HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

NOVEMBER 2026

Guidelines on Reporting of Adverse Effects, Product Defects and Product Recalls for Traditional Chinese Medicinal Products, Complementary Health Products and Cosmetic Products

GL-CHPB-1-014 Rev 001

The information in these Guidelines may be updated from time-to-time. For the latest version of the Guidelines, please refer to our website at www.hsa.gov.sg

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.

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1. INTRODUCTION

1.1. Purpose and scope

This guidance applies to traditional Chinese medicinal products[1] (**"TCM products"**) complementary health products [2] (**"CHP"**) and 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 TCM products, CHP and 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.

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:

General Investigations Division
Enforcement Group
Health Sciences Authority
Tel: (+65) 6866 3485
Email: HSA_IS@hsa.gov.sg

1.2. Definitions

For the purposes of this document, the definitions of the following terms apply.

Adulterated product has the same meaning given by Section 2(2)(a) of the HPA

[1] Traditional Chinese medicinal products include Chinese proprietary medicines (CPM) and Chinese medicinal materials (CMM)
[2] Complementary health products (CHP) include health supplements, traditional medicines, homeopathic medicines, medicated oils, balms and plasters. For more information on CHP, please refer here.

Adverse effect has the same meaning given by Section 2(1) of the HPA

Applicable health product

"Applicable health product" refers to traditional Chinese medicinal products, complementary health products and cosmetic products

Counterfeit product has the same meaning given by Section 2(2)(b) of the HPA

Dear Purchaser Letter

For the purpose of this guidance, a "Dear Purchaser Letter" is a letter issued by the person responsible for the applicable health product 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 has the same meaning given by Section 42(6) of HPA

Person Responsible

"Person responsible" in relation to TCM products refers to the manufacturer, importer, supplier or registrant of a TCM product

"Person responsible" in relation to CHP and cosmetic products refers to the person in Singapore who is instrumental in causing the product to be available for sale in Singapore which may be the manufacturer, importer, supplier or retailer.

Recall has the same meaning given by Section 2(1) of the HPA

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 has the same meaning given by Section 2(2)(c) of the HPA

Unwholesome product has the same meaning given by Section 2(2)(d) of the HPA

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 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.

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

3.1. What are the types of adverse effects to be reported to HSA, and reporting timelines?

The following adverse effects must be reported to HSA by the person responsible in accordance with the following timelines:

Product	**Type of adverse effects that must be reported to HSA**	**Reporting Timelines to HSA**
TCM products and CHP	Adverse effect that: i. may cause death or is life-threatening; ii. has resulted in a person being hospitalised or prolong a person's existing stay in hospital; or has caused any persistent or significant disability or incapacity in any person;	Inform HSA **immediately**, but in any case, **no later than 15 days** after the person responsible first becomes aware of the event or occurrence

Product	Type of adverse effects that must be reported to HSA	Reporting Timelines to HSA
	iii. has resulted in a congenital anomaly or birth defect; iv. is judged to be medically important even though the effect might not be immediately life-threatening or result in death or hospitalisation, but may jeopardise the person's health or may require intervention to prevent the person's death or one of the other outcomes referred to in paragraphs ii and iii.	
Cosmetic products	Adverse effect that has caused death or is life-threatening	Inform HSA **no later than 7 days** after the person responsible for cosmetic products 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 person responsible for cosmetic products first becomes aware of the event or occurrence

3.2. 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 online adverse event reporting form found here.

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:

a) an identifiable reporter;
b) an identifiable patient;
c) an adverse effect; and
d) 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).

3.3. What are the types of product defects to be reported to HSA, and reporting timelines?

Product defects that can pose a serious threat to persons or public health in Singapore are to be reported. In this guidance, a serious threat means a hazard that occurs in association with the use or administration of a product that may lead to the death, or a serious injury, to any person.

The following product defects must be reported to HSA by the person responsible in accordance with the following timelines:

Product	Types of product defects to be reported to HSA	Reporting timelines to HSA
CPM	Product defects that: i. may cause death or may be life-threatening; ii. may result in any person being hospitalised or prolonged hospital stay or may result in person's disability or incapacity	Inform HSA **within 48 hours** after the person responsible first becomes aware of the event or occurrence

Product	Types of product defects to be reported to HSA	Reporting timelines to HSA
CPM	All other product defects that may cause illness or affect the outcome of a person's medical treatment and/or affect the quality of a product	Inform HSA **within 15 days** after the person responsible first becomes aware of the event or occurrence
CHP/CMM	Product defects that: i. may cause death or may be life-threatening; ii. may result in any person being hospitalised or prolonged hospital stay or may result in person's disability or incapacity	Inform HSA **within 48 hours** after the person responsible first becomes aware of the event or occurrence
Cosmetic products	Product defects that may cause death or may be life-threatening	Inform HSA **no later than 7 days** after the person responsible for cosmetic products 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 defects that may result in any person being hospitalised or may cause 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 person responsible for cosmetic products first becomes aware of the event or occurrence

Examples of product defects to be reported to HSA include:

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

b) 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.

c) A product that has been manufactured using wrong ingredient(s) that may lead to the above consequences.

d) A product with missing or incorrect product labelling (such as active ingredient quantity, dosing) that may lead to the above consequences.

e) Product packaging errors leading to the above consequences

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.

3.4. 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 online defect reporting form.

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

a) Product information;
b) Description of defect;
c) Preliminary risk or safety assessment;
d) Immediate mitigation actions;
e) Number of product(s) and batch(es) affected;
f) Date of occurrence;
g) Expiry date of affected batch(es) supplied to the market;
h) Date of last distribution of the affected batches supplied to the market; and
i) An identifiable reporter.

The completed product defect reporting form and any other accompanying documents must be submitted within stipulated timelines to HSA.

The initial report of product defect should contain as much detail 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 person responsible 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 person responsible's detailed assessment.

3.5. 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):

a) 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;
b) Explain how the product defect occurred and the date of occurrence;
c) Explain how the product defect was discovered and the date it was discovered;
d) 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;
e) Local distribution records of affected batch(es) (i.e. date(s) of distribution, no. of units in batch(es), name(s) of purchaser(s));
f) Overseas distribution list of affected batch(es) exported from Singapore;
g) Indicate whether the product was sold under government tender contract or pending government tender consideration;
h) Review of batch records and any change controls or deviations associated with the batches;
i) Review of previous complaints, quality defect reports and relevant information for any indication of recurring problems (locally or globally);
j) 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;

k) 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.);
l) Identify possible root cause(s) of the product defect;
m) Risk or safety assessment on the potential short-term and long-term consequences of the product defect to intended users;
n) Certificate of Analysis of the affected batches;
o) Examine and test retention samples if needed;
p) 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
q) 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:

a) Potential consequences of the defect on the consumers;
b) Type and nature of the product involved (e.g. product’s intended use, etc.); and
c) Consumer population affected (e.g. children, elderly).

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.

3.6. 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 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.

3.7. 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, 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, the person responsible or as directed by HSA may remove the defective product from the market by recalling the affected batch(es) or, in extreme cases, recalling all batches of the product from the market.

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

The person responsible 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 person responsible establishes communication with HSA. This allows HSA to review and comment on the person responsible's recall strategy and offer guidance in the recall process.

* Not including Sundays and public holidays.

HSA may require the person responsible 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 person responsible in making assessment of the defects and reporting requirements for TCM products, CHP and cosmetic products can be found in Annexes I and Annex II.

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.
Notification to HSA	Person responsible should notify HSA **no later than 24 hours*** prior to the start of the intended recall.	Person responsible should notify HSA **no later than 24 hours*** prior to the start of the intended recall.
Issuance of Dear Purchaser Letter	Person responsible 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.	Person responsible 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. Person responsible should submit the Product Recall Completion Form to update HSA on the completion of recall.	The recall process is recommended to be completed **within 3 weeks**, unless otherwise justified. Person responsible should submit the Product Recall Completion Form to update HSA on the completion of recall.

* Not including Sundays and public holidays.

The person responsible should notify their stakeholders about the recall as soon as possible. To ensure prompt notification, person responsible 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 wholesalers and retailers 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 wholesalers and retailers 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 person responsible 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.

Person responsible 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 person responsible 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 person responsible to investigate the root cause of the recall and provide the investigation findings and CAPA report to HSA.

4.5. Recall process / procedures

The person responsible should ensure that their recall procedures are effective and the recall operation can be initiated promptly at any time. The person responsible 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 person responsible 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 person responsible should consider a strategy for returns and refunds.

4.6. Notification of recall actions to stakeholders

The person responsible should communicate the defects and the recall actions to be taken to the customers through appropriate means. The person responsible 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 person responsible 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 person responsible 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:

a) Audience / targeted recipient;
b) Purpose of letter;
c) Product details (brand and product name of product, affected batch number, product image, images to guide where to find the batch details if needed);
d) Description of issue, reason for recall and any potential health hazard(s);
e) Level of recall (wholesale, retail, consumer level);
f) Instruction to customers (e.g. remove product from sale, cease distribution, return product, conduct sub-recall if appropriate);
g) Refund mechanism;
h) Person responsible's contact; and
i) 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)

Person responsible does not need to seek approval from HSA for issuing a Dear Purchaser Letter. However, the person responsible 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

Person responsible must keep HSA informed of the progress of the recall. Person responsible 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 Person responsible 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.

Person responsible needs to furnish the Product Recall Completion Form 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 person responsible 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 person responsible should submit the certificate of destruction to HSA **within 3 months** from the completion of recall, unless otherwise justified. For this action, the person responsible 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 person responsible. For this action, the person responsible 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 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.

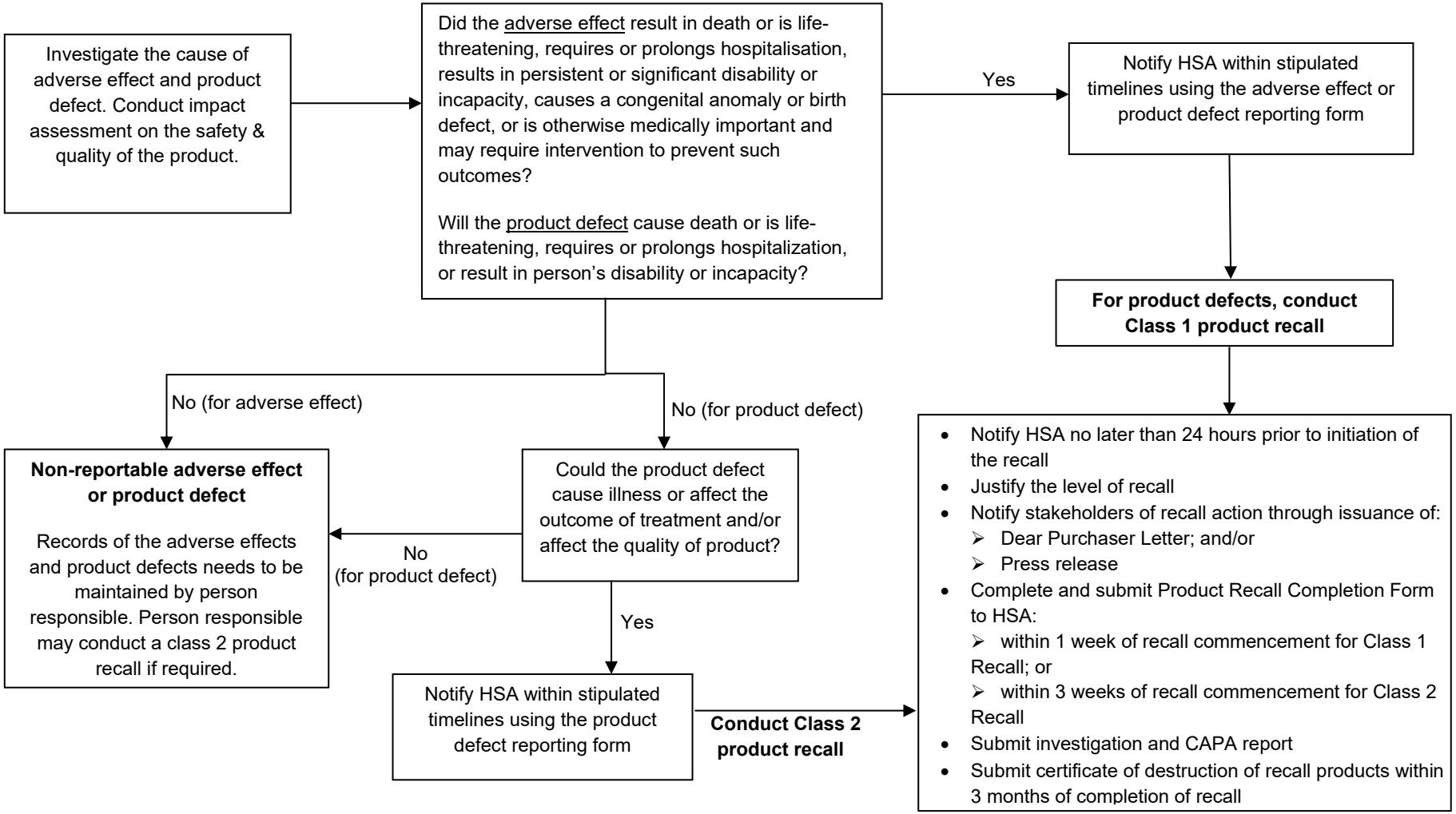
4.9. Reinstatement of supply

The person responsible 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.

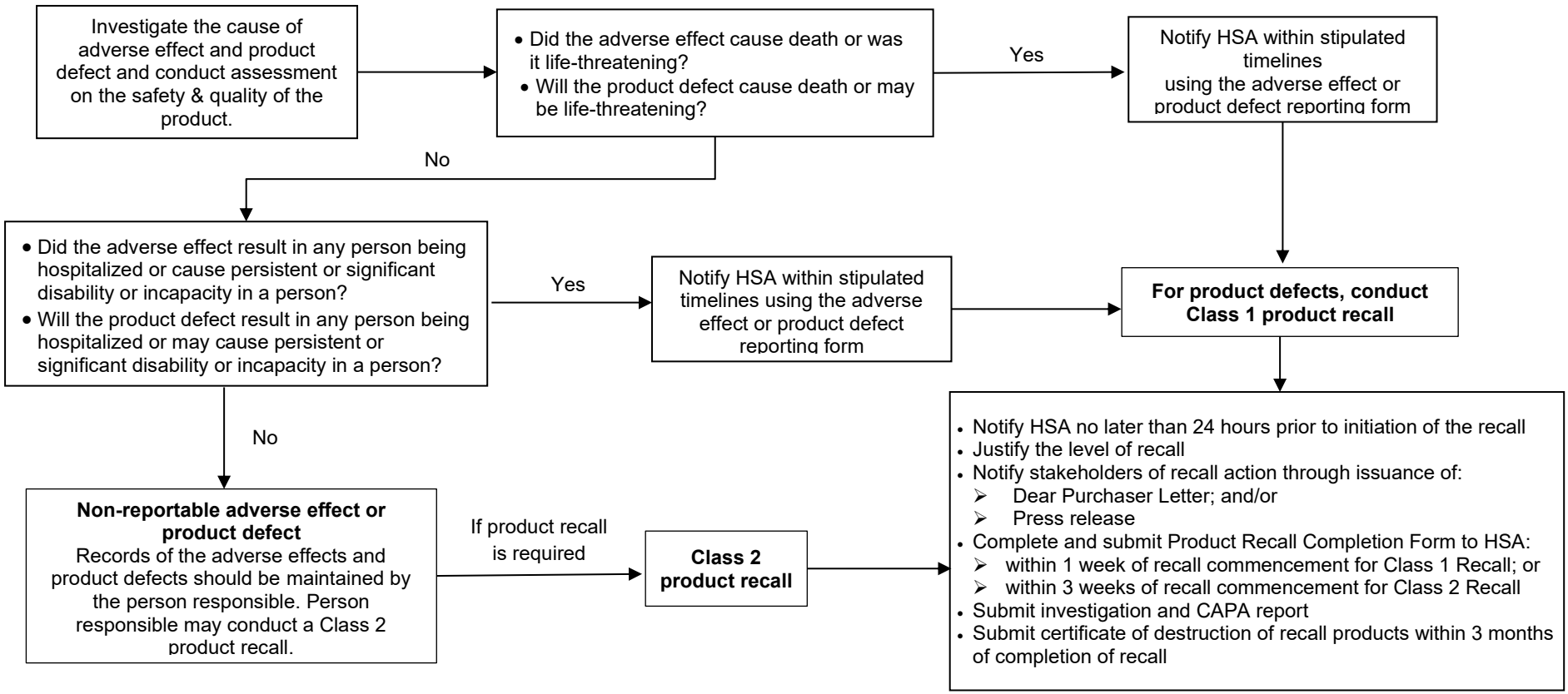
Annex I – Flowchart on assessment of product defects and product recalls for TCM products

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.



Annex II – Flowchart on reporting of adverse effects and product defects and product recalls for CHP, CMM and cosmetic products

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.



HEALTH SCIENCES AUTHORITY

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Integrated Health Regulation Group

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