APPENDIX 32

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.

Terms	Definitions
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.
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 for human use. 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 for human use.
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 for human use.

4. 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 approved immediate label (D1) to a container of a product	√	√	Primary repacker/ Secondary repacker	Refer to **Appendix 19: General Labelling Requirements** for Immediate Labels
5.	To affix an approved outer carton label (D2) to the packaging of a product	√	√	Secondary repacker	Refer to **Appendix 19: General Labelling Requirements** 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) d) Security label (Hologram)	√* √* √* √*	X X X X	Importer/ Primary Repacker/ Secondary Repacker	The importer/ repacker shall maintain the relevant documents (e.g. hologram records, stock card)
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 to **Appendix 20: Specific Labelling Requirements**
12.	To inkjet/ affix label 'Sample Not For Sale'/ 'Physician's sample not for sale'/ 'Professional sample not for sale'/ etc. onto the secondary packaging material	√*	X	Secondary repacker/ Importer	
13.	To affix label 'Diimport/diedarkan oleh' onto the primary/ secondary packaging material	√*	X	Primary/ Secondary repacker/ importer	
14.	To affix 'Halal' label onto the primary/ secondary packaging material	√*	X	Primary/ Secondary repacker/ importer	
15.	To shrink wrap several boxes or bottles together	√*	X	Secondary repacker/ Importer	
16.	To repack finished products into tertiary packaging materials without any changes to the product	√*	X	Secondary repacker/ Importer	
17.	To repack several registered finished products as a convenient pack for promotional sale only without changing the product immediate and unit outer carton label	√*	X	Secondary repacker/ Importer	Refer to **20.5 Application for a Convenient Pack**
18.	To affix security seal onto the secondary/ tertiary packaging material	√*	X	Secondary repacker/ Importer	
19.	To affix a 'QR code' label for e-labelling onto the outer carton label / immediate label	√	√	Primary/ Secondary repacker	Refer to **Guideline on Electronic Labelling (E-Labelling) for Pharmaceutical Products in Malaysia**

5. ADDITIONAL NOTES

5.1 √* denotes that the repacking activity has to be done in a Good Distribution Practice (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 Good Distribution Practice Guideline
6.2 Control of Cosmetic Products
6.3 USP 31; Volume 1, 2008
6.4 Guidance for Industry Container Closure Systems for Packaging Human Drugs and Biologics; May 1999
6.5 Irish Medicine Boards Guide to Parallel Imports; AUT-G0006-4.9
6.6 WHO GMP: Main Principles for Pharmaceutical Products.