Pihak Berkuasa Kawalan Dadah
Drug Control Authority
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

Ruj. Kami : (1)dlm.BPFK/02/5/1.4
Tarikh : 20/02/08

SEMUA PEMEGANG PENDAFTARAN

Tuan,

PERLAKSANAAN KONSEP PEK SAIZ PESAKIT (PATIENT PACK SIZE) BAGI PRODUK FARMASEUTIKAL

Adalah saya dengan segala hormatnya merujuk kepada keputusan Mesyuarat Pihak Berkuasa Kawalan Dadah (PBKD) kali ke **201** yang telah diadakan pada **31 JANUARI 2008** mengenai perkara di atas.

2. Pihak PBKD di dalam mesyuarat tersebut telah memutuskan:
   a) Untuk menetapkan keperluan **saiz pek maksima** ke atas **produk farmaseutikal** bagi **kategori tablet/kapsul, persediaan cecair oral dan persediaan untuk kegunaan luaran**.
   b) Perlaksanaan tersebut adalah berdasarkan garis panduan yang telah ditetapkan seperti di **LAMPIRAN 1, 2** dan **3**.
   c) Ia akan mula dilaksanakan secara voluntari pada **1 MAC 2008** dan berkuatkuasa secara wajib pada **1 SEPTEMBER 2008.**
   d) Pengilangan pek besar sama ada bagi produk import atau tempatan perlu dihentikan bermula dari tarikh perlaksanaan mandatori tersebut.

3. Pihak Pemegang pendaftaran produk adalah diarahkan untuk mematuhi arahan ini.

Sekian, terima kasih.

" BERKHIDMAT UNTUK NEGARA "
" UTAMAKAN KUALITI , EFIKASI , DAN KESELAMATAN "

Saya yang menurut perintah,

(ABIDA SYED M HAQ)
Setiausaha
Pihak Berkuasa Kawalan Dadah
Kementerian Kesihatan Malaysia.
fmdff/-310108- DCA\Pekeliling\2008\DCA201

s.k:

1. Pengarah Perkhidmatan Farmasi, Program Perkhidmatan Farmasi, KKM.
2. Pengarah Regulatori Farmasi, Biro Pengawalan Farmaseutikal Kebangsaan, KKM.
3. Timbalan Pengarah Pusat Kawalan Kualiti, BPFK, KKM.
4. Ketua Pusat Komplians & Pelesenan, BPFK, KKM.
5. Ketua Pusat Pembangunan Organisasi (PPO), BPFK.
6. Ketua Pusat Pasca Pendaftaran Produk (PPPP), BPFK.
7. Pharmaceutical Association of Malaysia (PhAMA).
8. Persatuan Industri Farmaseutikal Malaysia (MOPI).

LAMPIRAN 1

GUIDE FOR IMPLEMENTATION OF PATIENT DISPENSING PACK FOR PHARMACEUTICAL PRODUCTS IN MALAYSIA

Purpose

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

Strategic Objective

Improve patient safety by:

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

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's supply or per treatment for one patient's use.

Benefits

Key benefits identified:

- Ensuring patients recognise how to take medications and the need to take medications which will increase compliance.
- Clearly identifying 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 stability.
- Original packing will carry batch number and expiry dates.
- Prevent mix-ups (or contamination) during repacking and dispensing.
- Facilitate recall of products since the required information can be found on the packs.

Criteria for implementation of patient dispensing packs

- The patient dispensing pack size should be based on the medication, intended use, recommended dosage and dosage form sufficient for one month's supply or per treatment for one's patient's use,
- This guide does not apply to blister or strip packing.
- Maximum permitted supply is one month but may be less depending on the intended use of the medication.
- The Marketing Authorization Holder (MAH) is responsible to justify the proposed patient dispensing pack size based on these criteria as the dosing regime for certain medication may equate to high numbers of tablets/capsules. Justification should also address the definition of one month's i.e. 28, 30 or 31 days.

- Blister or strip packing is strongly encouraged for solid oral dosage forms (e.g. tablets and capsules) and bulk loose packs for supply more than a month are not permitted unless justified by the MAH.

Situations where patient dispensing pack is not appropriate/applicable

- Injectables , eye, ear and nasal drops, suppositories and pessaries.
- Products for export.
- Products under existing tender supply to government institutions (until tender expiry).
- Drugs, 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 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 are excluded from this requirement.
- Situations where a patient dispensing pack is not appropriate will be considered on a case to case basis.

Other Considerations for Implementation

1. Variation Applications
Variations to introduce a patient pack size may or may not involve a new pack type. All variations need to be submitted to the Variations Unit, Centre for Post Registration.

Supporting documentation required is:

- Justification for the new pack size and/or type,
- Accelerated stability data (3 or 6 months) and stability report for new pack types,
- Commitment to provide complete real time stability data and report when available.

2. List of products with recommended pack sizes for oral liquid preparations and dermatologicals are as attached in **Appendix A** and **Appendix B** respectively.

3. 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 .

Implementation Timeline

- Implementation of patient dispensing pack needs to be conducted in a phased manner as defined by the MAH to ensure smooth transition while ensuring no disruption in supply to patients. Patients dispensing packs are effective 1 March 2008 on a voluntary basis and mandated from 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.

- Current bulk packs or non patient dispensing packs already in the market will not need to be recovered from the market but will be allowed to be depleted.

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 errors. It will also result in a reduction in drug waste and better use of resources.

LAMPIRAN 2

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 – 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

LAMPIRAN 3

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 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 120ml
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 60g Bar – max 100g
D06A Antibiotics for topical use	Max 20g Except D06BB Antivirals - Max 10g D06B A 01 Silver sulphadiazine for management of burns – 500g
D07A Corticosteroids, plain 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 – Max 100g D07AB – Max 50g D07AC – Max 15g D07AD – Max 15g
D07C Corticosteroids, combinations with antibiotics D07CA Corticosteroids, weak, combinations with antibiotics D07CB Corticosteroids, moderately potent,	 D07CA – Max 100g D07CB – Max 50g D07CC – Max 15g D07CD – Max 15g

combinations with antibiotics D07CC Corticosteroids, potent, combinations with antibiotics D07CD Corticosteroids, very potent, combinations with antibiotics	
D08A Antiseptics and disinfectants	Liquid antiseptics/disinfectants – 1L Others – max 60g
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