

MINISTRY OF HEALTH MALAYSIA NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)



COSMETIC NOTIFICATION PROCESS



WHAT IS COSMETIC PRODUCT?

A cosmetic product shall mean "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 odors and/or protecting them or keeping them in good condition".

WHAT IS PRODUCT VARIANT?

Product variants shall mean items in a range of cosmetic products which are produced by the same manufacturer, similar in composition and are intended for the same use but are available in different colors, fragrances or flavors.

HOW IS COSMETIC REGULATED IN MALAYSIA?

- 1. Cosmetic products in Malaysia are regulated under the Control of Drugs and Cosmetic Regulations (CDCR) 1984 which were promulgated under the Sale of Drugs Act 1952. Regulation 18A (1) under CDCR 1984 provides that no person shall manufacture, sell, supply, import, possesses any cosmetics unless the cosmetic is a notified cosmetic. It is an offence for anyone to conduct such activities without prior notification to the DPS.
- 2. Starting from 1st January 2008, cosmetic products in Malaysia are controlled through <u>notification procedure</u>.
- 3. Cosmetic Notification Holder (CNH) is required to COMPLY with all requirements stated in the Guidelines for Control of Cosmetic Products in Malaysia and to make a declaration upon notification to the Director of Pharmaceutical Services through National Pharmaceutical Regulatory Agency (NPRA). Regulatory action will be taken in the event of false declaration and/or product found to be non-compliant to the stipulated regulations and guidelines.
- 4. The CNH is responsible to notify the DPS prior to manufacture, sell, supply, import or possess any cosmetic product.



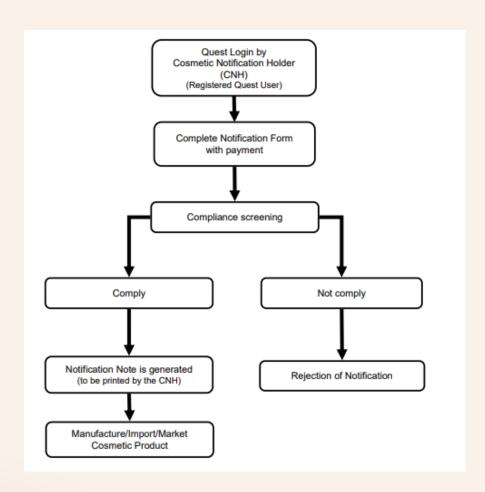
CNH refers to a company who is responsible for placing the cosmetic product in the market.

cnh must be a locally incorporated company or legal entity in the field of cosmetics, with permanent address and registered with Companies Commission of Malaysia (with the scope of business related to the health/cosmetic product as it appears in the `Memorandum and Article of Association' of the company).

03

CNH may or may not be the product owner.

WORKFLOW OF NOTIFICATION PROCESS



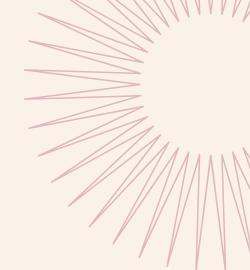
PROCESSING FEE

- 1. The processing fee for notification of a cosmetic product is RM50.00 for each product (and variant, if any).
- 2. The processing fee for renewal of notification of a cosmetic product is also RM50.00 for each product (and variant, if any).

COSMETIC NOTIFICATION VALIDITY

Notification shall be valid for two (2) years and renewal should be done no later than 1 month prior to expiry.

HOW TO SUBMIT A COSMETIC NOTIFICATION



STEP 1:

QUEST MEMBERSHIP REGISTRATION

A CNH must first register for a Quest membership. A detailed guide for Quest membership registration is available on NPRA's website



Go to www.npra.gov.my Click Industry > First Time User > Register Submit completed form with supporting documents: 1. Copy of IC / passport of authorised person 2. Letter of authorisation 3. Company registration certificate from SSM Application processed in 3 working days (Notification via email) Rejected Approved Download Submit a new membership slip and application with purchase USB Token amendment/s Install token &

LOG IN TO QUEST!

CHARGES FOR USB TOKEN

Туре	Validity Period	
	1 year (RM)	2 year (RM)
Main User (Certificate + USB Token)	260	290
Postage	Semenanjung - 10 Sabah/Sarawak - 20	

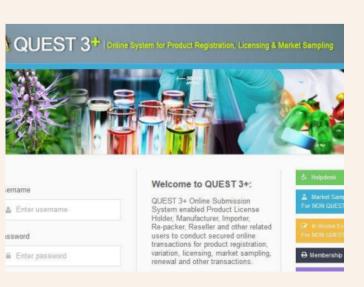


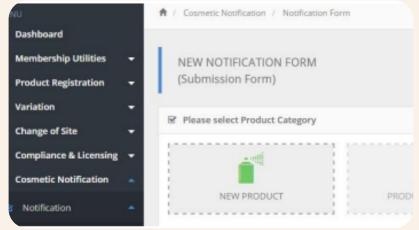
STEP 2:

NOTIFICATION OF COSMETIC PRODUCTS (AND VARIANT)

The cosmetic notification must be submitted online. The CNH must complete the notification form in the Quest system for each cosmetic product, and variant, if any, and proceed with the payment to the NPRA.









National Pharmaceutical Regulatory Agency (NPRA) Lot 36, Jalan Prof. Diraja Ungku Aziz, 46200 Petaling Jaya, Selangor, Malaysia.

> Website: www.npra.gov.my Phone: +603-7883 5400