- The contents of the original bulk product to be repackaged are repackaged at one time.
- The unit-dose container meets testing requirements for either class A or B containers.
- The unit dose container meets or exceeds the manufacturer's specification for light resistance.
- The conditions of storage meet the storage specifications as provided by the manufacturer of the bulk product. Where no specific conditions are specified, the product should be maintained at the required manufacturer's temperature and in a dry place during repackaging.
- The BUD used for the repackaged product does not exceed 6 months from date of repackaging.
- The BUD does not exceed the manufacturer's expiry date.
- Documentation should be in place to show that the criteria above are met and to show the type of packaging material used. The testing for these materials should also kept on file.
- The re-packer may not repackage if the manufacturer specifically states "Do not Repackage". However, the re-packer may affix the re-packager's labelling, if it is in accordance with MCA requirements and in agreement with the manufacturer of the product (see Section 6).
- The re-packer may not use the expiry date and BUD interchangeably because they imply the presence or absence of stability testing respectively.

5.5.3. For **multiple-unit** packaging, the following criteria should be considered in assigning BUD:

- The original bulk container of the medicine to be used for repackaging has not been previously opened.
- The contents of the original bulk product to be repackaged are repackaged at one time.

- The conditions of storage meet specifications of the labeling of the manufacturer's bulk product. Where no specific storage conditions are specified, the product should be maintained at the manufacturer's requirement and in a cool and dry place during repackaging.
- The type of container system used for repackaging should be the same type used by the manufacturer for the market container or equivalent.
- The container meets or exceeds the test results of the manufacturer's multiple-unit market container for light transmission.
- The container meets or exceeds the manufacturer's container in special protective features, methods used to prevent leaching of container materials or the use of desiccants to maintain low moisture content (NB: desiccants should always be packed on top of drug product).
- For all products, if the re-packager uses a container that is equivalent to the manufacturer's container or one that has a higher barrier, then BUD should be 12 months or manufacturer's expiry date, whichever is less.

5.6 Repackaging of specific medicines

- 5.6.1. A re-packager is expected to repack highly sensitising products such as penicillins, in facilities separate from those facilities used for other medicines.

Moisture and temperature sensitive products

- 5.6.2. For products identified by the manufacturer as moisture and temperature sensitive, the re-packager must follow the specifications provided by the manufacturer during repacking and ensure appropriate distribution.
- 5.6.3. A re-packager may not repackage a moisture or temperature sensitive product if the manufacturer so instructs, except if the re-packager is only altering the labelling in accordance with MCA labelling requirements.
- 5.6.4. For moisture sensitive products, a higher-barrier container should be used for repackaging.
- 5.6.5. The re-packager should have proper documentation in place to show the higher-barrier protection of the container used.
- 5.6.6. The storage and handling of the product should meet the conditions specifically instructed by the manufacturer of the product.
- 5.6.7. The re-packager should label the container "contains moisture sensitive products".

6. LABELLING

6.1 General requirements

- 6.1.1. A re-packager should provide appropriate labelling of the product with the same labelling information as the market label that is used by the manufacturer.
- 6.1.2. All repackaged products should be labelled with beyond use date (BUD) in the absence of stability data, or with an expiry date in cases where stability studies have been performed on the product using the re-

packager's container. The expiry date will ensure that the products meet applicable stability and quality.

- 6.1.3. The labels may be used on the secondary packaging as well as on the primary packaging.
- 6.1.4. The information being affixed to the package has to be of the permanent type in a tamper proof way i.e. any attempt to remove the label will create permanent damage to the packaging.
- 6.1.5. Labels must be large enough to contain the required information in a large enough font for adequate legibility and occupy a prominent place on the package.
- 6.1.6. The font is of great significance to legibility.
 - Simple fonts are suitable;
 - Narrow (condensed) or wide fonts should be avoided;
 - Clear areas around the text improve legibility;
 - The various text items should not therefore be located too close together;
 - Fonts less than 7 points should be avoided; justification should be provided if smaller fonts are used.
- 6.1.7. If coloured text or background is used the greatest possible contrast must be aimed for.
- 6.1.8. Labels should not cover any existing information on the packaging, especially if the information being covered is not being replaced by the information being affixed e.g. expiry date, batch number, etc.
- 6.1.9. All relevant information on labels **must be in English**.
- 6.1.10. Where the medicine is not labelled in English, a complete translation of the relevant information should be fixed to the secondary packaging of the product. If this is not possible, the English translation should be inserted in the package.
- 6.1.11. Where the patient information leaflet (PIL) is not in English, English translation should be inserted in the package.
- 6.1.12. All information present on labels must be printed, using indelible ink. The stamping with ink is not allowed.

6.2 Information on labels

- 6.2.1. Information to be included in the labelling should be in line with current MCA requirements.
- 6.2.2. The labelling information below are required by the MCA:
 - Generic name of the medicine as registered, or brand name (where applicable).
 - Active ingredients and contents by weight, volume or unit (if not included in the name), and excipients known to have a pharmacological effect
 - Strength and pharmaceutical form (if not included in the name)
 - Route of administration
 - Direction for use

- Batch number and expiry date/before use date as applicable (see Sections 5.4 and 5.5)
 - Storage conditions
 - Warnings and precautions as required by current guidelines.
 - Name and address of the marketing authorisation holder
- 6.2.3. The generic name of the medicine should include the strength and the pharmaceutical form.
- 6.2.4. The warnings considered critical and included in the approved labelling following authorisation are to be included on the label of the repackaged product. These warnings are usually necessary immediately prior to administering the product.
- 6.2.5. The above information should appear in the same field of view, where practical.
- 6.2.6. The name should appear on at least two non-opposing faces of the pack to aid accurate identification of the medicine.

6.3 Consideration for certain containers

Small containers

- 6.3.1. Where the labelling requirements cannot be legibly applied to a small container (nominal value of 10 ml or less), the following should appear:
- Name of the medicine followed by its strength and pharmaceutical form;
 - Contents by weight, volume or unit;
 - Route of administration, if necessary;
 - Batch number and expiry date/before use date as applicable
- 6.3.2. The required information listed in section 6.2.2 should appear on the secondary package.

Blister packs

- 6.3.3. The minimum information to be included on a blister pack are as follows:
- The name, strength and dosage form of the medicine
 - The name of the Marketing Authorization Holder/manufacturer
 - The batch number
 - The expiry date
- 6.3.4. The name and strength of the product should appear over each blister or be oriented centrally across the pack. The particulars should remain available to the user up to the point at which the last dose is removed from the blister pack. Sufficiently large font should be used for ease of use by the patient.
- 6.3.5. The required information listed in section 6.2.2 should appear on the secondary package.
- 6.3.6. Self-stick labels may be used for the addition of the following information:
- The Marketing Authorization/Registration Number of the product in The Gambia granted by the MCA;

- The name and address of the Marketing Authorization Holder of the product in The Gambia, responsible for placing it on the market.

7. RETENTION OF SAMPLES FOR REPACKAGED MEDICINES

- 7.1. Samples need to be retained and may be requested at any time by the MCA for e.g. analytical testing.
- 7.2. Samples may therefore fall into two categories:
 - Reference sample: a sample of a batch of packaging material and/or finished product which is stored for the purpose of being analysed should the need arise during the shelf life of the batch concerned.
 - Retention sample: a sample of a fully packaged unit from a batch of finished product. It is stored for identification purposes. For example, presentation, packaging, labelling, summary of product characteristics / patient information leaflet, batch number, expiry date) should the need arise during the shelf life of the batch concerned.
- 7.3. The reference and/or retention samples serve as a record of the batch of finished product and can be assessed in the event of, for example, a dosage form quality complaint, a query relating to compliance with the marketing authorisation/licence, a labelling packaging query, a Pharmacovigilance report or a stability query.
- 7.4. Reference and retention samples from each batch of finished product should be retained for at least one year after the expiry date.
- 7.5. The reference sample should be of sufficient size to permit the carrying out, on two occasions, of the full analytical controls on the batch in accordance with the Marketing Authorisation.
- 7.6. The authorised person of the repackaging entity who releases a batch for distribution should ensure that all relevant reference and retention samples are accessible at all reasonable times.
- 7.7. Where the packs are not opened, only the packaging material used needs to be retained, as there is no or little risk of product mix up. Where the packages are opened, for example, to replace the carton or patient information leaflet, then one retention sample, per repackaging operation, containing the product should be taken, as there is a risk of product mix-up during the assembly process. It is important to be able to identify quickly who is responsible in the event of a mix-up (original manufacturer or assembler) as it would affect the extent of any resulting recall.

8. FINAL PROVISIONS

- 8.1. This guideline is the first version published by the MCA.
- 8.2. This guideline will become effective on 01 January 2018.
- 8.3. The guideline will be reviewed within 2 years of becoming effective.

9. REFERENCES

- Medicines and Related Products Act, 2014
- MCA Guideline for Storage and Distribution of Medicines and Related Products, 2017
- WHO good manufacturing practices for pharmaceutical products: main principles, Annex 2, WHO Technical Report Series No. 986, 2014

10. DOCUMENT HISTORY

| Version No | Issue Date | Reasons for Change |
|------------|------------|--------------------|
| 1.0 | 13 Dec 17 | New document |
| | | |

11. DEFINITION OF TERMS

The definitions provided below apply to the words and phrases used in the MCA guidelines. Although an effort has been made to use standard definitions as far as possible, minor alterations have been made in some cases.

Batch (or Lot):

A defined quantity of products processed in a one process or series of processes so that it is expected to be homogeneous.

Batch number (or Lot number):

A distinctive combination of numbers and/or letters which specifically identifies a batch

Beyond-use-date (BUD):

The date after which a compounded preparation or repackaged medicine shall compounded or the medicine repackaged. The date is assigned by the pharmacy for a preparation that the pharmacy has compounded or by a re-packager that the re-packager has assigned to a repackaged medicine

Brand name (or Trade name):

A name given to a medicine by the pharmaceutical company/manufacturer

Bulk product:

Any product which has completed all processing stages up to, but not including, final packaging

Container

The material employed in the packaging of a medicine; containers include primary, secondary and transportation containers

Container-closure system (or Packaging system):

Refers to the sum of packaging components that together contain and protect the dosage form; this includes primary packaging components and secondary

packaging components, if the latter are intended to provide additional protection to the medicine

Contamination:

The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a medicine or related product during handling, sampling, packaging or repackaging, storage or transportation

Cross contamination:

Contamination of a material or of a product with another material or product

Dispensing:

Refers to the process of preparing and giving a medicine to a named person or animal on the basis of a prescription

Distribution

The holding, storing, selling, supplying, importing, exporting, or movement of medicines or related products, with the exception of the dispensing or providing medicines directly to a patient or his/her caregiver

Equivalent container-closure system:

Refers to a container–closure system that is at least as protective or more protective than the original container–closure system in terms of moisture vapour transmission rate, oxygen transmission, light transmission, and compatibility of the container–closure system with the medicine

Excipient:

A constituent of a medicine other than the active substance

Expiry Date:

The date given on the individual container (usually on the label) of the medicine or related product up to and including the date on which the product is expected to remain within specifications, if stored correctly; it is established for each batch by adding the shelf life to the date of manufacture and is determined by using stability studies

Finished pharmaceutical product (FPP):

A medicine that is presented in its finished dosage form and has undergone all stages of production, including packaging in its final container and labelling

Good Manufacturing Practice (GMP):

A code of standard practices concerning the production, processing, packing, release and holding of a medicine which ensure that medicines are consistently produced and controlled according to quality standards appropriate to their intended use and as required by marketing authorisation

Guideline:

A document providing guidance on the scientific or regulatory aspects of medicines; MCA expects that justification is provided for any deviations and is approved by MCA

Importation:

The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone)

Labelling:

Information on the primary or secondary packaging of a medicine

Manufacture:

Includes the operations involved in the production, preparation, processing, refining, transformation, packaging, re-packaging and labelling of medicines or related products

Manufacturer:

A company or entity that carries out operations such as production, packaging, repackaging, labelling and relabelling of medicines or related products

Marketing authorisation (or Registration):

A legal document issued by the MCA for the purpose of marketing or free distribution of a product in The Gambia after evaluation for safety, efficacy and quality.

It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using INNs or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based (e.g. "The product(s) must conform to all the details provided in your application and as modified in subsequent correspondence"). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization.

Once a product has been given marketing authorization, it is included on a list of authorized products — the register — and is often said to be "registered" or to "have registration". Market authorization may occasionally also be referred to as a "licence" or "product licence".

Marketing authorisation holder (MAH):

The manufacturer or other legal entity in whose name the marketing authorization for a product has been granted and is responsible for all aspects of the product and compliance with the conditions of marketing authorisation to market a medicine in one or several countries

Medicine:

A substance or mixture of substances prepared, sold or represented for use in the diagnosis, treatment, mitigation or prevention of disease, disorder or abnormal physical state or the symptoms of it, in man or animal, restoring, correcting or modifying organic functions in man or animal, including nutritional supplements or herbal medicines

Multiple-unit packaging:

Is a package that contains more than one single-dosage unit

Package leaflet (or Patient information leaflet (PIL)):

The leaflet in every pack of medicine that contains information on the medicine for end-users, such as patients and animal owners

Packaging (or Packing):

All operations, including filling and labelling, which a bulk product has to undergo in order to become a finished product

Pharmacist:

A pharmacist registered under the Pharmacy Council Act 2014, holding a current certificate of registration

Pharmacovigilance (PV):

The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine related problem (WHO).

Primary container/packaging (or Immediate packaging):

Container that is in direct contact with the product

Product:

Refers to a medicine and/or a related product

Product information:

Documents providing officially approved information for healthcare professionals and patients on a medicine; the product information includes the summary of product characteristics, package leaflet and labelling

Recall:

The removal of specific batch/batches of a medicine or related product from the market for reasons relating to deficiencies in the quality, safety or efficacy

Related product:

An article other than medicine which includes cosmetics, homeopathic medicines, medical device, instrument or apparatus including, components, parts and accessories of it, manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptom of it in man or animal

Repackaging:

The act of taking a medicine from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the medicine

Re-packager:

Is a person or entity who purchases and removes a medicine from the manufacturer's marketed container or bulk container and places the product into a different container for distribution for human or animal use; a re-packager may or may not take ownership from the manufacturer

Route of administration:

The way in which a medicine is given, e.g. orally (by mouth), intravenously (into a vein), subcutaneously (under the skin), etc

Sampling:

Operations designed to obtain a representative portion of a medicine or related product, based on an appropriate statistical procedure, for a defined purpose, e.g. quality testing, acceptance of consignments or batch release

Secondary container/packaging (or Outer packaging):

Container that is not in direct contact with the medicine

Shelf-life:

The period of time during which a medicine or related product, if stored correctly, is expected to comply with the specifications as determined by stability studies on a number of batches of the product; the shelf-life is used to establish the expiry date of each batch

Storage:

The storing of medicines and related products from manufacturing up to their point of use

Summary of product characteristics (SmPC):

A document describing the properties and the officially approved conditions of use of a medicine; summaries of product characteristics form the basis of information for healthcare professionals on how to use the medicine safely and effectively

Supplier:

A person or entity engaged in the activity of providing products and/or services; this may be a manufacturer, importer, wholesaler or distributor