Frequently Asked Questions on Product Registration

1. **What is a registered drug?**

A registered drug is a drug that is approved by the Drug Control Authority (DCA) for sale/use in Malaysia. This drug has been evaluated and tested for its efficacy and safety. Every registered drug is given a registration number, which must be printed on its label or package. These numbers start with MAL. Example of a registration number is: MAL19976399X

2. **What needs to be registered?**

a. Pharmaceutical products containing scheduled poisons.
b. Pharmaceutical products containing non-scheduled poisons (OTC)

Includes:
+ Medicated plaster with medicines
+ Antiseptic/ Disinfectants for use on the human body
+ Diagnostic agents for human use (in vivo)
+ Dietary supplement e.g. Probiotics, Chitosan

c. Traditional products

Includes:
+ Homeopathic medicines
+ Ayurvedic medicines
+ Medicated plaster
+ Herbal teas
+ Dietary supplements eg. Spirulina, Chlorella, Royal Jelly, Bee Pollen, Aloe Vera juice, Noni juice, Extract of chicken with herbs

d. Veterinary products

Includes:
+ Oral solution, oral suspension, emulsion
+ Granules
+ Paste
+ Water soluble powder
+ Injectable
+ Powder for injection
+ Oral powders
+ Capsule, tablet
+ Topical ophtalmic and otic products

*please refer to subtitle 'Regulatory Information' > 'Other guidelines' > 'Classification decision tree' for further details.

3. **What do not need to be registered?**

a. Raw herbs, including those that are dried & cut into pieces
b. Diagnostic agents/ test kits for in vitro use - please refer to this link for more information. Diagnostic agents/ test kits for laboratory use must be labeled 'FOR LABORATORY USE ONLY'. Products which are not labeled as such shall be deemed to be for human or animal use and need to be registered with the DCA.
c. Medical devices - please refer to this link for more information.

Includes:
+ Blood bags containing anti-coagulants
+ Visco-elastic products for mechanical or physical protection of tissues during or after surgical procedures
+ Non-medicated plasters
+ Wound care/dressing materials containing hydrogel, collagen, calcium alginate
+ Disinfectants for equipments/ devices
+ Lubricants for gloves, condoms and endoscopes
+ Contact lens care products
+ Copper IUDs
+ Bone cement, tissue adhesives

e.Insect repellents
f. Body-building products containing protein/whey/ soya bean
g. Food - as defined under the Food Act 1983 and Food Regulations 1985, includes every article manufactured, sold or represented for use as food or drink for human consumption or which enters into or is used in the composition, preparation, preservation, of any food or drink and includes confectionery, chewing substances and any ingredient of such food, drink, confectionery or chewing substances. This includes food for special dietary use for persons with a specific disease, disorder or medical condition, and food which contain quantities of added nutrients allowable under the Food Act and Regulations.

* For information on Food - Drug Intephase products, please refer to subtitle 'Regulatory Information' > 'Other guidelines' > 'Classification decision tree' for further details.

h. Detergents/ disinfectants for domestic use

4. **What is the procedure for the registration of pharmaceutical products?**

Currently, only on-line submission is accepted for product's registration. This could be done by through NPCB's website www.bpfk.gov.my. An applicant must buy a membership for Quest before the applicant can proceed with registration. There are several packages available to choose to become a member of Quest. Any assistance/advice shall be forwarded to Digicert Customer Service Department: 03-89928888. Once the applicant has received the user and password from BPFK (via email), he/she will be able to enter the registration site and proceed with online submission. This online registration system is also applicable for NCE and bitoech products, traditional registration, re-registration of products and licensing.

The summary of the online registration procedure for products are as follows:-

1) Go to NPCB website (www.bpfk.gov.my)
2) Become Quest member (as First-time User)

* Requirements :
i. Company Registration Form

ii. Company Authorization Letter
iii. Photocopy of I/C

3) After making payment to Digicert, within 7 working days (East Malaysia might take more time), Digicert will send the Digital certifcate via POSLAJU. The login name and password will be emailed to the email address specified during the registration of Quest member.
4) With the login name and password, enter Quest, go under registration, and register the product on-line. All forms are available in the form tray.
5) Submit data requested
6) Correspondences with NPCB officer if additional data is needed
7) Products tabled to DCA meeting

5. **What is the fee for drug registration?**

Processing fee
Every application for registration shall be accompanied with a processing fee, as follows (effective January, 2007) :-

No	Product Classification	Processing Fees (RM)	Analysis Fees (RM)	Total Fees (RM)
1	New Chemical Entity	1,000.00	Single active ingredient : 3,000.00	4,000.00
			Two or more active ingredients : 4,000.00	5,000.00
2	Pharmaceutical	1,000.00	Single active ingredient : 1,200.00	2,200.00
			Two or more active ingredients: 2,000.00	3,000.00
3	Traditional	500.00	700.00	1,200.00

Applications without the correct fees will not be accepted. Foreign currencies are not acceptable. The processing fee is NOT REFUNDABLE.

Other charges
The DCA will charge any applicant such costs as it may incur for the purpose of carrying out laboratory investigations/ testing prior to the registration of any product.

Mode of Payment
The processing fee and any other charges shall be paid in the form of a bank draft/money order made payable to "Biro Pengawalan Farmaseutikal Kebangsaan".

NB. A separate bank draft is required for each application for registration.

6. **What is the next step to take after my product is registered?**

After a product is registered, the applicant must apply for a manufacturer/ import/ wholesale license.
The processing fees are as below:

Licence	Registration fee	**Time line ***	Validity
1. Import licence	RM 500	Not more than 1 month	1 year
2. Manufacturer	RM 1000	Not more than 1 month	1 year
3. Wholesaler	RM 500	Not more than 1 month	1 year

** Effective Date: 4 October 2007*

7. **What is the timeline (time-frame) for registration?**

The duration for each product to be registered is calculated from the date of final and complete submission.

Below are the timeline for product of each category:

Category of product	**Timeline**
Full Evaluation	
To evaluate application for registration of : • Prescription drugs • Non- prescription drugs • New drugs and biologicals	• 210 working days * • 210 working days * • 245 working days *
Abridged Evaluation	
To evaluate application for registration of health supplements and traditional products containing: • Single active ingredient • 2 or more active ingredients **** Upon receipt of complete aplication***	• 60 working days * • 80 working days *

* Update: January 2011

8. **What are the criteria for drug registration?**

A product will be registered only if it satisfies ALL the requirements of the DCA, especially with respect to safety, efficacy and quality of the products.

Other criteria taken into consideration are:-

i. Whether that product is needed or not. Aspects like potential of abuse, number of registered products, different dosage forms, etc. are considered.
ii. Therapeutic effect.

9. I**s all the information declared in the registration form confidential?**

Yes, confidentiality of data is assured.

10. **Can unregistered medicines for personal use be brought into Malaysia?**

Under the Control of Drugs and Cosmetics Regulations 1984, the requirements for drug registration does not apply to a person who arrives in Malaysia and imports, as part of his personal luggage, any product for his use or his family's use, in a quantity that does not exceed one month's use by one person.

11. **Can I amend the label/ formula of my product after it is registered?**

Yes, an application to amend the particulars of a registered product can be made through Quest online submission. This information can be found in FORMS TRAY under VARIATION menu. All changes / amendments requires prior approval from NPCB before it can be implemented.The approval and decision will be notified on-line. Formulation of a product cannot be altered if the change of active is involved. In this case, new application must be made.

12. **How can an overseas company register and distribute its product in Malaysia?**

All pharmaceutical products must be registered with the Drug Control Authority before it can be marketed in Malaysia. A foreign company wishing to bring pharmaceutical products into Malaysia would first have to appoint a local agent (a company registered in Malaysia) to be the holder of the registration certificate. The appointed agent would then be responsible for all matters pertaining to the registration of the products.

There are specific forms to complete during the process of registration and under the labeling requirements for products registered with the Drug Control Authority, the name and address of the actual manufacturer must be declared on the label.

13. **Do cosmetics need to be registered?**

Effective 1st January 2008, the online registration procedure for all cosmetics products has been replaced with the online notification procedure. Companies intending to market new cosmetic products must notify NPCB before placing the products in the local market.Please refer to this link for more information on guidelines for control of cosmetic products in Malaysia.

14. **What is the definition of "cosmetic"?**

A cosmetic product shall mean "any substance or preparation intended to be places in contact

with various external part 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".

15. **What is a traditional medicine?**

A Traditional Medicine means any product employed in the practice of indigenous medicine, whereby the drugs used consist of one or more naturally occurring substances of plant, animal or mineral or part thereof, or in extracted form or non-extracted form, and any homeopathic medicine.
(Indigenous Medicine - means a system of treatment and prevention of diseases involving the traditional use of naturally occurring substances.)

16. **What are the quality requirements for Traditional Medicines?**

Traditional medicines are subjected to the following tests:-
+ Test for contamination of heavy metals:-

Mercury - 0.5 ppm
Arsenic - 5.0 ppm
Lead - 10 ppm
Cadmium - 0.3 ppm

+ Test for microbial contamination
+ Disintegration test for tablet and capsule

17. **How are homeopathic medicines controlled in Malaysia?**

Homeopathic medicine means any drug in a pharmaceutical dosage form that is used in the homeopathic therapeutic system in which diseases are treated by the use of minute amounts of such substance which is capable of producing in healthy persons symptoms similar to those of the disease being treated.

Homeopathic medicines in finished dosage forms have to be registered with the Drug Control Authority before they can be imported and sold in the country. A foreign company wishing to bring such products into Malaysia has to appoint a local agent to be the holder of the registration certificate. The appointed agent will be responsible for all matters pertaining to the registration of the products.

18. **How do I report on ADR?**

If it is suspected that a patient has suffered an adverse reaction to a traditional medicine, it should be reported to the Malaysian Adverse Drug Reactions Advisory Committee either through its Website, through the ADR reporting form or even by a letter. All information on the name of the remedy, its ingredients and source (if known) should be included. In order to facilitate better assessment and to allow further action to be taken, when necessary please include the label/packing material of the product where possible. If it is suspected that the product is contaminated with some other medicines such as steroids, painkillers, hypoglycemic agents etc., please include a sample of the product to enable analysis to be performed.

19. **What should I do if my contract manufacturer license is revoked?**

A contract manufacturer's license may be revoked due to closure or suspension of premise. Your product registration will not be cancelled, however you will need to apply a change of manufacturing site form in order to continue the validity of your products. This is covered under Change of Manufacturing Site type V (which also includes circumstances like natural disasters or matters related to breach of product quality, safety and efficacy). Approval from NPCB is required prior to implementation of change Please fill up the Borang BPFK 415.3[NMJ1] to proceed with the change of manufacturing site..For further information please browse our Guidelines on Requirements for change of manufacturing site [NMJ2].

20. **Hologram Security Device (Meditag TM)**

No	Question	Answer
1.	Which regulation covers the implementation of mandatory hologram labelling?	As provided under Regulation 8(1) of the Control of Drugs and Cosmetics Regulations 1984.
2.	What types of products that required hologram labelling?	The requirement for the affixation of this security device to product labels, is applicable to pharmaceuticals products, traditional Products and health supplements. Cosmetics and OTC External Personal Care (EPC) products are currently excluded from the exercise. OTC External Personal Care (EPC) products can be sub-divided into the following: * External personal care - Anti-acne * External personal care - Anti-dandruff * External personal care - Oral care * External personal care - Skin Protectant * External personal care - Antibacterial
3.	What happens to those products already available for sale or on the shelves? Will a recall need to be done?	Any product which is manufactured or imported before1st May 2005 is exempted from the implementation of hologram labelling. A recall need not be instituted for products already on the market. Companies are advised to project and plan realistically to ensure that there is no overstocking of products without the security label. Products placed on shelves after the implementation dates should preferably bear the hologram labels. It is possible that consumers may exercise their choice immediately after implementation and purchase only those products that have the hologram label.
4.	What is the size and shape of the hologram label?	The size of MeditagTM is 8mm x 16mm. It is rectangular in shape.
5.	What is the price of MeditagTM ?	Each label costs RM0.056. The price is not inclusive of delivery charges, nor insurance charges, tax and sales duties. The minimum order is 1 roll or 2 sheets. Each roll

		consists of 15,000 labels and is usually used with labelling machines. The sheets each contains 100 labels and is suitable for manual labelling.
6.	What is the size of the roll form?	Each roll is 220mm in diameter. Roll width is 10mm. Core diameter is 76mm. Space in between each MeditagTM is 4mm. The backing of the MeditagTM is glassine.
7.	Where is the hologram label to be applied? How about products that are meant to be supplied to hospitals and to be used by doctors or nurses for their patients (injections, TPN & etc). Where is the hologram label to be applied for "Large Volume Parenteral"?	The hologram shall be affixed onto the outer packaging of the product on the product label. Where there is no outer packaging, the label shall be applied to the immediate packaging, i.e. the bottle label. The hologram label cannot be applied onto the outer shrink wrap. The customer purchasing a product should be able to locate the presence of the hologram without having to open the packaging. All products that are meant to be supplied to hospitals and to be used by doctors and nurses for their patients (include large volume parenteral) should also be affixed with hologram label to each individual unit of IV Drip. None of the product particulars on the label shall be covered over by the security device. Outer box or each unit.
8.	Where should the security label be affixed for promotional packs containing 2 or more items?	Each individual item that is a product registered with the DCA will have to bear the security label.
9.	If manufacturers and importers packed and sold their products in a box of one dozen to their dealers, must they apply the hologram label onto the box of one dozen or on each individual pack/bottle? How about products to be sold in loose form (strips, blisters, sachets, loose tablet & etc)	The hologram label is to be applied to each individual unit of sale. It is not however required that each blister strip be affixed with a hologram label. The unit of sale for blister/strip/sachet packed products would be the box or sachet of 4's, 8's, 10's or 20's that they are packed in. A similar situation applies for injectables. The box unit pack for sale is to be labelled and not the individual ampoules/vials in each box.
10.	Are registered importers allowed to send the hologram labels to their manufacturers who are located outside Malaysia?	Yes, the labels can be sent to the overseas manufacturer and the product is then imported fully labelled. The importer to whom the labels have been sold will remain the responsible party.
	Who is supposed to buy and apply	The company that is on record with the DCA as the importer for a particular product will be the party responsible for the security labels on the product in question.

11.	the security label if both principals and distributors are companies in Malaysia as well as registered with BPFK?	Even if the registered importer outsources the actual process of stickering the labels onto the physical stock to another agent, the importer will still be accountable. SOP's for the labelling procedure, including documentation and reconciliation records should be maintained.
12	How detailed should the security label reconciliation record be?	Reconciliation records should be as required under GMP requirements as for any other type of product label.
13.	When will DCA begin inspection or enforcement on the use of the labels? (At point of entry, imported products without hologram would be a hassle to the enforcement officers regarding its authenticity.)	Enforcement will be at the point of sale (retailers and wholesalers), and can begin any time after implementation. Enforcement will not be carried out at the point of entry. However, in cases where the imported products are brought in without hologram label, the importers are responsible to ensure such of imported products should be labelled with hologram prior to distribution of such products. The implementation will be in 2 phases, with the 1st phase for all non-injectable products starting 1st May 2005. All non-injectables which are imported or manufactured on or after 1st May 2005 should carry the security label. The 2nd phase of implementation for parenteral preparations will begin 1st July 2005.
14.	Would food supplements and plaster products require security label?	All products registered with the DCA , with the exception of OTC External Personal Care (EPC) e.g medicated soap and cosmetic products, will need to be affixed with the security label. Please refer back to Question no.10 on the implementation phases.
15.	Are registered importers and manufacturers of cosmetic products allowed to purchase and apply MeditagTM onto their products?	Currently the requirement for security label does not apply to cosmetics. It is NOT recommended that cosmetic products carry the MeditagTM label as it may lead to confusion.
16.	If manufacturers and importers are unable to get sufficient stocks, can they be allowed to sell their products without the label?	NO, all products manufactured and imported after the stated implementation date(s) will need to bear the label. Forecast of orders for the security labels are needed by the supplier to understand requirement needs. As demand is dynamic, the information supplied is vital to ensure adequate stocks are kept to fulfill customer orders.
17.	Will registered manufacturers and importers be liable if their assigned MeditagTM (serial number) is found in unregistered products?	There are security features, both overt (visible) and covert (hidden) that can be used for verification of label authenticity. The MeditagTM labels supplied to registered importers and manufacturers will carry unique serialised

	What happens if they are caught distributing unregistered products? Who would be charged? The importers or the product holders?	numbers. As such each label can be traced to its "owner". If genuine MeditagTM labels are found on unregistered products, the owner would definitely have some explanations to do.
18.	Who can buy the MeditagTM labels? Are product holders allowed and the one actually responsible to purchase the hologram tag? Are repackers also responsible to buy the hologram labels?	Only licensed manufacturers and importers of pharmaceutical, traditional medicine and health supplement products can purchase the labels. The local manufacturer (meaning also the repacker for products which are imported in bulk and packed locally) or the importer shall be responsible for affixing the security device onto the individual unit packs.
19.	Does statement of "Diluluskan oleh Kementerian Kesihatan Malaysia" remain one of PBKD requirements in product labelling?	With the affixation of the hologram security device onto the product label, the requirement to label all products with "diluluskan oleh KKM" does not remain and may be considered optional.
20.	What is the penalty for those who fail to implement the hologram label?	Any person who contravenes this requirement will be fined as follow:- 1st time: not exceeding RM 25, 000 or by imprisonment for a term not exceeding 3 years or both. 2nd time: not exceeding RM 25, 000 or by imprisonment for a term not exceeding 5 years or both. Where as any body corporate that found guilty will be charged as follow:- 1st time: not exceeding RM 50, 000. 2nd time: not exceeding RM 100, 000.
21.	How do I ensure an authentic purchase of MeditagTM labels?	The distributor authorized by the Government to supply the hologram security device is Mediharta Sdn Bhd. Should more information be required on the technical and supply aspects , please contact Mediharta. Tel: +6(03) 2093 3075 Fax: +6(03) 2093 9763 Website: www.mediharta.com.my Email: enquiries@mediharta.com.my

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