APPENDIX 23

PATIENT DISPENSING PACK FOR PHARMACEUTICAL PRODUCTS

Contents:

1. PURPOSE

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

2. OBJECTIVES

Improve patient safety by:

- maintaining product integrity;
- preventing unnecessary exposure of the product;
- avoiding product contamination due to handling, especially in non-GMP premise; and
- having fewer steps in the dispensing process to minimise errors and improve efficiency.

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.

4. BENEFITS

Key benefits include:

- Improving medication adherence by ensuring that patients know how to take their medications and the importance of their medicines
- Facilitating identification of the medicine with manufacturer's information
- Providing complete instructions on how to take the medicine
- Ensuring the stability of the product because the original packaging will maintain the integrity of the pack
- Preventing mix-ups (or contamination) during repacking and dispensing
- Facilitating recall of products because the required information can only be found on the original packaging. The original packaging will have the batch number and expiry date information

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.
- The 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 for justifying the proposed patient dispensing pack size based on these criteria as the dosing regimen for certain medications may equate to large amounts of tablets/ capsules. The justification provided should also define one month supply, whether for 28, 30 or 31 days.
- Blisters or strip packs are strongly recommended for solid oral dosage forms (e.g. tablets and capsules). Bulk loose pack for supply of more than one month is not permitted unless properly justified by the PRH.
- Oral chemotherapeutics in tablet or capsule must be packed in blisters to reduce personnel exposure and presumable risk to minimise the toxic effect of the chemotherapeutics.

6. EXEMPTED PRODUCTS

These 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 in 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.

7. OTHER CONSIDERATIONS FOR IMPLEMENTATION

VARIATION APPLICATIONS

- Change in patient pack size (regardless of whether a new pack type is involved) shall be submitted to the Variation Unit, Centre of Product & Cosmetic Evaluation (PPPK).

- The following supporting documents are required:
  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.

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

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

8. IMPLEMENTATION TIMELINE

- Implementation of patient dispensing pack has been conducted in a phased manner to ensure smooth transition and prevent supply disruption to patients. This implementation was made effective on 1 March 2008 on a voluntary basis and mandated on 1 September 2008.

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

9. CONCLUSIONS

Patient Dispensing Pack is convenient, safe and improves the quality of dispensed medicines. It increases efficiency in dispensing and improves patient safety by reducing the risk and possibility of error. It also reduces drug waste and promotes better use of resources.

TABLE 1:

Recommended Maximum Pack Sizes for Pharmaceutical Oral Liquid Preparation

ATC Code		Recommended Maximum Pack Sizes
R05	**Cough & cold preparation**	120ml (except for Pholcodine –90ml)
R05A	Cold preparation	
R05C	Antitussives	
R05D	Expectorants	
R06A	**Antihistamines systemic**	120ml (except for Hydroxyzine HCl Syrup - 200ml)
R03	**Anti-asthma & COPD products**	120ml (except for Procaterol - 250ml)
R03A	Beta2 stimulants	
R03B	Xanthines (theophyllines)	
R03C	Non-steroidal respiratory anti-inflammatory (ketotifen)	
N02B	**Non-narcotic analgesics**	120ml
M01A	**Antirheumatics non-steroid**	120ml
H02	**Systemic corticosteroids**	120ml
H02A	Plain corticosteroids	
M06A	**Anti-inflammatory enzymes**	500ml
A02A	**Antacid antiflatulents**	250ml
A02B	**Antiulcerants**	
A06A	**Laxatives**	120ml (except for Lactulose - 500ml)
A03	**Functional GI disorder drugs**	120ml
A03A	Antispasmodic	
A03E	Other GI combinations (Colimix)	
A03F	Gastroprokinetics (Metoclopramide, Motilium)	
A07	Antidiarrhoea	
A04A	**Antiemetic + Antinauseants**	120ml
N07C	**Antivertigo products**	
N03A	**Antiepileptics**	250ml (Except for Sodium Valproate Syrup - 300ml)

ATC Code	Recommended Maximum Pack Sizes
N06A Antidepressant & Mood stabilizer **N06D Anti Dementia** **N07D Anti-Alzheimer products** **N05A Antipsychotics**	250ml
P01B Antihelmintics	60ml
N05C Tranquillizers/ Anxiolytics	250ml
A05B Hepatic protector – lipotropics	150ml
J05 Antivirals for systemic use J05B Antivirals excluding Anti-HIV J05C HIV antivirals	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**	120ml
N06D Nootropics **N06E Neurotonics & Miscellaneous**	125 ml
G01A1 Trichomonacides	120ml

TABLE 2:

RECOMMENDED MAXIMUM PACK SIZES FOR PHARMACEUTICAL DERMATOLOGICAL PREPARATION

ATC Code	Recommended Maximum Pack Sizes
D01A Antifungals for topical use	Liquid preparation - 250ml Others - 60g
D02A Emollients and protectives	Non poisons (liquid preparation) - 250ml Others - 60g (500g for emollients) Except D02AC Soft paraffin and fat products and D02AX Other emollients and protectives (Aq. Cream) - 500g
D03 Preparations for treatment of wounds and ulcers	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
D04A Antipruritics, anesthetics, etc. Except D04AA Antihistamines for topical use (not allowed for registration)	Liquid –250ml Others – 60g

ATC Code	Recommended Maximum Pack Sizes
D05A Antipsoriatics for topical use	Liquid –500ml (with a dispenser). Others –*500g Bar –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	20g Except D06BB Antivirals - 10g D06B A 01 Silver Sulphadiazine for management of burns - 500g
D07A Corticosteroids, plain D07AA Corticosteroids, weak (group I) D07AB Corticosteroids, moderately potent (group II) D07AC Corticosteroids, potent (group III) D07AD Corticosteroids, very potent (group IV)	D07AA –100g to **500g D07AB –50g to **500g D07AC –15g to 100g D07AD –15g to 100g ** ***Note:*** Pack size of 500g is for hospitals and skin specialist clinics use.

ATC Code	Recommended Maximum Pack Sizes
D07C Corticosteroids, combinations with antibiotics D07CA Corticosteroids, weak, combinations with antibiotics D07CB Corticosteroids, moderately potent, combinations with antibiotics D07CC Corticosteroids, potent, combinations with antibiotics D07CD Corticosteroids, very potent, combinations with antibiotics	D07CA - 100g D07CB - 50g D07CC - 15g D07CD - 15g
D08A Antiseptics and disinfectants	Liquid antiseptics/ disinfectants - 1Litre Others - 60g
D10A Anti-acne preparations for topical use Except for D10AA Corticosteroids, combinations for treatment of acne	Liquid preparation - 250ml (recommended to be used with a dispenser) Bar - 100g All others - 60g
D11AF Wart and anti-corn preparations	15ml
M02A Topical products for joint and muscular pain	Liquid – 250ml Others, – 60g
D11AX11 Hyperpigmentation	60g

References:

i. *Bil. (16) dlm. BPFK/02/5/1.3*
Kawalan Saiz Pek Persediaan Ubat Batuk Mengandungi Pholcodine (13 October 2003)

ii. *Bil. (22) dlm. BPFK/02/5/1.3*
Lanjutan Tempoh Untuk Menarik Balik Saiz Pek Persediaan Ubat Batuk Mengandungi Pholcodeine Yang Melebihi 90mL Dari Pasaran (7 November 2003)

iii. *Bil. (21) dlm. BPFK/02/5/1.3*
Kawalan Penetapan Saiz Pek Maksima Bagi Semua Persediaan Ubat Batuk (7 November 2003)

iv. *Bil. (24) dlm. BPFK/02/5/1.3*
Pindaan Kepada Kawalan Penetapan Saiz Maksima Bagi Semua Persediaan Ubat Batuk (8 March 2004)

v. *Bil. (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)