National Pharmaceutical Control Bureau
Ministry of Health Malaysia

GUIDANCE ON CLASSIFICATION

This is a 'Guidance Note' for applicant/ Marketing Authorization Holder (MAH) who wishes to register product with National Pharmaceutical Control Bureau (NPCB).

The applicant/Marketing Authorization Holder (MAH) must ensure the product has fulfilled the definition of product which is under control of the Drug Control Authority (DCA), in order to be registrable with NPCB.

1. What is Product?

The Control of Drugs and Cosmetics Regulation 1984 (Amendment 2009)

"product" as defined in the Regulations, means

- a drug in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a medical purpose;
- a drug to be used as an ingredients of a preparation for a medicinal purpose.

The Sale of Drugs Act 1952 (Revised-1989)

- "drug" includes any substance, product or article intended to be used or capable, or purported or claimed to be capable of being used on humans or any animal, whether internally or externally for a medicinal purposes.
- "medicinal purpose" means any of the following purposes:

  (a) allevating, treating , curing or preventing a disease or a pathological condition or symptoms of a disease;
  (b) diagnosing a disease or ascertaining the existence, degree or extent of a physiological or pathological condition;
  (c) contraception;
  (d) inducing anaesthesia;
  (e) maintaining, modifying, preventing, restoring, or interfering with, the normal operation of a physiological function;
  (f) controlling body weight;
  (g) general maintainance or promotion of health or wellbeing

2. Why Do We Need To Register?

The Control of Drugs and Cosmetic Regulations 1984 was promulgated under the Sale of Drugs Act 1952 (Revised 1989)
SUB REGULATION 7(1)

No person shall manufacture, sell, supply, import, possess or administer any product unless, the product is a registered product; and the person holds the appropriate license required and issued under these Regulations.

3. Laws & Regulations

- Registration of Pharmacists Act 1951 (rev. 1989)
- Poisons Act 1952 (rev. 1989)
- Sale of Drugs Act 1952 (rev. 1989)
- Control of Drugs and Cosmetics Regulations 1984
- Dangerous Drugs Act 1952 (rev. 1980)
- Medicines (Advertisement and Sale) Act 1956 (rev. 1983)
- Others - Patent Act 1983, Trade Description Act 1972, Pesticides Act 1974, Food Act 1983 and Food Regulations 1985

4. Product Code & Maintenance of Registration

Product Code

a) Medicine

- **Registration number: MALyymm$$$$##**
- **Code(##)**
  A:Scheduled Poisons/NCE/biotech
  X: Non-scheduled Poisons (over the counter products)
  N: Health Supplement (starting 2011)
  T: Traditional Medicines
  H: Veterinary Product
  C: Contract Manufactured
  E: Export Only
  R: Repacked
  S: Second source

b) Cosmetic (starting 2008)

- **Notification number : NOTyymm$$$$$K**

Legend:
y: year m: month $: serial number

Maintenance of Registration

- **Validity period of registration – 5 years**
- **Renewal of product registration should be done not later than 6 month prior to expiry of product registration**

5. Product Classification

Generally, a product can falls under four groups:

1. Medicine 2. Food-Drug Based 3. Medical Device-Drug Based 4. Cosmetic

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1) MEDICINE

There are 6 categories of medicine product:

New Chemical Entities (NCE), Biotechnology product, Generic Product (poison / non poison), Health Supplement product, Traditional product and Veterinary Product.

A) NCE –

- a new chemical entity or a biological entity
- a new combination of existing chemical/biological entity(s);
- existing chemical or biological entity(s) in a new dosage form
- existing chemical or biological entity(s) for use by a different route of administration

NOTE : you can check whether or not the active substance have been registered by visiting our website at www.bpfk.gov.my → Product Registered Search.

B) BIOTECH –

- Includes the use of the new genetic tools of **recombinant DNA** to make new genetically modified organisms or genetic engineering, bioinformatics, transformation, diagnostics and vaccine technology.
- Biological products include, but are not limited to, **bacterial and viral vaccines, therapeutic serums, antitoxins, human blood components** and their derivatives, and certain products produced by means of biotechnology.

C) GENERIC –

- a generic product is a product that is essentially similar to a currently registered product in Malaysia. The term generic is not applicable to biological & biotechnology products

i) POISON : Products registrable under Phase 1 are pharmaceutical products which contain scheduled poison(s) as defined in the POISON ACT 1952

(please refer to www.pharmacy.gov.my → Services → Poison Board → Poison List)

ii) NON-POISON (OTC): Other than listed in the scheduled poison list under POISON ACT 1952

OTC – Abridge Evaluation

- ✓ Lozenges/pastilles
- ✓ Topical analgesic/counter-irritants
- ✓ Topical nasal decongestants
- ✓ Emollient/demulcent/protectants
- ✓ Keratolytics

OTC – Full Evaluation

- ✓ OTC other than listed above
  Example: Internal product
  (oral e.g glucosamine tablet)
- ✓ Antifungal

D) HEALTH SUPPLEMENT (HS) –

- ❖ Products that are intended to **supplement the diet** taken by mouth in forms such as pills, capsules, tablets, liquids or powders and not represented as conventional food/sole item of a meal or diet.
- ❖ Please refer to www.bpfk.gov.my → Regulatory Information → Drug Registration Guidance Document (DRGD) → Appendix 9
- ❖ If a product contains **combination of traditional and health supplement** ingredients, the product is considered HS.

Note : Please be informed that products contain active ingredient listed in 'Drug Registration Guidance Document' Appendix 9 List A & B are under control of Health Supplement Unit. It is advisable for you to provide acceptable safety profile, clinical study or justification to support the combination of ingredients that are NOT listed in List B upon registration. Failure to do so may result in REJECTION of product registration application.

E) VETERINARY –

- ❖ " Any drug which includes any substance, product or article, intended to be used, or capable or purpoted or claimed to be capable of being used on human or **any animal** whether internally or externally, for a medicinal purpose"
  (from REGOVP : Registration Guideline of Veterinary Products)
- ❖ Please refer to www.bpfk.gov.my → Veterinary

F) TRADITIONAL -

- Traditional medicine is defined as any product used in the practice of indigenous medicine, in which the drug consists solely of one or more naturally occurring substances of a plant, animal or mineral, or parts thereof, in the unextracted or crude extract form and a homeopathic medicine.
- Please refer to www.bpfk.gov.my → Regulatory Information → Drug Registration Guidance Document (DRGD) → Appendix 12.

Eg. Registrable Traditional Medicine Products

- **Pharmaceutical dosage form** (eg. pill, tablet, cream, etc) that contains single or in combination of natural ingredients.
- **External use** of traditional medicine that contains combination of traditional medicine and the following ingredients as excipient:
  - e.g. Camphor, menthol
- Traditional medicine that combine with one or more other excipients.
- **Plaster form** of traditional medicine that contain natural ingredients/ extract from plants, animals and minerals.
- **Herbal tea** based on 20/80%, the active ingredients other than camelia sinensis (green tea) is more than 20%.
- **Wine** that contain traditional medicine or have therapeutic claims.
- **Homeopathic medicine** that exists in pharmaceutical dosage form and whereby the ingredients are used in Homeopathic Medicine System. (Please refer to www.bpfk.gov.my →Regulatory Information → Circulars → "Garispanduan Pendaftaran Produk Homeopati" Ruj: Bil (5) dlm BPFK/PPP/01/03 Jld 1).

Eg. Non- Registrable Traditional Medicine Products

- **Extemporaneous medicine** that practiced by herbalist.
- Herbal medicine that contains certain ingredients or mixture of plants, animals, minerals in which only for the process of **drying, grinding, blending.**
- Herbal medicine that contains certain ingredients or mixture of plants, animals, minerals or extract that mainly **used as food, spices or flavoring without therapeutic labeling.**
- **Premix** (Please refer to www.bpfk.gov.my →Regulatory Information → Circulars → Larangan Penggunaan Bahan 'Premix' dalam Formulasi Produk Semulajadi (Tradisional); Ruj: Bil (71) dlm BPFK/02/5/1.3.

2) FOOD-DRUG BASED

A) FOOD

- A product is considered as food if the active ingredient is less than 20%
- The food based ingredient is more than 80%
- It is not in pharmaceutical dosage form such as capsule, softgel, swallowed whole tablet.

Note : It is advisable that the company change the dosage form to classify a product as food if the food ingredient is more than 80% (e.g liquid, powder etc)

If a product categorised as food, please refer to:

Food Safety & Quality (FSQ) Division, Ministry of Health
Aras 4, Bangunan Plot 3C4, No. 26, Jalan Persiaran Perdana,Presint 3, 62675 Putrajaya.
(http://www.fsq.moh.gov.my)

NOTE: Criteria for Food-Drug Based Classification is subject to change in accordance to decision made in Food Drug Interphase (FDI) meeting held at least twice annually.

B) DRUG/ MEDICINE

- A product is considered as drug/medicine if the active ingredient is more than 20%.
- It is in pharmaceutical dosage form (e.g capsule, softgel, swallowed whole tablet).

Note : If the product is considered as drug/medicines, the applicant/ MAH are responsible to fulfill all requirements of registration in Drug Registration Guidance Document (DRGD). Please refer to www.bpfk.gov.my → Regulatory Information → Drug Registration Guidance Document (DRGD).

TRADITIONAL

- A product falls under category of traditional if it fulfills the definition of traditional product (please refer, **5. Product Classification** →Medicine, F)

HEALTH SUPPLEMENT (HS)

- A product falls under category of Health Supplement if it contains ingredients listed in Appendix 9 (please refer, **5. Product Classification** →Medicine, D)
- If a product is a **combination of traditional and health supplement** ingredients, the product is considered HS.

Note : Please be informed that products contain active ingredient listed in 'Drug Registration Guidance Document' Appendix 9 List A & B are under control of Health Supplement Unit. It is advisable for you to provide acceptable safety profile, clinical study or justification to support the combination of ingredients that are NOT listed in List B upon registration. Failure to do so may result in REJECTION of product registration application.

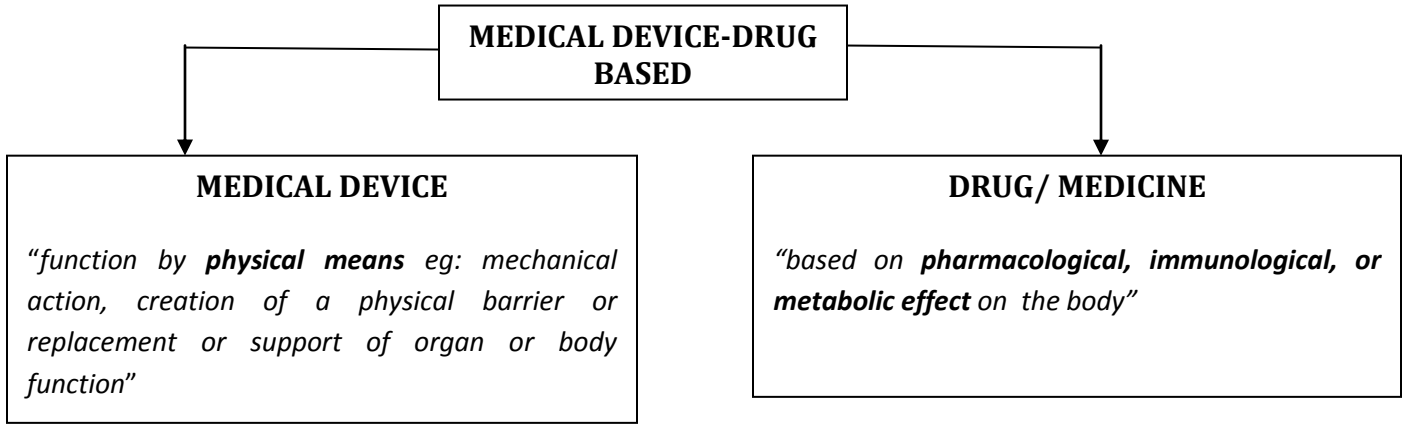
3) MEDICAL DEVICE-DRUG BASED

A medical device- drug product is classified based on three criteria's:

1) Whether or not the product **contains poison** ingredients (please refer to www.pharmacy.gov.my → Services → Poison Board → Poison List).

   If the product contains poison, then it is likely to be classified as drug/ medicine controlled by DCA, registrable with NPCB.

2) The **intended purpose** and the **Mechanism of Action (MOA)** of the product:



You can also refer to other relevant guidelines as stated below:

- **EUROPEAN COMMISSION DG ENTERPRISE and INDUSTRY**
  at http://ec.europa.eu/consumers/sectors/medical-devices/files/meddev/2_1_3_rev_3_122009_en.pdf
- **AUSTRALIAN MEDICAL DEVICES GUIDANCE DOCUMENT**
  at www.tga.gov.au/word/devices-guidelines-35.docx
- **MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY REGULATORY FRAMEWORK FOR MEDICAL DEVICES**
  at http://ec.europa.eu/consumers/sectors/medical-devices/files/wg_minutes_member_lists/version1_6_borderline_manual_en.pdf

 # For product classified as Medical Device, please refer to Medical Device Bureau, Ministry of Health, Aras 5, No. 26, Boulevard Plot 3C4, Presint 3, 62675 Putrajaya (http://www.mdb.gov.my).

4) COSMETIC

- Please be informed that for a product to be classified under Cosmetic, the product must fulfill the definition of Cosmetic and all requirements in Cosmetic Guideline.

- In Malaysia, Cosmetic is defined as:
  "any substance or preparation intended to be placed in contact with various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition".

- Please refer to www.bpfk.gov.my → Cosmetic.

NOTE:

1. For Slimming Cream/Lotion, do refer to Pharmaceutical Services Director Circular:
   - www.bpfk.gov.my →News & Announcements →'Produk Dengan Nama, Tuntutan Dan Kegunaan Untuk Melangsingkan Badan Tidak Dikelaskan Sebagai Produk Kosmetik' (31 March 2011); Ruj : (81)dlm.BPFK/17/K/2.4.
   - No slimming claims are allowed for cosmetic products, unless amended to acceptable claims allowable under cosmetic guideline in order to be classified as cosmetic product.

2. For 'leave-on' Cream/Lotion at private part for sexual intercourse , do refer to Pharmaceutical Services Director Circular:
   - www.bpfk.gov.my →Regulatory Information → Circulars →' Produk Untuk Digunakan Pada Bahagian Alat Kelamin/Genital Lelaki Atau Wanita Bagi Tujuan Rangsangan Seksual Lelaki Atau Wanita Tidak Dikelaskan Sebagai Produk Kosmetik' (18 August 2010); Ruj: Bil (5) dlm BPFK/PPP/01/03 Jld 1.

3. For External Personal Care (EPC) Products, do refer to Pharmaceutical Services Director Circular:
   - www.bpfk.gov.my →Regulatory Information → Circulars →' Tarikh Perlaksanaan Pengkelasan Produk 'External Personal Care (EPC)' kepada Kosmetik (27 Dec 2006); Ruj : Bil (68) dlm BPFK/02/5/1.3.
   - Examples of EPC product classified as Cosmetic; shampoo, hair conditioner, leave on hair tonic, hair cream, toothpaste, mouthwash, bar soap, liquid soap, lotion, gel, crème.

4. Applicant/ MAH are also adviced to check on List of Ingredients banned in Cosmetic (7.1, Guidelines for Control of Cosmetic).

 # For product classified as cosmetic, please refer to Cosmetic Unit, Centre for Post-Registration, NPCB.

OTHER INFORMATIONS:-

- ✓ Knowing the category of your product, you can directly submit online application of **product registration** via National Pharmaceutical Control Bureau system (www.bpfk.gov.my → QUEST3).
- ✓ For Cosmetic product, please submit online application of **product notification** via National Pharmaceutical Control Bureau system (www.bpfk.gov.my → QUEST3).
- ✓ Further information can be obtained at www.bpfk.gov.my → Frequently Asked Questions (FAQ).
- ✓ Registration product is based on Control of Drug and Cosmetic Regulation 1984, Drug Registration Guidance Document (DRGD) and other requirements where your product has been classified. Applicant/ MAH are also advised to check on DRGD Appendix 6 - List of ingredients (active) not allowed to be registered by the Drug Control Authority (DCA).
- ✓ The DCA will only register a product that is safe, of quality and efficacious. If it appears that the data submitted upon registration is not satisfactory, product registration may be REJECTED.
- ✓ Drug Registration Guidance Document (DRGD) is available to be downloaded at www.bpfk.gov.my → Regulatory Information.
- ✓ Laws & Regulations are available at www.pharmacy.gov.my → Acts & Policies → Pharmacy Laws.
- ✓ Applicants / MAH can refer to our website, www.bpfk.gov.my → **Registered Product Search** to search for product that contains the same active ingredient, thus can be categorised under the same category. Applicants / MAH can do a search by:

  1. Product Name
  2. Product Registration Number/ Notification No
  3. Registration Holder / Company who notify
  4. **Active Ingredients**

- ✓ If after reading this guidance on classification, you're still having difficulties categorizing your product, you can fill in the Classification Form [BPFK-003] available at our website, www.bpfk.gov.my → Application Forms.
  - Please be informed, one form is meant for one product ONLY.
  - Only COMPLETE form will be processed.

    Please submit your complete form either through;

    Email: classification@bpfk.gov.my or
    Fax : 03 - 7958 1312 or
    Mail : Centre for Product Registration, National Pharmaceutical Control Bureau, Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor.

  - Result of classification and all correspondence regarding to classification are via e-mail.