GLOSSARY

Active Pharmaceutical Ingredient (API): Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when used so, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body (*WHO Technical Report Series No.970,2012*).

Bulk Product: A product that has completed all processing stages up to, but not including, final packaging.

Contract Manufacturer: Any person who manufactures any product on the order of another person to whom a manufacturer's licence has been issued under these Regulations (*as defined in Regulation 2, CDCR 1984*).

Finished Product: A product that has undergone all stages of production and quality control, including packaging in its final container and labelling.

Licensed Importer: A person to whom an import license has been issued under Regulation 12, CDCR 1984 (*as defined in Regulation 2, CDCR 1984*).

Licensed Manufacturer: A person to whom a manufacturer's licence has been issued under these Regulations, and includes a contract manufacturer (*as defined in Regulation 2, CDCR 1984*).

Licensed Wholesaler: A person to whom a wholesaler's licence has been issued Regulation 12, CDCR 1984 (*as defined in Regulation 2, CDCR 1984*).

Manufacturer: A person carrying out one or more of the steps specified in the definition of manufacture.

Manufacture, in relation to any product includes –

a) The making or assembling of the product;
b) The enclosing or packing of the product in any container in a form suitable for administration or application, and the labelling of the container and;
c) The carrying out of any process in the course of any of the foregoing activities. (*as defined in Regulation 2, CDCR 1984*).

Maximum Residual Limit (MRL): The maximum concentration of residue resulting from the use of a veterinary medicinal product (expressed in mg/kg or g/kg on a fresh weight basis) which may be accepted to be legally permitted or recognised as acceptable in or on a food.

OTC: Refers to Generic product (Non-Scheduled Poison).

Overages of active ingredient: Overages may be used during manufacture. An overage is where the amount of an ingredient added during manufacturing that is greater than the nominated on the product label. Details of the overage used must be available.

Product Owner: A person, company or entity who is the legal/ registered owner of the product formulation and/or process with whom the marketing authorization holder has a contract *(glossary used in ACTD and ACTR).*

Product Registration Holder: The company or corporate or legal entity in the field of pharmaceuticals whose name the marketing authorization has been granted. This party is responsible to all aspects of the product, including quality and compliance with the conditions of marketing authorization. The authorized holder must be subjected to legislation in the country that issued the marketing authorization, which normally means being physically located in that country *(glossary used in ACTD and ACTR)*.

Repacker: *Please refer *"Explanatory Notes for Repackers"* as below

The Authority: Refers to Drug Control Authority (DCA)

The System: Refers to the QUEST system in the NPRA's website

Withdrawal Period: The period between the last administration of the veterinary product to animals under normal conditions of use and the production of foodstuffs from such animals.

EXPLANATORY NOTES FOR REPACKERS

1. Introduction

This chapter is intended to provide guidance to those engaged in repackaging of finished products with the aim to provide information to any person/ establishments who removes finished products from their original container-closure system and repackages them into a different container-closure system for sale and/or for distribution.

2. Objectives

a) To provide uniform guidance and a means of assessing the operations of repackers/ relabelers as they relate to the provisions of the GMP and GDP requirements.
b) To identify the type of repacking activity and whether there is a need to comply with GMP and GDP requirements.

3. Definitions

Terms	Definitions
Manufacture	Manufacture, in relation to any product includes – a) The making or assembling of the product; b) The enclosing or packing of the product in any container in a form suitable for administration or application, and the labelling of the container and; c) The carrying out of any process in the course of any of the foregoing activities.
Packaging	All operations, including filling & labelling, that a bulk product has to undergo in order to become a finished product. Filling of a sterile product under aseptic conditions or a product intended to be terminally sterilized, would not normally be regarded as part of packaging.
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.

Terms	Definitions
Labelling	The term 'labeling' 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 or the outside of the consumer package, is exempted from labelling requirements.
Labeller/ relabeller	A company that affixes the original label to a finished product (i.e labeller) or changes in any way the labelling on a product without affecting the product or its container (i.e. relabeller).
Packaging system	Composed of a container system with its closure. This system may include several layers of protection for the Pharmacopeia preparation along with any sealing devices, delivery devices, labelling and package inserts.
Repacker	A company who removes a finished product from its final packaging and places the finished products into a different container which is labelled or to be labelled before the product is for sale and/or distribution. Repacker may consist of primary and secondary repacker.
Primary repacker	A company who performs repacking activity that places the finished products into a primary/ immediate container which labelled or to be labelled before the product is for sale and/or distribution.
Secondary repacker	A company who does the repacking activity relating to a) labelling of the product container; and/or b) packing the finished product which is already enclosed in its labelled primary container into a carton which is labelled or to be labelled. before the product is for sale and/or distribution.

4. Examples of types of repacking activity

No.	Description of Repacking Activity	Require GMP/GDP Control	Product to be included in Manufacturing License List	Responsibility	Remarks (If any)
1.	Packing/ blistering of imported product (tablet/capsule/liquid/etc.) into a different container	√	√	Primary repacker	
2.	De-blistering of blister strips of tablets/capsules to repack into a new blister pack/container	√	√	Primary repacker	e.g. Blister packs de-blistered and repack into new blister pack due to market purposes, etc.
3.	To form a secondary packaging material (unit box) to pack blister strips, bottles, etc. into this packaging material	√	√	Secondary repacker	e.g. 5 strips in a unit box to be repack to 1 strip in a unit box
4.	To affix an immediate label to a container of product that contains information such as Product Name, Dosage Form, Name of Active Substance(s), Strength of Active Substance(s), Batch Number, Manufacturing Date, Expiry Date, Route of Administration, Storage Condition, etc.	√	√	Primary repacker/ Secondary repacker	Refer Appendix 3 and Section 2; Step 2; Section D: Labelling Requirement for Immediate Labels
5.	To affix label of outer carton that contains information such as Product Name, Dosage Form, Name of Active Substance(s), Strength of Active Substance(s), Batch Number, Manufacturing Date, Expiry Date, Route of Administration, Storage Condition, etc.	√	√	Secondary repacker	Refer Appendix 3 and Section 2; Step 2; Section D: Labelling Requirement for Unit Outer Carton

No.	Description of Repacking Activity	Require GMP/GDP Control	Product to be included in Manufacturing License List	Responsibility	Remarks (If any)
6.	To affix country specific label requirements for Malaysia a) Name & content of preservative(s) where present b) The words “Keep medicine out of reach of children” or words bearing similar meaning in both Bahasa Malaysia & English c) The words “Controlled Medicine/ Ubat Terkawal” (For scheduled poisons only)	√* √* √* √*	X X X X	Importer/ Primary Repacker/ Secondary Repacker	The importer/ repacker shall maintain the relevant documents
7.	To insert new Package Insert/ to change original Package Insert into the inside of the secondary packaging product (unit box)	√	√	Secondary repacker	e.g. Remove Germany package insert from the product and replace with Malaysia specific Package Insert
8.	To attach/ tape Package Insert on the outside of the secondary packaging product (unit box)	√	√	Secondary repacker	
9.	To inkjet the Product Registration Number on the primary/secondary packaging material (unit box)	√	√	Primary/ Secondary repacker	
10.	To inkjet of the Manufacturing Date, Expiry Date and Batch Number on the primary/secondary packaging material (unit box)	√	√	Primary/ Secondary repacker	

No.	Description of Repacking Activity	Require GMP/GDP Control	Product to be included in Manufacturing License List	Responsibility	Remarks (If any)
11.	To affix specific labelling requirement of a product	√	√	Primary/ Secondary repacker	Refer Appendix 3 and Section 2; Step 2; Section D: Labelling Requirements
12.	To affix label 'Diimport/diedarkan oleh' onto the primary/ secondary packaging material	√*	X	Primary/ Secondary repacker/ importer	
13.	To shrink wrap several boxes or bottles together	√*	X	Secondary repacker/ Importer	
14.	To repack finished products into tertiary packaging materials without any changes to the product	√*	X	Secondary repacker/ Importer	
15.	To affix security seal onto the secondary/ tertiary packaging material	√*	X	Secondary repacker/ Importer	

5. Additional notes

5.1 √* denotes that the repacking activity has to be done in a Good Distribution Practise (GDP) controlled or licensed facility.

5.2 The repacking activities as listed in Para 4 is non-exhaustive. Product and license holders shall be responsible to ensure that the registered products are repacked in an appropriate manner and all relevant documents is maintained (batch packaging records/logbooks/inventory records/ procedures).

5.3 The conditions of the product must meet the storage requirements as stated in the Good Distribution Practice Guideline by National Pharmaceutical Regulatory Division (NPRA).

5.4 In deciding whether a particular bulk product is suitable for repacking, the repacker should take into consideration any available information from the manufacturer, published literature and any reference pharmacopoeia.

6. References

6.1 Drug Registration Guidance Document; First Edition; January 2013