

Surveillance and Complaints Notified Cosmetic

Introduction

All notified cosmetics in the local market are required to comply with the Guidelines for Control of Cosmetic Products in Malaysia. This is to safeguard and protect public health from any potential risks associated with adulterated, unsafe, or substandard cosmetics.

Frequently Asked Questions (FAQ)

1. What type of Post-Market Surveillance (PMS) activities does SVA, NPRA conduct for notified cosmetics?

The SVA, NPRA conducts a range of Post-Market Surveillance (PMS) activities to ensure the safety, quality, and regulatory compliance of cosmetics. These activities include:

- I. Sampling and testing of cosmetic for microbial contamination and heavy metals;
- II. Monitoring cosmetic labels for compliance with regulatory requirements;
- III. Handling consumer complaints and investigating reports of adverse effects related to cosmetics;
- IV. Surveillance of advertisements and claims to prevent misleading information;
- V. Issuing and coordinating alerts through the ASEAN Post-Marketing Alert System (PMAS) for cosmetics found to be non-compliant or hazardous.

2. How does NPRA conduct sampling of notified cosmetics to ensure compliance with regulations?

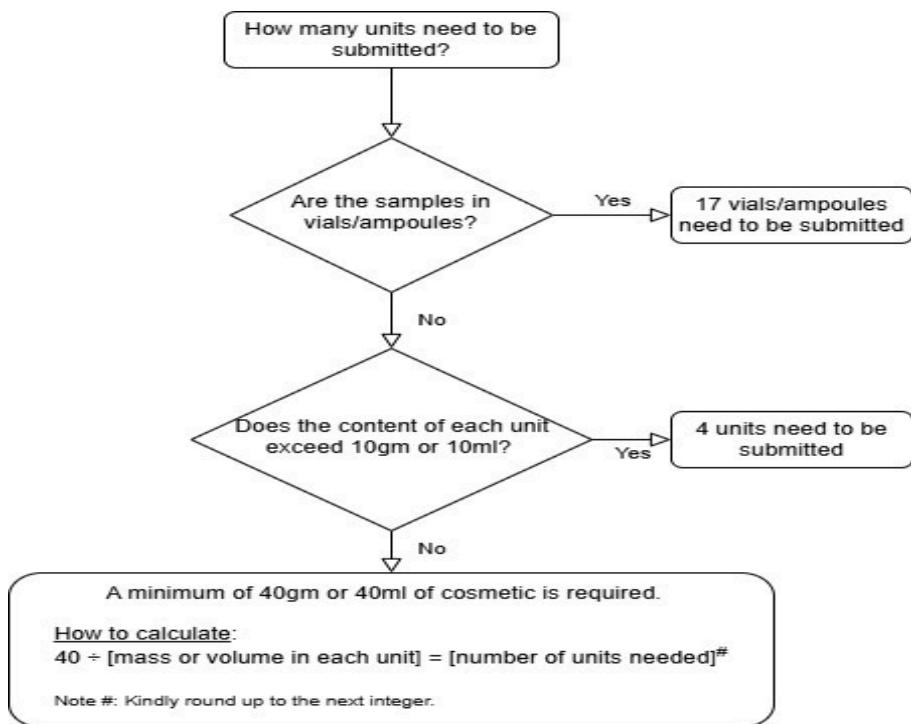
Once notified, cosmetics are subject to sampling to verify quality and/or label compliance with the Guidelines for Control of Cosmetic Products in Malaysia. Sampling may be conducted through various methods, including:

- i. Direct purchase from the market (via authorized distributors or retailers), or
- ii. Requesting samples from the Cosmetic Notification Holder (CNH).

3. How many cosmetic samples are CNHs required to submit to NPRA after receiving the official request letter?

The number of cosmetic samples required depends on the type and its packaging format of the cosmetics. Upon receiving the official request letter, CNH must:

- i. Refer to the instructions stated in the letter, which will specify the required quantity and conditions for submission such as samples submitted must in their final packaging, from the same batch number and so on.
- ii. Follow the sample quantity guide or chart provided below.



4. Can CNHs send the samples by hand or by post?

Yes. CNHs may submit the requested samples using either of the following methods:

By hand:

CNHs must make an appointment with the relevant NPRA officer in advance and follow the map and directions provided by NPRA.

By post/courier:

CNHs may send the samples to the following address:

Seksyen Surveilans dan Aduan
Pusat Komplians dan Kawalan Kualiti
Bahagian Regulatori Farmasi Negara (NPRA)
Lot 36, Jalan Prof Diraja Ungku Aziz,
46200 Petaling Jaya, Selangor
(U/P: [officer's name])

Note: Ensure that all samples are properly labelled and packaged to avoid damage or rejection.

5. What should CNHs do if the cosmetic sample is out of stock, not yet manufactured/imported, or has been discontinued?

- i. If the requested cosmetic is out of stock, not yet manufactured, or not yet imported:
CNHs must submit a commitment letter listing the affected cosmetics. The letter should confirm that the samples will be submitted once they become available. If possible, include the estimated date of restocking, manufacturing, or importation.
- ii. If the cosmetic has been discontinued:
CNHs must withdraw the notification via the QUEST3+ system.

6. What happens if a cosmetic is found to be non-compliant during post-market surveillance?

If a cosmetic is found to be non-compliant during NPRA's post-market surveillance, it may be subject to one or more regulatory actions, including:

- i. Issuance of a warning
- ii. Cosmetic recall

iii. Cancellation of cosmetic notification

The Cosmetic Notification Holder (CNH) is fully responsible for ensuring the cosmetic's compliance and must take prompt corrective action as instructed by NPRA.

7. What should CNHs do if they receive a directive recall from the authority?

CNHs should refer to Annex I, Part 16: Guidance for Industry – Reporting and Recall of Cosmetic Products for detailed procedures and requirements related to cosmetic recall.

However, if a cosmetic is found to contain harmful or prohibited ingredients during the Post-Market Surveillance (PMS) program, immediate regulatory actions will be taken against the CNH. These actions may include cancellation of the cosmetic's notification status and a directive to recall all affected batches from the market.

8. Where can consumers or the public find information on cosmetics found to contain harmful or prohibited ingredients during the PMS program?

NPRA informs the public of such findings through press releases published on its official website under:

Navigation: INFORMATION > General Information > Press Release.

Additionally, a list of cosmetic with cancelled notifications due to the presence of prohibited ingredients is available at:

<https://www.npra.gov.my/index.php/en/informationen/safety-information-2/cancellation-of-notified-cosmetic-products-2.html>

Navigation: INFORMATION > Safety Information < Cancellation of Notified Cosmetic Products

9. How can consumers or companies report a cosmetics complaint to NPRA?

Complaints regarding cosmetic can be submitted to NPRA if a notified cosmetic is suspected to be unsafe, causes adverse effects, is of poor quality, or contains misleading claims in its advertisement.

Complainants may report complaints related to NPRA through the following methods:

a) Online

Via the official NPRA website at www.npra.gov.my, under:

Navigation: CONSUMERS > Reporting > Reporting on Notified Cosmetic

b) Manually (printed or digital copy):

Submit the completed complaint form through any of the following channels:

- i. Email: aduankos@npra.gov.my
- ii. Postal mail
- iii. Walk-in submission at NPRA
- iv. Suggestion / Complaint Box provided at NPRA premises

10. Do I need to submit a cosmetic sample when making a complaint?

No. Complainants are not required to submit a sample. Instead, they should provide a clear photo of the cosmetic, including the batch number and the manufacturing/expiry date.

NPRA will conduct further investigation and, if necessary, obtain the cosmetic sample directly from the market.

11. Can a complainant lodge a complaint with NPRA if they suspect that a cosmetic being sold or used is counterfeit?

Yes. However, complainants are advised to first contact the company or the Cosmetic Notification Holder (CNH) to verify the authenticity of the suspected cosmetic.

If the company or CNH confirms that the cosmetic is counterfeit, the information should be forwarded to the Ministry of Domestic Trade and Consumer Affairs (KPDN) for further action.

Disclaimer: This FAQ is intended for general guidance only and does not replace the official guidelines and regulations issued by the National Pharmaceutical Regulatory Agency (NPRA) Malaysia. Always refer to the latest official documents and contact NPRA directly for specific advice or clarification.