HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

December 2023

GUIDANCE FOR INDUSTRY

Procedures for Reporting of Adverse Effects, Product Defects and Product Recalls for Cosmetic Products

HSA
Health Sciences Authority

PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action / decision taken or not taken as a result of using this document. If you need specific legal or professional advice, you should consult your own legal or other relevant professional advisers.

In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

TABLE OF CONTENTS

1. INTRODUCTION

1.1. Purpose and scope

This guidance applies to all cosmetic products supplied in Singapore.

The purpose of this document is to provide guidance on reporting of adverse effects, product defects and product recalls of cosmetic products to the Health Sciences Authority (HSA) in accordance with the:

a) Health Products Act 2007 ("HPA"); and
b) Health Products (Cosmetic Products – ASEAN Cosmetic Directive) Regulations 2007 ("ACD Regs").

HSA maintains oversight of investigations into adverse effects and product quality defects in the Singapore market to assess the level of risk, appropriate market actions and appropriate corrective and preventive actions (CAPA), if any, to mitigate risk.

This Guidance does not apply to the reporting of counterfeit products. Please submit reports related to counterfeit products to:

Enforcement Branch
Health Products Regulation Group
Health Sciences Authority
Tel: (+65) 6866 3485
Email: HSA_IS@hsa.gov.sg

1.2. Definitions

Adulterated product

An "adulterated product" is a product which contains or has been mixed with any substance or ingredient that is not stated on its label, except where the substance is an inactive ingredient —

a) Which is permitted as a food additive or flavouring agent according to the Codex Alimentarius or such other similar document as may be prescribed; or
b) Which is approved by HSA.

Adverse effect

"Adverse effect", in relation to a health product, means any debilitating, harmful, toxic or detrimental effect that the health product has been found to have or is likely to have on the body or health of humans when such a health product is used by or administered to humans.

Company

"Company" refers to the person responsible for placing a cosmetic product in the market ("person responsible"), or the manufacturer, importer or supplier of a cosmetic product under the scope of this guidance.

Counterfeit product

A product is "counterfeit" if (i) it is presented to resemble or pass off as a registered product when in fact it is not; or (ii) it is presented with any false information as to its manufacturer or origin.

Dear Purchaser Letter

For the purpose of this guidance, a "Dear Purchaser Letter" is a letter issued by the company to its purchasers (such as retail stores, downstream distributors/sellers, pharmacies) to inform them of the administrative or logistic matters related to the product defect and/or recall.

Defective product

A "defective product" is a product which:

a) Has or has possibly been adulterated or tampered with;
b) Is or is possibly an unwholesome health product;
c) Is or is possibly of inadequate quality or unsafe; or

d) Fails or could possibly fail to satisfy such other standards or requirements as may be prescribed.

Person Responsible

"Person responsible" in this guidance refers to the person in Singapore who is instrumental in causing the cosmetic product to be available for sale in Singapore which may be an importer, a manufacturer, a distributor or a retailer. The company has to be a company that is registered with the Accounting and Corporate Regulatory Authority.

Recall

"Recall" means any action taken by its manufacturer, importer, or supplier to remove the product from the market or to retrieve the product from any person to whom it has been supplied, because the product —

a) May be hazardous to health;
b) May fail to conform to any claim made by its manufacturer or importer relating to its quality or safety; or
c) May not meet the requirements of the Health Products Act.

Note: Retrieval of product (for quality defect, non-compliance, or safety reasons) after it has been made available for sale or supply is considered a recall.

Tampered product

A "tampered product" is a product which has been modified or interfered with in any way, including introduction or incorporation of any substance or component that is not in the manufacturer's specifications.

Unwholesome product

A product is "unwholesome" if —

a) It does not comply with the manufacturer's specifications with regards to strength, quality or purity;

b) Its strength, or standard of purity or quality, falls below that stated on the product label;
c) Any of the labelled ingredients or substances has been omitted from the product;
d) It contains any prohibited substance or any substance in excess of the prescribed permitted concentration;
e) It consists in whole or in part of any filthy, putrid (foul smelling) or decomposed substance;
f) It has been manufactured or stored under unsanitary conditions;
g) It has been kept in a package which is composed in whole or in part of any substance which may cause the product to become harmful for use;
h) It has been packed with any substance which affects the purity, quality, strength or beneficial properties of the product; or
i) It has passed its expiry date as assigned by its manufacturer.

2. RESPONSIBILITIES OF COMPANIES

Companies are responsible for the safety and quality of the products they are supplying in Singapore.

Companies should have adequate systems and appropriate procedures in place to receive, investigate, review and report adverse effects and product defects to HSA, and if necessary, to take appropriate action such as to promptly recall the product from the distribution network.

Appropriately trained and experienced personnel should be responsible for managing complaint, adverse effect and quality defect investigations and for deciding the measures to be taken to mitigate any potential risk(s) including product recalls. Sufficient personnel and resources should be made available for the handling, reviewing and investigation of complaints, adverse effects and product defects and for implementing any risk mitigation measures, as well as for the management of interactions with HSA.

3. PROCESS AND REQUIREMENTS OF REPORTING ADVERSE EFFECTS AND PRODUCT DEFECTS

3.1. What types of adverse effects need to be reported to HSA?

The following adverse effects must be reported to HSA by the person responsible.

Adverse effect that:

1) has caused death or is life threatening; or
2) has resulted in any person being hospitalised or has caused any persistent or significant disability or incapacity in any person.

3.2. Timelines for reporting adverse effects

Upon becoming aware of a reportable adverse effect, the person responsible must report the defect to HSA in accordance with the following timelines:

Type of adverse effect	**Reporting Timelines to HSA**
Adverse effect that has caused death or is life-threatening	Inform HSA **no later than 7 days** after the supplier first becomes aware of the event or occurrence; and submit a detailed report to HSA on the event or occurrence within **8 days** after the initial report
Adverse effect that has resulted in any person being hospitalised or has caused any persistent or significant disability or incapacity in any person	Submit a detailed report on the event or occurrence to HSA **no later than 15 days** after the supplier first becomes aware of the event or occurrence

3.3. How to report adverse effects?

Upon becoming aware of a reportable adverse effect, the person responsible is to report the adverse effect to HSA using the reporting form found on the webpage: https://www.hsa.gov.sg/adverse-events

The completed form is to be submitted to Vigilance and Compliance Branch (email: HSA_productsafety@hsa.gov.sg) within the stipulated timelines.

Reports of adverse effects should be as complete as possible and contain essential information to facilitate causality assessment. The minimum information required for the submission of the initial report is:

- an identifiable reporter;
- an identifiable patient;
- an adverse effect; and
- a suspected product.

The person responsible is to comment on whether there is a causal association between the suspected product and adverse effect and explain how the causality assessment was made. When additional medically relevant information is received for a previously reported case, the person responsible is required to submit the follow-up report as soon as possible within 15 days. The reports are to be clearly labelled as follow-up reports (with appropriate cross-referencing).

3.4. What types of product defects need to be reported to HSA?

The following product defects must be reported to HSA by the person responsible.

Product defect that:

1) may cause death or may be life-threatening; or
2) may result in an any person being hospitalised or may cause persistent or significant disability or incapacity in any person.

Examples include:

a) A product adulterated or contaminated with prohibited substance(s) that may lead to the above consequences e.g. steroids, hydroquinone, mercury, tretinoin, etc.

b) A product contaminated with chemical(s) that may lead to the above consequences e.g. talc with asbestos, heavy metals.

c) A product that does not comply with product specification that may lead to the above consequences e.g. contamination with microorganism(s) that can cause serious infections, contamination with high levels of heavy metals.

d) A product that has been manufactured using wrong ingredient(s) that may cause the above consequences.

e) A product with missing information or containing incorrect information on the product label that may lead to the above consequences.

3.5. Timelines for reporting product defects

Upon becoming aware of a reportable product defect, the person responsible must report the defect to HSA in accordance with the following timelines:

Type	**Reporting Timelines to HSA**
Product defect that may cause death or may be life-threatening	Inform HSA **no later than 7 days** after the supplier first becomes aware of the event or occurrence; and submit a detailed report to HSA on the event or occurrence within **8 days** after the initial report
Product defect that may result in any person being hospitalised or may cause any	Submit a detailed report on the event or occurrence to HSA **no later than 15 days** after

persistent or significant disability or incapacity in any person	the supplier first becomes aware of the event or occurrence

Please note that notwithstanding the reporting timelines, if there is a product defect which poses a risk to public, the person responsible should still take prompt measures to minimise the risk (including market actions) even if it needs to be done during non-working hours.

3.6. How to report product defects?

Upon becoming aware of a reportable product defect, the person responsible is to report the product defect to HSA using the following Product Defect Reporting Form - Cosmetic Products.

The minimum information required for the submission of an initial report of product defect is:

1. Product information;
2. Description of defect;
3. Preliminary risk or safety assessment;
4. Immediate mitigation actions;
5. Number of product(s) and batch(es) affected;
6. Date of occurrence;
7. Expiry date of affected batch(es) supplied to the market;
8. Date of last distribution of the affected batches supplied to the market; and
9. An identifiable reporter.

The completed product defect reporting form and any other accompanying documents must be submitted within stipulated timelines to Vigilance and Compliance Branch (email: HSA_productdefect@hsa.gov.sg).

The initial report of product defect should contain as much details as available but reporting should not be delayed due to the time needed to gather the full information.

Product complaints by consumers should generally be validated and confirmed by the company to rule out other factors (e.g. improper handling or storage by consumers) before considering it reportable as a product defect. However, if it is evident that the product complaint is related to a serious threat to the intended users or public health in Singapore, it will be prudent to report this to HSA ahead of the company's detailed assessment.

3.7. Submission of investigation report and risk assessment for product defects

Following the initial report of adverse effect or product defect, a thorough investigation should be completed in a timely manner and an investigation report should be submitted to HSA within 30 days after the initial report.

Information and actions that would be required in the investigation report after the initial review includes (but not limited to):

1. Full description of the product defect. For example, if it is due to a contaminant, to indicate the level of contaminant. If it is due to a failure to meet product specifications, to provide the specifications and all test reports;
2. Explain how the product defect occurred and the date of occurrence;
3. Explain how the product defect was discovered and the date it was discovered;
4. Evaluation of sample(s) of the product obtained from the complainant (if any). The product need not be submitted unless requested by HSA for examination and/or independent testing. If photos of the product defect are available, please submit them when reporting the product defect;
5. Local distribution records of affected batch(es) (i.e. date(s) of distribution, no. of units in batch(es), name(s) of purchaser(s);
6. Overseas distribution list of affected batch(es) exported from Singapore;

7. Indicate whether the product was sold under government tender contract or pending government tender consideration;
8. Review of batch records and any change controls or deviations associated with the batches;
9. Review of previous complaints, quality defect reports and relevant information for any indication of recurring problems (locally or globally);
10. Indicate if the product defect affects all batches or only selected batches. Review of whether other batches and, if other products could be affected. Explain why the product defect affects only selected batches;
11. List down the regulatory actions taken or to be taken by other regulatory authority or by the person responsible (e.g. issuance of communication, suspension of sales, recall, etc.);
12. Identify possible root cause(s) of the product defect;
13. Risk or safety assessment on the potential short-term and long-term consequences of the product defect to intended users;
14. Certificate of Analysis of the affected batches;
15. Examine and test retention samples if needed;
16. Assessment of the appropriate market actions necessary for the affected batches, including whether it is necessary to suspend sales or recall any existing batches. As comprehensive information on the nature and extent of the quality defect may not always be available at the early stages of an investigation, appropriate risk-reducing actions should be considered at appropriate timepoints during the investigations. Please note that supply of batches where sales have suspended can only be resumed with HSA's concurrence, when it has been determined that there is no risk in the use of the product or after appropriate corrective actions had been taken to address the risk; and
17. Provide description of the CAPA, if any, taken or to be taken to prevent a similar defect from recurring.

In assessing the risks associated with the defect, the following should be considered:

1. Potential consequences of the defect on the consumers;
2. Type and nature of the product involved (e.g. product’s intended use, etc.); and

3. Consumer population affected (e.g. children, elderly, etc.).

Some investigation may be more complicated and could exceed the time frame for submission of information. The length of the extension request should be made based on the complexity of the investigation. An interim report at 30 days may be provided if closure is not possible and the person responsible should provide regular updates to HSA on the progress of the investigation into the root cause.

The person responsible should monitor and assess the effectiveness of the CAPAs and continue to perform trend analyses regularly for any indication of recurring problems requiring attention.

Any decision not to execute a risk mitigation measure, which would otherwise be required, should be agreed with HSA in advance.

3.8. Duty to maintain records of adverse effects and product defects

The person responsible should maintain records of every adverse effect and product defect for **at least 2 years** after the date on which the product was supplied . The records should contain the following information:

- The brand and product name of the product;
- The date on which the manufacturer, importer or the person responsible first became aware of the adverse effect or product defect;
- The lot, batch or serial number;
- The nature of the adverse effect or product defect; and
- Any information that HSA may specify in writing.

3.9. What regulatory actions can HSA take arising from an adverse effect or product defect report?

Upon receipt of the report, HSA will review the information provided in the report and may request for the person responsible to provide any further information required for HSA's assessment. Depending on the potential risk to the intended users or to public health, HSA may require additional risk control measures such as suspension of sales, product recall, issuance of Dear Purchaser Letter and/or press release. HSA may also cancel the product notification if there are defects which have not been addressed. This will be assessed on a case-by-case basis.

In addition, the person responsible is required to submit information when requested by HSA to assist in the investigation of adverse effects or product defects which have been brought to HSA's awareness through any other means and where HSA assesses that the defect (regardless of whether it has affected local or overseas batches) has potential impact on the batches already supplied or will be supplied in Singapore.

4. PRODUCT RECALL

Where a product is considered to present a risk to the intended user and/or public health, HSA may require the person responsible to remove the product from the market by recalling the affected batch(es) or, in extreme cases, recalling all batches of the product from the market.

A company may also initiate a recall of a product when a product defect is detected, or has caused adverse effects or for other reasons (e.g. commercial reasons).

Any retrieval of product from the distribution network (including one-to-one exchange) as a result of a quality defect should be regarded and managed as a recall. All recalls would need to follow the classification of recall and recall timelines.

4.1. Duty to notify product recalls

Every company who intends to recall a product should notify HSA of, and the reasons for, the intended recall **no later than 24 hours*** before the start of the intended recall (i.e. issuance of a notice to the customers or public). After the decision to recall is made, it is recommended that the company establishes communication with HSA. This allows HSA to review and comment on the company's recall strategy and offer guidance in the recall process.

* Not including Sundays and public holidays.

HSA may require the company to:

a) Investigate the matter leading to the recall of the product and provide a report of the findings of the investigation; and / or
b) Take other measures as HSA deems necessary. This includes, but not limited to, an escalation of the class and/or level of product recall so as to safeguard public health and safety.

A flowchart for guiding the company in making assessment of the defects and reporting requirements can be found in Annex I.

4.2. Class of recall and recall timelines

A recall is classified either as Class 1 or Class 2 depending on the risk of the adverse effect or the potential risk of the product defect.

	Class 1 recall	**Class 2 recall**
Description	There is a reasonable probability that the use of or exposure to a product may cause serious adverse health consequences or death.	The use of or exposure to a product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

	Class 1 recall	**Class 2 recall**
Notification to HSA	Company should notify HSA **no later than 24 hours*** prior to the start of the intended recall.	Company should notify HSA **no later than 24 hours*** prior to the start of the intended recall.
Issuance of Dear Purchaser Letter	Company should issue a Dear Purchaser Letter **within 1 day*** 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 should issue a Dear Purchaser Letter **within 3 days*** of recall commencement, notifying of the recall action and providing the required instructions to purchasers.
Recall process	The recall process is recommended to be completed **within 1 week**, unless otherwise justified. Company should submit the Product Recall Completion Form - Cosmetic Products to update HSA on the completion of recall.	The recall process is recommended to be completed **within 3 weeks**, unless otherwise justified. Company should submit the Product Recall Completion Form - Cosmetic Products to update HSA on the completion of recall.

* Not including Sundays and public holidays.

Company should notify their stakeholders about the recall as soon as possible. To ensure prompt notification, companies may consider disseminating the recall notice to their stakeholders via telephone and/or email first and follow-up with the letter to confirm this notification.

4.3. Level of recall

The level of product recall will depend on the potential hazard of the affected product, extent of distribution and whether other mitigating measures can be taken to address the defect. There are 3 levels of recall:

a) Consumer level

- Usually initiated when the risk to consumers is assessed to be unacceptable.

- 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 (e.g. or recall of a product that had been widely supplied to consumers).
- 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).

b) Retail level

- 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 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 including:
  - Wholesale distributors;
  - Retail outlets, e.g. beauty care stores, supermarkets, departmental stores;
  - Retail pharmacies; and
  - Medical, dental practitioners' establishments and healthcare institutions.
- 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.

c) Wholesale level

- Usually initiated when the risk to patients or consumers is assessed to be low.
- All wholesale supply of the affected product or batch(es) should be suspended. Affected product or batch(es) are to be recalled from:
  - All wholesalers;
  - All distributors; and
  - All 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).

4.4. Initiation of recall

Product recalls may be initiated by the company as a result of reports of adverse effects or product defects from various sources such as those from healthcare professionals and members of the public. All product recalls should be conducted promptly and the affected product or batch(es) should be effectively removed from the distribution chain.

Company does not need to seek approval from HSA for initiating a product recall, but should notify HSA of, and the reasons for, the intended recall **no later than 24 hours*** before the start of the intended recall. If the recall only extends to the wholesale level, the company needs to explain the rationale for not recalling at retail / consumer level.

* Not including Sundays and public holidays.

HSA reserves the right to review the class and level of the product recall. If necessary, HSA may escalate the class and/or level of product recall. HSA may require the company to investigate the root cause of the recall and provide the investigation findings and CAPA report to HSA.

4.5. Recall process / procedures

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 of supplied customers in an electronic spreadsheet format (e.g. Microsoft Excel file) to HSA upon request.

In the event of a recall, the company should consider a strategy for returns and refunds.

4.6. Notification of recall actions to stakeholders

The company should communicate the defects and the recall actions to be taken to the customers 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 customers will have record of the recall and instructions. Addressing the recall notice to a contact person of each customer 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.

4.6.1. Dear Purchaser Letter

A Dear Purchaser Letter is a letter issued by the company to its purchasers (such as, retail stores, beauty care stores, supermarkets, departmental stores, retail pharmacies) to alert them to the administrative or logistic matters related to the product recall.

A Dear Purchaser Letter should include (but not limited to) the following information:

1. Audience / targeted recipient;
2. Purpose of letter;
3. Product details (brand and product name of product, affected batch number, product image, images to guide where to find the batch details if needed);
4. Description of issue, reason for recall and any potential health hazard(s);
5. Level of recall (wholesale, retail, consumer level);
6. Instruction to customers (e.g. remove product from sale, cease distribution, return product, conduct sub-recall if appropriate);
7. Refund mechanism;
8. Company's contact; and
9. 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 HSA for issuing a Dear Purchaser Letter. However, the company should send a copy of the signed Dear Purchaser Letter to HSA for reference and indicate when the Dear Purchaser Letter was sent out to its purchasers.

If the affected product has been distributed outside of Singapore, the wholesaler should also notify their stakeholders outside of Singapore and ensure that the product is recalled effectively.

4.7. Press release

HSA 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, defects that may cause serious injury, defects where the affected product is widely supplied to consumers/patients). HSA may also issue a press release for such situations to update the public.

4.8. Completion of recall

Company must keep HSA informed of the progress of the recall. Company should perform an effectiveness check to verify that the recall communication was received by the customers and that they understood and followed through the recall instructions. If the effectiveness checks indicate that the recall communication was not received and/or its instructions were not followed, the company should take steps to rectify any issue. These steps may involve using alternative means of contacting the customers or sending out a follow up communication.

Company needs to furnish the Product Recall Completion Form - Cosmetic Products upon completion of the product recall, together with a report of reconciliation of quantities of each affected batch (i.e. sold and returned quantities). As part of the recall completion report, the company should update HSA of the follow-up actions that will be taken for the recalled products. Such actions include, but are not limited to:

a) Destruction of the recalled products locally. The company should submit the certificate of destruction to HSA **within 3 months** from the completion of recall, unless otherwise justified. For this action, the company is not required to seek and obtain prior approval from HSA. The recalled product should be stored separately in a secure area while waiting for disposal. Documentary proof of action taken and quantity disposed is to be submitted once the recalled products are destroyed; or

b) Reintroduction of the recalled products back into the market after appropriate CAPA has been implemented by the company. For this action, the company is required to seek and obtain prior approval from HSA. In general, recalled products should only be re-introduced back into the market after appropriate CAPA has been implemented, and if:

    i) The products are in good condition;

ii) It is known that the products have been transported, stored and handled under proper conditions;

iii) The remaining shelf life period is acceptable; and

iv) The products have been examined and assessed by appropriate and qualified personnel, taking into account the nature of the product, any special storage conditions required, and the time which had elapsed since it was distributed.

If any other actions are to be taken, please specify them on the Product Recall Completion Form - Cosmetic Products, and they will be subjected to approval from HSA. The recalled products should be stored separately in a secure area while awaiting a decision on their disposal.

The completed Product Recall Completion Form – Cosmetic Products and any other accompanying documents must be submitted to the Vigilance and Compliance Branch.

4.9. Reinstatement of supply

The company needs to perform corrective action(s) to address the quality defect and carry out preventive action(s) to prevent recurrence of the defect in the future before reinstating supply of product.

Please note that supply of batches where sales have suspended can only be resumed with HSA's concurrence, when it has been determined that there is no risk in the use of the product or after appropriate corrective actions had been taken to address the risk.

For enquiries on this document, please contact:

Cosmetics Control Unit

Health Products Regulation Group

Health Sciences Authority

11 Biopolis Way #11-01 Helios

Singapore 138667

Email: hsa_cosmetics_control@hsa.gov.sg

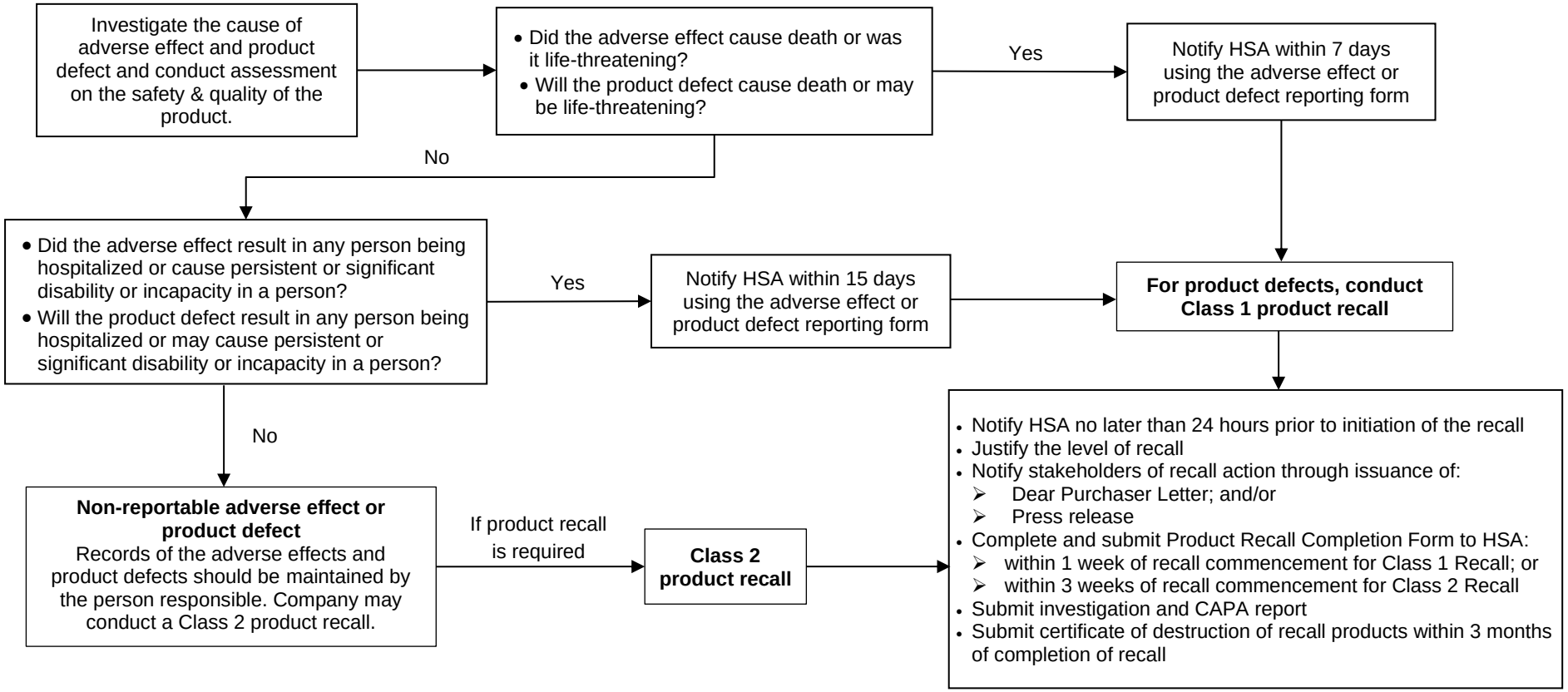
Revision History

Version	Date of publicatio	Summary of changes*
	4 December 2023	New document

*Editorial changes are not reflected

Annex I – Flowchart on reporting of adverse effects and product defects and product recalls

This flowchart is meant to be a guide to assist in the determination of adverse effect and product defect classification and to facilitate the decision-making process on product recalls. It should be used for reference only.



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