

Annex I, Part 16

GUIDANCE FOR INDUSTRY – REPORTING AND RECALL OF COSMETIC PRODUCT

1. INTRODUCTION

The purpose of this document is to provide guidance for industry on reporting and recall of cosmetic product in accordance with the Sale of Drug Act 1952 and Control of Drug and Cosmetic Regulation 1984.

2. OBJECTIVE

The objective of this guidance is to ensure that cosmetic industry are responsible for the safety and quality of their cosmetic products and should have adequate systems and appropriate procedures in place to investigate, review and report the product recall to authority, and if necessary, to promptly recall the cosmetic product from the distribution network.

3. DEFINITION

3.1 “Recall” means any action taken by its manufacturer, importer, wholesaler to remove or withdraw a particular cosmetic product from the market or to retrieve the product from any person to whom it has been supplied.

3.2 The removal or withdrawal may be due to critical quality defects discovered or serious adverse reactions reported which might cause health risks to users of the cosmetic.

4. TYPES OF RECALL

The decision for recall of a product shall be made when there is actual or potential risk to the product users. There is two types of recall as below:

4.1 Directive Recall

The decision for recall of a product as directed by the Director of Pharmaceutical Services Division, Ministry of Health.

4.2 Voluntary Recall

The decision for recall of a product is initiated and voluntarily undertaken by the company after consulting/informing the authority.

5. DEGREE AND LEVEL OF RECALL

5.1 Degree of Recall

The degree of recall is classified according to the severity of quality defects and adverse reactions of the cosmetic.

	Degree I	Degree II	Degree III
Description	Cosmetics with major health risks that might cause serious injuries or death.	Cosmetics with minor health risks or are substandard.	Cosmetics with other reasons for recall that can cause health risks to users
Notification to Authority	Company must notify authority no later than 24 hours prior to the start of the intended voluntary recall.	Company must notify authority no later than 48 hours prior to the start of the intended voluntary recall.	Company must notify authority no later than 72 hours prior to the start of the intended voluntary recall.
Issuance of Communication/notification to purchaser	Company is required to issue a Communication/notification to purchaser within 24 hours of recall commencement, notifying of the recall action and providing the required instructions to purchasers, including immediate cease in sale and supply of the product.	Company is required to issue a Communication/notification to purchaser within 48 hours of recall commencement, notifying of the recall action and providing the required instructions to purchasers, including immediate cease in sale and supply of the product.	Company is required to issue a Communication/notification to purchaser within 72 hours of recall commencement, notifying of the recall action and providing the required instructions to purchasers, including immediate cease in sale and supply of the product.

Time Frame to remove product from sale and supply in market	Should be under an embargo within 24 hours.	Should be under an embargo within 72 hours.	Should be under an embargo within 30 days or as specified.
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Company should notify their stakeholders about the recall as soon as possible. To ensure prompt notification, company may consider disseminating the recall notice to their stakeholders via telephone and/or email first and follow-up with the letter / facsimile to confirm this notification.

5.2 Level of Recall

The level of recall depends on the nature of problem, extent of the cosmetic's distribution and degree of hazard involved.

5.2.1 Level A: To all consumers (end users)

- Usually initiated when the risk to consumers is assessed to be unacceptable, and where the product is directly supplied to consumers.
- All wholesale and retail supply of the affected product or batch(es) should be suspended.
- Affected product or batch(es) are to be recalled from all wholesale and retail distributors as well as consumers who had been supplied with the affected batch(es).
- Where necessary, the recall notification to consumers may need to be done via announcement on mass media such as press announcement, newspaper notification, television and/or radio.
- The recalled product or batch(es) should be segregated in a secured area before the implementation of follow-up actions (e.g. destruction of the products)

5.2.2 Level B: To all points of sales/ retailer outlets

- Usually initiated when the risk to consumers is assessed to be moderate to high but recall at consumer level is not deemed necessary

- All wholesale and retail supply (e.g. supermarkets, beauty center/salon/outlet, cosmetic booth/kiosk, departmental store, groceries store) of the affected product or batch(es) should be suspended.
- The recalled product or batch(es) should be segregated in a secured area before the implementation of follow-up actions, e.g. destruction of the products.

5.2.3 Level C: To all distributors, wholesalers and manufacturer

- Usually initiated when the risk to consumers is assessed to be low or where other measures can be taken to mitigate the risk
- All wholesale supply of the affected product or batch(es) should be suspended. Affected product or batch(es) are to be recalled from all affected:
 - wholesalers;
 - distributors;
 - manufacturers
 - third-party logistics providers holding the product for distribution to retailers etc.
- The recalled product or batch(es) should be segregated in a secured area before the implementation of follow-up actions, e.g. destruction of the products.

6. RECALL PROCESS AND PROCEDURE

Appropriately trained and experienced personnel or committee should be responsible for managing product recall investigations and for deciding the measures to be taken to mitigate any potential risk, as well as for the management of interactions with authority. The contact details of the designated person or committee should be included in the procedure.

6.1 Notification of Recall Actions to Stakeholders

The company should communicate the recall actions to be taken to the stakeholders through appropriate means. The company needs to indicate the method of recall communication (e.g. mail, facsimile, email, phone). A written communication is recommended so that stakeholders will have record of the recall and instructions. Addressing the recall notice to a contact person of each stakeholder will expedite the recall process and reduce the potential for the recall letter to be misdirected.

If the company has a website, it should consider posting the recall notification on its website as an additional way to disseminate information about the recall.

6.1.1 Communication/notification to purchaser

A “Communication/notification to purchaser” is a letter issued by the company to its stakeholders/purchasers (such as distributors or retail stores) to inform/alert them of the administrative or logistic matters related to the product recall.

A Communication/notification to purchaser should include (but not limited to) the following information:

1. Audience / targeted recipient;
2. Purpose of letter;
3. Product details (e.g. product name, notification number, batch number, manufacturing date & expiration date);
4. Description of issue, reason for recall and any potential health hazard(s), as appropriate;
5. Instruction to stakeholders or customers (e.g. remove product from sale, cease distribution, return product);
6. Company’s contact; and
7. Return response card / form (include a space for purchaser’s signature and date to acknowledge the recall and that they have followed through the recall instructions)

Company does not need to seek approval from authority for issuing a Communication/notification to purchaser. However, the company should send a copy Communication/notification to purchaser together with **Product Recall Notification Form** to authority for reference and indicate when the Communication/notification to purchaser was sent out to its purchasers.

If the cosmetics are exported, the overseas counterparts and/or regulatory authorities must be informed of the recall.

6.2 Product Recall Completion Report

The company should ensure that their recall procedures are effective and the recall operation can be initiated promptly at any time. The company is required to maintain an accurate list of all supplied customers (i.e. wholesalers and direct supplied customers for its products distributed locally, exported overseas and given out as samples) so that they can be notified expeditiously in the event of a recall.

The company will need to provide a list and detail of supplied customers, together with reconciliation of quantities of each affected batch (i.e. sold and returned quantities).

Company must keep authority informed of the progress of the recall, as required. If the recall communication was not received and/or its instructions were not followed by all supplied customers, the company should take steps to rectify any issue. These steps may involve using alternative means of contacting the stakeholders or sending out a follow up communication.

The company has up to **30 days** (from the date recall decision has been made) to complete the product recall report and to submit investigation report of the cause of non-compliance and corrective/preventive actions to be taken for improvement.

6.3. Disposal

Cosmetics intended for destruction should be appropriately identified, segregated accordingly and handled in accordance with written procedure.

Destruction of cosmetics should be carried out in accordance with the national legislative and regulatory requirements and with due consideration to protect the environment.

Proof of destruction of the recall product should be recorded.

Documentary proof of action taken and quantity disposed is to be submitted once the recalled products are destroyed.

Disposal records should be maintained for a defined period.

7. Press release

Authority may require the issuance of a mass media announcement (e.g. newspaper advertisement) to notify the public on the recall in a timely manner, if deemed necessary (e.g. consumer-level recalls, critical defects, defects where the affected product is widely supplied to consumers). Authority may also issue a press release for such situations to update the public.