PHARMACY BULLETIN

Pharmacy Department,
Hospital Canselor Tuanku Muhriz

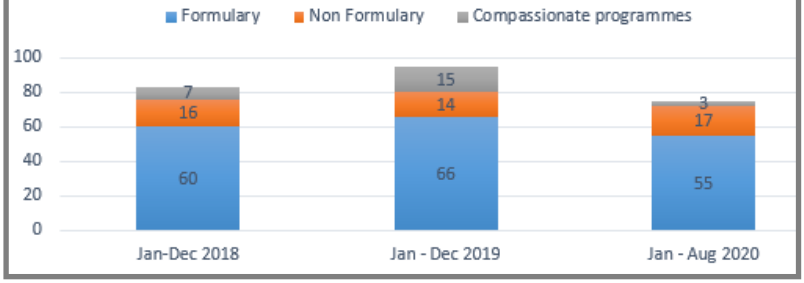
Edition 20, Issue 4

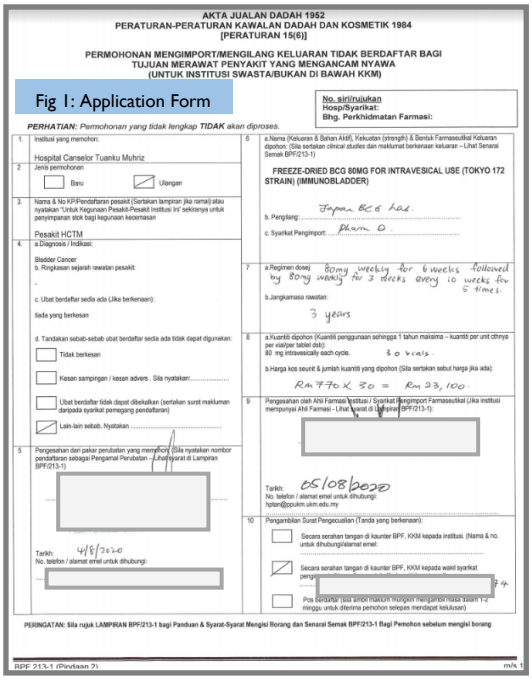
UNREGISTERED PRODUCTS : THINK TWICE BEFORE IMPORTING

Registered products are products approved by the Drug Control Authority (DCA) following the evaluation for **quality, safety and efficacy** by the National Pharmaceutical Regulatory Agency (NPRA), whereas unregistered products are products that have not been approved by the DCA for sale or use in Malaysia. Without that approval or licensure, a manufacturer may not distribute the product except for use in the clinical trials. However, exceptions apply under certain circumstances where importation of unregistered products are permitted for life-saving purposes, and when access to investigational drugs are required as compassionate use.

In HCTM, there have been increasing number of applications for unregistered alternatives which require an import permit. **Unregistered** medical products do not undergo safety and efficacy evaluation by the National Regulatory Authority for the market in which they are marketed. Their use should only be brought into Malaysia for life-saving purposes if the current available drugs have failed. In the recent years, many registered products have been deregistered owing to low sales, hence Pharmacy will source for items via this pathway.

Graph I: UNREGISTERED ITEMS ACCORDING TO NUMBER OF APPLICATIONS PER YEAR




AKTA JUALAN DADAH 1952
PERATURAN-PERATURAN KAWALAN DADAH DAN KOSMETIK 1984
[PERATURAN 15(6)]

PERMOHONAN MENGIMPORT/MENGILANG KELUARAN TIDAK BERDAFTAR BAGI TUJUAN MERAWAT PENYAKIT YANG MENGANCAM NYAWA (UNTUK INSTITUSI SWASTA/BUKAN DI BAWAH KKM)

Fig 1: Application Form

*Any person who wishes to import any product solely for the purpose of treatment of any person suffering from a life-threatening illness may on application be exempted by the Director of Pharmaceutical Services from the provision of regulation 7(1) subject to such condition or restrictions as he may impose in such exemption. (**Sales of Drugs Act 1952**)*

Each application must be accompanied by a strong justification on the Application Form (Fig 1)why an unregistered product is needed :

i) failed existing treatment options

ii) experienced severe adverse effects to existing medications.

It should be understood that the prescriber's responsibility and potential liability are increased when prescribing unregistered medicines as the safety, quality and efficacy has not been assessed by the Regulatory Agency.

> The use of unregistered medicinal products should only be considered for life -saving therapies or where there is an unmet medical need such as in situations where a there is absence of registered treatment option, and the patient's health will be clinically compromised without treatment with the unregistered product.


AKTA JUALAN DADAH 1952
PERATURAN-PERATURAN KAWALAN DADAH & KOSMETIK 1984
(Peraturan 15(6))

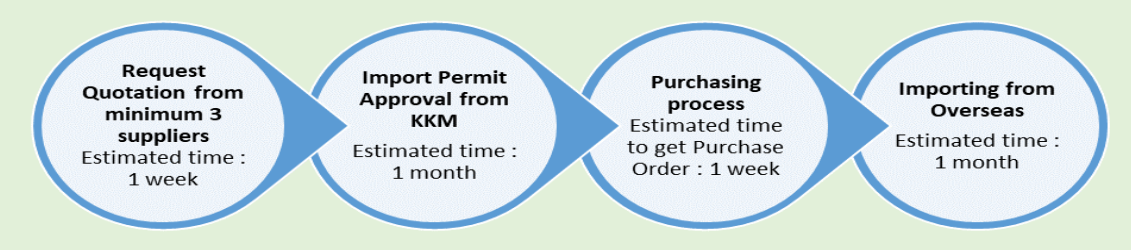
PENGECUALIAN UNTUK MENGIMPORT KELUARAN TIDAK BERDAFTAR BAGI TUJUAN RAWATAN PENYAKIT YANG MENGANCAM NYAWA (No. Siri: 1482/20)

Fig 2: Import Permit

Exemption approval by Director-General of Health or Senior Director of Pharmaceutical Services must be obtained for each of the unregistered therapeutic product before it can be imported into Malaysia. Once approved, an official import permit (Fig 2) will be issued out, which can then be used to bring the drug into the country . Regulatory/Enforcement pharmacists at all entry ports (airports/ports/borders) will inspect and endorse entry of unregistered products by checking all relevant information eg : formulation / dose/ quantity/ importing company etc before allowing product entry into Malaysia. The maximum quantity of each consignment cannot exceed the total amount approved in the import permit and validity of the approved import permit is for a maximum of one year. Hence, that is why the process will take 2-3 months for drug arrival.

Examples of unregistered products in HCTM includes : Vasopressin inj, Phenylephrine inj, Papaverine inj, Bactrim (Sulphamethoxazole/Trimethoprim) inj, Urokinase Inj, Acetazolamide Inj, Pamidronate Inj, Thiamine Inj, Cyclophosphamide Tab , Ketoconazole Tab , Mitotane Tab, Phosphate Sandoz Tab , Diazoxide Tab, Pyrimethamine Tab, Flucytosine Tab etc.

Fig 3: Timeline of Approval and Importation



Drug arrival is usually after 2-3 months as approval for import permit will take some time at the National Pharmaceutical Control Bureau level. Applications will be rejected if there is an existing registered item in Malaysia. So, much consideration is needed to be taken before importing the drug into the country to ensure quality and safe use of drugs.

Manufacturer Problem with Lubricant Eye Gel

LUBRICANT EYE GEL, 10G (GENTEAL GEL) : shortage for the past few months due to manufacturer problem .

Alternative :

Siccapos® Gel. *(Please indent under : LUBRICANT EYE GEL)*

Active ingredient: Polyacrylic acid (Carbomer 980).

Therapeutic indications: Artificial tear solution during tear deficiency and dry eye.

Shelf Life : 4 weeks after opening

Storage: do not store above 25°C

Only one brand will be made available at any one time depending on stocks availability from manufacturer.

DRUGS AND THERAPEUTICS (JKTU) MEETING

14th July 2020

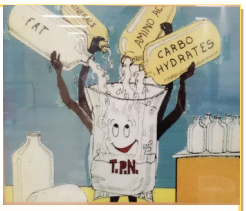
New Drug Listing Policies in Kedai NF

The items below will **not be** enlisted for sale in Kedai NF:

- Herbals (Urticor Nasal Spray , Tribestan 250mg Tab)
- Supplements (Eg: Legalon liver tonic, cranberry extract 18%, Medikril Omega 3))
- Drugs with generic alternatives in PPUKM Formulary (Eg : Lipitor/ Keppra/ Fastum gel)
- Items listed under Medical Device Act (intra-articular injections)

Pharmacy System :

Updates in TPN Indenting



CENTRAL LINE	PERIPHERAL LINE
Solutions of mixtures with an osmolarity above 800 mosmol/L	**Solutions of mixtures with an osmolarity < 800 mosmol/L**
Fat emulsion source: Soy bean oil & MCT	
TPN CENTRAL 1.25L	**TPN PERIPHERAL** 1.25L
With fish oil (amino acid/glu/fat emulsion)* *Fat emulsion source: soy bean oil/MCT/ olive oil/fish oil* OMEGA-3	
SMOFKABIVEN **CENTRAL** 1477ML	**SMOF**KABIVEN **PERIPHERAL** 1477ML
NUTRIFLEX LIPID SPECIAL 625ML (amino acid/glu/fat emulsion#) -for fluid restricted/IDPN/ critically ill #Fat emulsion source: soy bean oil & MCT	Not for peripheral line
IMMUNONUTRIENTS	
DIPEPTIVAN 100ML (L-Alanyl-glutamine concentrated solution) For peripheral infusion, dilute 100ml Dipeptiven + 100ml Saline and infuse continuously over 20-24 hours per day	

IDPN= intradialytic parenteral nutrition; TPN= Total Parenteral Nutrition; MCT= Medium Chain Triglycides

For any enquiries please consult your TPN Pharmacist (ext 6702)

References:
Garis Panduan Permohonan Memperolehi dan Menggunakan Ubat ubatan Yang Memerlukan Kelulusan Khas Ketua Pengarah Kesihatan (KPK) / Pengarah Kanan Perkhidmatan Farmasi (PKPF)
https://www.hsa.gov.sg/therapeutic-products/register/special-access-routes/import-for-patients
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Imported unlicensed medicines: recurrent and current examples. The Pharmaceutical Journal . Dec 2008

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PPUKM Formulary App is now available on:

A publication of Drug Information Centre

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