APPENDIX 10 : GUIDELINE ON PATIENT DISPENSING PACK FOR PHARMACEUTICAL PRODUCTS IN MALAYSIA

Outline:

10.1 Purpose
10.2 Objective
10.3 Definition
10.4 Benefits
10.5 Criteria for Implementation of Patient Dispensing Pack
10.6 Products Exempted from this Requirements
10.7 Other Considerations for Implementation
10.8 Implementation Timeline
10.9 Conclusion

10.1 PURPOSE

To provide guidance on the implementation of patient dispensing pack or original dispensing pack for pharmaceutical products in Malaysia.

10.2 OBJECTIVE

Improve patient's safety by:

- maintaining product integrity;
- prevent unnecessary exposure of the product;
- avoid product contamination due to handling especially in non-GMP premise; and
- Fewer steps in dispensing process hence less possibility for errors and improvement in efficiency.

10.3 DEFINITION

Patient dispensing pack or original dispensing pack is a ready-to-dispense pack with sufficient quantity equivalent to an amount not more than one month supply or per treatment for one patient's use.

10.4 BENEFITS

Key benefits identified:

- Ensuring patients on how to take medications and the importance of it, which will eventually increase patient's compliance.
- Clear identification of the medicine, by whom and where it was manufactured.
- Providing complete instructions on the use of the medicine.
- Original packing will maintain the integrity of the pack therefore ensuring the stability of the product.
- Original packing will carry batch number and expiry date.
- Prevent mix-ups (or contamination) during repacking and dispensing.
- Facilitate recall of products since the required information can only be found on the original pack.

10.5 CRITERIA FOR IMPLEMENTATION OF PATIENT DISPENSING PACK

- The patient dispensing pack size should be based on the medication, intended use, recommended dosage and dosage form sufficient for one month supply or per treatment for one patient's use.
- This requirement does not apply for blister or strip pack.
- Maximum permitted supply is one month but may be less depending on the intended use of the medication.
- The Product Registration Holder (PRH) is responsible to justify the proposed patient dispensing pack size based on these criteria as the dosing regimen for certain medication may equate to high numbers of tablets/ capsules. Justification should also address the definition of one month i.e. 28, 30 or 31 days.
- Blister or strip pack are strongly recommended for solid oral dosage forms (e.g. tablets and capsules) and bulk loose pack for supply more than one month are not permitted unless justified by the PRH.
- Oral chemotherapeutics in tablet or capsule must be packed in blister to reduce personnel exposure and presumably risk which can minimise the toxic effect of the chemotherapeutics.

10.6 PRODUCTS EXEMPTED FROM THESE REQUIREMENTS

The requirements do not apply to the following products:

- Injectables, eye, ear and nasal drops, suppositories and pessaries.
- Products for export only (FEO).
- Drug where the risk of issuing more than the amount required by the patient outweigh the benefits of the patient dispensing pack e.g. products containing substances with potential for abuse or cytotoxic agents where precise dosing are required.
- Drugs where the dosing needs to be tailored according to patient's body weight e.g. drugs used in oncology, HIV etc.
- Medically critical products and hospital packs for rare diseases with very low volumes where it is not viable to produce special packs for a single market.
- Products sold with devices with a fixed number of doses
- Situations where a patient dispensing pack is not appropriate will be considered on a case to case basis.

10.7 OTHER CONSIDERATIONS FOR IMPLEMENTATION

VARIATION APPLICATIONS

- Change in patient pack size with or without involving new pack type shall be submitted to Variation Section, Centre for Post Product Registration.

- Supporting documents required are:
  a. Justification for the new pack size and/or type;
  b. Accelerated stability data (3 or 6 months) and stability report for new pack types; and
  c. Commitment to provide complete real time stability data and report when available.

- List of products with recommended pack sizes for oral liquid preparations and dermatological are as in **Table 1** and **Table 2** respectively.

- For tablets and capsules in loose pack, the maximum packing size will depend on the highest dosage and frequency per patient's treatment or one month supply.

10.8 IMPLEMENTATION TIMELINE

- Implementation of patient dispensing pack has been conducted in a phased manner to ensure smooth transition while ensuring no supply disruption to patients. This implementation is effective since 1 March 2008 on a voluntary basis and mandated on 1 September 2008.

- All products manufactured from 1 September 2008 regardless whether it is imported or locally manufactured will need to conform to the principles of this guide.

10.9 CONCLUSION

Patient Dispensing Pack is convenient, safe and improves quality of dispensed medicines. It will increase efficiency in dispensing and improve safety by reducing the risk and possibility of error. It will also result in a reduction in drug waste and better use of resources.

TABLE 1:

Oral Liquid Preparation Maximum Pack Size Recommendations for Pharmaceutical Products

ATC Code	Recommended Pack sizes
R05 Cough & cold preparation R05A Cold preparation R05C Antitussives R05D Expectorants	Max 120ml (except for Pholcodine – Max 90ml)
R06A Antihistamines systemic	Max 120ml (except for Hydroxyzine HCl Syrup - 200ml)
R03 Anti-asthma & COPD products R03A Beta2 stimulants R03B Xanthines (theophyllines) R03C Non-steroidal respiratory anti-inflammatory (ketotifen)	Max 120ml (except for Procaterol - 250ml)
N02B Non-narcotic analgesics	Max 120ml
M01A Antirheumatics non-steroid	Max 120ml
H02 Systemic corticosteroids H02A Plain corticosteroids	Max 120ml
M06A Anti-inflammatory enzymes	Max 500ml
A02A Antacid antiflatulents **A02B Antiulcerants**	Max 250ml
A06A Laxatives	Max 120ml (except for Lactulose - 500ml)

A03 Functional GI disorder drugs A03A Antispasmodic A03E Other GI combinations (Colimix) A03F Gastroprokinetics (Metoclopramide, Motilium) A07 Antidiarrhoea	Max 120ml
A04A Antiemetic + Antinauseants **N07C Antivertigo products**	Max 120ml
N03A Antiepileptics	Max 250ml (Except for Sodium Valproate Syrup - 300ml)
N06A Antidepressant & Mood stabilizer **N06D Anti Dementia** **N07D Anti-Alzheimer products** **N05A Antipsychotics**	Max 250ml Max 20ml for drops
P01B Antihelmintics	Max 60ml
N05C Tranquillizers/ Anxiolytics	Max 250ml
A05B Hepatic protector – lipotropics	Max150ml
J05 Antivirals for systemic use **J05B Antivirals excluding Anti-HIV** **J05C HIV antivirals**	Max 250ml

J01 Antibiotics systemic J01A Tetracyclines & combination J01B Chloramphenicols + combinations J01C1 Oral broad spectrum Penicillins J01D1 Oral Cephalosporins J01E Trimethoprim combinations J01F Macrolides & similar type J01H Medium & narrow spectrum penicillins J01X Other antibiotics **J02A Systemic Antifungals Agents**	Max 120ml
N06D Nootropics **N06E Neurotonics & Miscellaneous**	Max 125 ml
G01A1 Trichomonacides	Max 120ml

TABLE 2:

DERMATOLOGICALS PREPARATION MAXIMUM PACK SIZE RECOMMENDATIONS FOR PHARMACEUTICAL PRODUCTS

ATC Code	Recommended Pack sizes
D01A Antifungals for topical use	Liquid preparation - max 250ml Others - max 60g
D02A Emollients and protectives	Non poisons (liquid preparation) - 250ml Others - 60g (max 500g for emollients) Except D02AC Soft paraffin and fat products and D02AX Other emollients and protectives (Aq. Cream) - max 500g
D03 Preparations for treatment of wounds and ulcers	Max 500ml to 1L ***Notes:*** ▪ Chlorhexidine gluconate aqueous 1L ▪ Povidon 10% 500ml ▪ Povidon-iodine 1L ▪ Dermacyn 500ml ▪ Hydrogen peroxide 1L ▪ Prontosan 500ml ▪ Octenisan 500ml ▪ Acetic acid 500ml ▪ Cetrimide 500ml

ATC Code	Recommended Pack sizes
D04A Antipruritics, anesthetics, etc. Except D04AA Antihistamines for topical use (not allowed for registration)	Liquid – max 250ml Others – 60g
D05A Antipsoriatics for topical use	Liquid – max 500ml (with a dispenser). Others – max *500g Bar – max 100g ***Notes:*** ▪ Tar Preparations ▪ Coal Tar Ointment/ Solution ▪ Liquor Picis Carbonis (LPC) 500g ▪ Dithranol Ointment 500g ▪ Cocois Co Lotion 500ml
D06A Antibiotics for topical use	Max 20g Except D06BB Antivirals - Max 10g D06B A 01 Silver Sulphadiazine for management of burns - 500g

ATC Code	Recommended Pack sizes
D07A Corticosteroids, plain	
D07AA Corticosteroids, weak (group I)	D07AA – Max 100g to **500g
D07AB Corticosteroids, moderately potent (group II)	D07AB – Max 50g to **500g
D07AC Corticosteroids, potent (group III)	D07AC – Max 15g to 100g
D07AD Corticosteroids, very potent (group IV)	D07AD – Max 15g to 100g
	** ***Note:*** Pack size of 500g is for hospitals and skin specialist clinics use.
D07C Corticosteroids, combinations with antibiotics	
D07CA Corticosteroids, weak, combinations with antibiotics	D07CA - Max 100g
D07CB Corticosteroids, moderately potent, combinations with antibiotics	D07CB - Max 50g
D07CC Corticosteroids, potent, combinations with antibiotics	D07CC - Max 15g
D07CD Corticosteroids, very potent, combinations with antibiotics	D07CD - Max 15g
D08A Antiseptics and disinfectants	Liquid antiseptics/ disinfectants - 1Litre Others - max 60g

ATC Code	Recommended Pack sizes
D10A Anti-acne preparations for topical use Except for D10AA Corticosteroids, combinations for treatment of acne	Liquid preparation - max 250ml (recommended to be used with a dispenser) Bar - max 100g All others - max 60g
D11AF Wart and anti-corn preparations	Max 15ml
M02A Topical products for joint and muscular pain	Liquid – 250ml Others, Max – 60g
D11AX11 Hyperpigmentation	Max 60g

Reference: Circulars

i) (Bil 16) dlm bpfk02/5/1.3.pdf
Kawalan Saiz Pek Persediaan Ubat Batuk Mengandungi Pholcodine (13 October 2003)

ii) Bil (22) dlm BPFK/02/5/1.3.pdf
Lanjutan Tempoh Untuk Menarik Balik Saiz Pek Persediaan Ubat Batuk Mengandungi Pholcodeine Yang Melebihi 90mL Dari Pasaran (07 November 2003)

iii) Bil (21) dlm.BPFK/02/5/1.3.pdf
Kawalan Penetapan Saiz Pek Maksima Bagi Semua Persediaan Ubat Batuk (07 November 2003)

iv) Bil (24) dlm BPFK/02/5/1.3.pdf
Pindaan Kepada Kawalan Penetapan Saiz Maksima Bagi Semua Persediaan Ubat Batuk (08 March 2004)

v) (1) dlm. BPFK/02/5/1.4
Perlaksanaan Konsep Pek Saiz Pesakit (Patient Pack Size) bagi Produk Farmaseutikal (20 February 2008)

vi) Bil (4) dlm BPFK/PPP/01/03 Jld 1
Direktif Justifikasi Untuk Perubahan Pek Saiz Pesakit Untuk Penyakit Kulit Tertentu Bagi Produk-produk Dermatologi (14 December 2010)