HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

01 NOVEMBER 2016

GUIDANCE FOR INDUSTRY

REPORTING OF THERAPEUTIC PRODUCT DEFECTS AND RECALL OF THERAPEUTIC 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.

REVISION HISTORY

Guidance Version 1 (26 October 2016)

TABLE OF CONTENTS

INTRODUCTION

1.1 Purpose and scope

This guidance applies to registrants, manufacturers, importers and suppliers of the following categories of Therapeutic Products (TP):

a) Registered TP in Singapore;
b) Unregistered TP for patients' use in Singapore;
c) Registered TP imported on consignment basis.

The purpose of this document is to provide guidance on reporting product defects ("defects") and/or product recall ("recall") of TP to the Vigilance and Compliance Branch of the Health Sciences Authority (HSA) in accordance with the Health Products Act (HPA) and Health Products (Therapeutic Products) Regulations 2016 (HP (TP) Regulations). This Guidance does not apply to the reporting of counterfeit TP. Please submit reports related to counterfeit TP to:

Enforcement Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-01 Helios
Singapore 138667
Tel: +65- 6866 3485 Fax: +65- 6478 9065
Email: hsa_is@hsa.gov.sg

1.2 Definitions

Adulterated therapeutic product

A TP is *adulterated* if it 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 to be likely to have on the body or health of humans when such health product is used by or administered to humans.

Company

"Company" refers to the registrant, manufacturer, importer or supplier of a TP under the scope of this guidance.

Counterfeit therapeutic product

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

Dear Healthcare Professional Letter

For the purpose of this guidance, a "Dear Healthcare Professional Letter" is a letter issued by the company and intended to alert doctors, pharmacists, dentists and relevant healthcare professionals about important new or updated information regarding major safety, quality and efficacy concerns related to the use of a TP that presents potential risks to patients and/or public health.

Dear Purchaser Letter

For the purpose of this guidance, a "Dear Purchaser Letter" is a letter issued by the company to its stakeholders (such as hospitals, clinics, retail stores) to alert them to the administrative or logistic matters related to the product recall.

Recall

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

a) may be hazardous to health;

b) may fail to conform to any claim made by its manufacturer or importer relating to its quality, safety or efficacy; or
c) may not meet the requirements of the Health Products Act.

Serious adverse reaction

"Serious adverse reaction" means an adverse effect that is unintended and occurs in association with the use or administration of a TP at doses normally used in humans for prophylaxis, diagnosis or therapy of a disease or for the restoration, correction or modification of a physiological function, and that —

a) may result in a person's death;
b) may threaten a person's life;
c) results in a person being hospitalised or prolong a person's existing stay in hospital;
d) results in a person's persistent or significant disability or incapacity;
e) results in a congenital anomaly or birth defect; or
f) 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 sub-paragraphs (*c*), (*d*) and (*e*).

Tampered therapeutic product

A TP is *tampered with* if it 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.

Therapeutic product (TP)

"Therapeutic product" is a category of health products regulated under the HPA and is defined in the First Schedule of the HPA. A TP is intended for use by and in humans for a therapeutic, preventive, palliative or diagnostic purpose, and its scope includes chemical and biologic drugs.

Therapeutic product defect

A "defective TP" is defined as a TP 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 inefficacious for its intended purpose.

Unwholesome therapeutic product

A TP 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.

1. CLASSIFICATION OF PRODUCT DEFECTS

TP defects which (a) pose a *serious threat* to the intended users or public health in Singapore and/or (b) may cause illness or affect the outcome of a person's medical treatment and/ or (c) significantly affect the quality of the TP have to be reported to HSA according to the prescribed timelines.

A defect is classified into either “critical defect” or “non-critical defect” according to the potential impact to public health and the risks posed to the intended user of the TP.

2.1 Critical defect

A critical defect is deemed as one that can pose a *serious threat* to the intended users or public health in Singapore. In this guidance, a *serious threat* means a hazard that occurs in association with the use or administration of a TP and that may lead to the death of, or a *serious injury* to, any person.

Serious injury refers to an incident that –

a) may result in a person being hospitalised or prolong a person’s existing stay in hospital;
b) may result in a person’s disability or incapacity; or
c) may result in a congenital anomaly or birth defect.

2.2 Non-critical defect

A non-critical defect is one which does not meet the criteria of “critical defect” but may cause illness or affect the outcome of a person’s medical treatment and/ or significantly affect the quality of a TP.

Examples of critical and non-critical defects commonly associated with TPs are listed in Annex I. As the list of examples is non-exhaustive, companies may wish to clarify with HSA on specific cases/ scenarios not mentioned in Annex I.

2. RESPONSIBILITIES OF THE COMPANY

Companies are responsible for the safety, quality and efficacy of their TPs and should have adequate systems and appropriate procedures in place to investigate, review and report the product defects to the Authority, and if necessary, to promptly recall the TPs from the distribution network.

Upon becoming aware of a defect in a TP, the company should gather all relevant information to assess the extent of the defect and the health risk to the intended users. Information and actions that would be useful in the preliminary investigation includes:

- Full description of the defect and an examination of samples, if available;
- Correspondence with the individual(s) who reported the defects, if available;
- Review of batch records and any change controls or deviations associated with the batch(es);
- Identify possible cause(s) of the defect; and
- Assess appropriate market actions necessary for the affected stocks, including whether it is necessary to quarantine or recall any existing stocks. Please note that quarantined stocks can only be released, with HSA's concurrence, when it has been determined that there is no safety risk in the use of the product or after appropriate corrective actions had been taken to address the safety risk.

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

- the potential consequences of the defect on the patients;
- the type and nature of the product involved (e.g. the route of administration, forensic classification, etc.); and
- the patient population affected (e.g. children, elderly, immunocompromised, etc.).

Upon completion of the company’s investigation, a detailed investigation report detailing the following information should be prepared by the company, which includes:

- description of the defect;
- determination of the extent of the defect;
- test results of the defective product, if available;
- information on whether other similar defect had occurred locally or globally;
- assessment of the risk(s) posed by the defect;
- recommendation and/or decision on risk mitigation actions to be taken such as batch or product recall or other market actions;

- identification of the potential root cause(s) of the defect; and
- description of the Corrective and Preventive Actions (CAPAs) taken or to be taken.

Refer to Section 4.1 for details on reporting requirements.

3.1 Duty to report product defects to HSA

Every company must, upon becoming aware of any defect in the TP, report the defect to HSA in accordance with the following timelines:

- critical defects (as described in section 2.1) to be reported **within 48 hours***;
- non-critical defects (as described in section 2.2) to be reported **within 15 calendar days**.

(See HP (TP) Regulations – Reg 34 (1))

[1] Not including Sundays and public holidays.

3.2 Duty to maintain records of product defects

All manufacturers, importers and registrants of TPs must maintain records of every defect in a TP for **at least 2 years** after the expiry date of the TP and produce such records for inspection by HSA when required. The records must contain the following information:

- the proprietary name of the TP;
- the date on which the manufacturer, importer or registrant first became aware of the defect;
- the lot, batch or serial number of the TP; and
- the nature of the defect.

(See HP (TP) Regulations – Reg 33 (1))

3.3 Duty to notify HSA concerning product recalls

Every company who intends to recall a TP must notify HSA of, and the reasons for, the intended recall **no later than 24 hours*** before the start of the intended recall. HSA may require company to:

(a) investigate the matter leading to the recall of the TP and provide a report of the

findings of the investigation; and / or

(b) take such other measures as HSA thinks 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.

(See HP (TP) Regulations – Reg 35)

* Not including Sundays and public holidays.

The requirements for reporting defects and recall of TPs are detailed in the subsequent sections. A flowchart for guiding the company in making assessment of the defects and reporting requirements can be found in Annex II.

SECTION A: REPORTING AND REVIEW OF THERAPEUTIC PRODUCT DEFECTS

4. REPORTING AND REVIEW OF THERAPEUTIC PRODUCT DEFECTS

4.1 What and how to report?

(a) What needs to be reported to HSA

- Critical or non-critical (see section 2) defects of TPs affecting:
  - batches which have been imported for supply or supplied in Singapore;
  - batches which have not been supplied in Singapore but where the company is aware that the root cause of the defect could potentially affect the local and / or future importation.

Please note that the above defects include those resulting from manufacturing deviations or non-compliances to GMP at a manufacturing plant (which may be located in Singapore or overseas).

In addition, the company may be required to submit information when requested by HSA to assist in the investigation of 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) have potential impact on the TPs supplied in Singapore.

(See HPA – Sec 42 (2))

(b) Timelines of reporting

The timelines of reporting starts from the day immediately following the day that the local company becomes aware of the defect, and will depend on whether it is a critical or non-critical defect, where reporting has to be completed **within 48 hours*** for critical defects and **15 calendar days** for non-critical defects.

Please note that not-withstanding the reporting timelines, if there is a critical defect which poses a safety risk to public, the company should still take prompt measures to minimise the risk (including market actions) even if it needs to be done during non-working hours.

* Not including Sundays and public holidays.

(c) How to report a product defect to HSA

Company should use the reporting form provided in Annex III to report product defects to HSA. The company is required to provide the key preliminary information of the defect such as classification of the defect, description of the defect, details of the affected product(s) and batches, company's preliminary assessment, as well as any immediate mitigation actions. The completed product defect reporting form and any other accompanying documents must be submitted to:

Vigilance and Compliance Branch
Email: hsa_productdefect@hsa.gov.sg

HSA will contact the company if the defect has to be reclassified based on the assessment of the preliminary information provided. Please note that the classification of the defect may change as more information becomes available.

(d) Submission of investigation report

In general, an investigation report will be requested by HSA for all critical and non-critical defects. Please refer to Section 3 of this guidance for the types of information to be included into the investigation report.

(e) Reporting of local serious adverse reaction related to a product defect

In addition to reporting the defect to HSA, if the company is aware of any local serious adverse reaction (SAR) that is assessed or suspected to be caused by the defect, a separate report for the SAR is to be submitted based on the reporting requirements. This report could be submitted using HSA's adverse event reporting form and submitted to the Vigilance and Compliance Branch of HSA. For more details on SAR reporting such as the channels of reporting and timelines for reporting a SAR, please refer to the "Guidance For Industry: Post-Marketing Vigilance Requirements For Therapeutic Products".

(f) Recalls related to product defect

The company must also inform HSA of any recalls that it wants to conduct in accordance with the stipulated timeline. For details on recalls, please refer to Section B of this guidance.

4.2 What regulatory actions can HSA take arising from a product defect?

Upon receipt of the product defect report, HSA will review the information provided in the report and may request for the company 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, e.g. product recall, issuance of Dear Health Care Professional Letter and/or issuance of press release. HSA may also suspend or cancel the product registration if there are critical and/or major defects which have not been addressed. This will be assessed on a case by case basis.

SECTION B: RECALL OF THERAPEUTIC PRODUCTS

Where a defective TP is considered to present a risk to the intended user and/or public health, HSA may require the company to remove the defective TP 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 TP even if the defect does not pose a risk to the intended user and / or public health, or for reasons other than product defects (e.g. commercial reasons).

All recalls of TPs would need to follow the classification of recall and recall timelines described in Section 5.

In the event of a recall, companies are advised to plan ahead (to their best ability) for scenarios where there may be potential disruption of product supply, particularly for TPs where there are no other available alternatives in Singapore.

5. CLASSIFICATION OF RECALL AND RECALL TIMELINES

A recall is classified as Class 1 or Class 2 depending on the potential hazard of the defect.

	Class 1 recall	**Class 2 recall**
Description	There is a reasonable probability that the use of or exposure to a TP with **critical defect** which may cause serious adverse health consequences or death.	The use of or exposure to a TP with **non-critical defect** which may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
Notification to HSA	Company must notify HSA within 24 hours (**1 day)*** prior to the start of the intended recall.	Company must notify HSA within 24 hours (**1 day)*** prior to the start of the intended recall.
Issuance of Dear Purchaser Letter	Company is required to 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 is required to 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 *(refer to Section 7.5 for details)*	The recall process is recommended to be completed within **1 week**, unless otherwise justified. Company 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. Company should submit the Product Recall Completion Form to update HSA on the completion of recall.

*Not including Sundays and public holidays.

6. 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 patients or consumers is assessed to be unacceptable, and where the product has been supplied to consumers.
- Affected product or batch(es) are to be recalled from all wholesale and retail distributors as well as patients/consumers who had been supplied with the affected batch(es).
- 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.
- All wholesale and retail supply of the affected product or batch(es) should be suspended.

b) Retail level

- Usually initiated when the risk to patients or consumers is assessed to be moderate to high but recall at consumer level is not deemed necessary (e.g. if the product is administered by healthcare professionals and not directly supplied to patients).
- 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:
  - Restructured and private hospital pharmacies;
  - Retail pharmacies;
  - Medical, dental and other healthcare practitioners' establishments;
  - Community hospitals, nursing homes and other related institutions;
  - Other retail outlets, e.g. health food stores, supermarkets.
- 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 or where other measures can be taken to mitigate the risk to prevent

disruption in supply of critical TPs (e.g. visual inspections or other interventions by healthcare professionals before supply to patients).

- 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.
- 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.

7. CONDUCTING THERAPEUTIC PRODUCT RECALL

7.1 Initiation of recall

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

Companies do not need to seek approval from HSA for initiating a product recall, but they must notify HSA of, and the reasons for, the intended recall **no later than 24 hours*** before the start of the intended recall.

(See HP (TP) Regulations – Reg 35)

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.

*Not including Sundays and public holidays.

7.2 Recall process / procedures

The requirements for management of recall, including the types of records that should be kept for supply chain traceability, as well as sale and distribution records

of wholesale or retail supply, are also described in the HP (TP) Regulations and the Guidance Notes on Good Distribution Practice. Companies should ensure that their recall procedures are effective and the recall operation can be initiated promptly at any time.

7.3 Notification of recall actions to stakeholders

The company should communicate the presence of defects and the recall actions taken, to the customers through appropriate means, such as a Dear Purchaser Letter. A Dear Purchaser Letter should include the following information:

- Audience / targeted recipient;
- Purpose of letter (with product identification, class and level of recall);
- Description of problem and potential health hazard(s);
- Instruction to customers; and
- Company's contact

Companies do not need to seek approval from HSA for issuing the Dear Purchaser Letter, but they should send a copy of the Dear Purchaser Letter to HSA for reference and documentation purposes.

7.4 Press release

For critical and non-critical defects and/or where the affected product is widely distributed, HSA may require the issuance of a press release to update the public on the recall in a timely manner.

7.5 Completion of recall

Company must inform HSA on the completion of a product recall by furnishing the Product Recall Completion Form (please refer to Annex IV for the form). As part of the recall completion report, companies 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. 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. Documentary proof of action taken is required 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 and this will be subjected to approval from HSA.

The completed Product Recall Completion Form and any other accompanying documents must be submitted to:

Vigilance and Compliance Branch
Email: hsa_productdefect@hsa.gov.sg

For enquiries on this document, please contact:

Vigilance & Compliance Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-01 Helios
Singapore 138667
Tel: (65) 6866 1111; Fax: (65) 6478 9069
Email: hsa_productdefect@hsa.gov.sg

Annex I – Examples of Defects Commonly Associated with TPs

The examples listed under each classification are not meant to be exhaustive. Companies may contact HSA should they encounter cases/ scenarios outside of the mentioned examples.

(1) **Critical defect**

Defects that may lead to the death of, or serious injury to, the person using or being administered the product.

Examples:

- Product labelled with incorrect information (e.g. strength, active ingredient, dosing information), which could result in serious medical consequences;
- Microbial contamination of sterile injectable or ophthalmic product;
- Chemical contamination of product with serious medical consequences;
- Product mix-up (e.g. blister pack or container packed with wrong product) which could result in serious medical consequences;
- Wrong active ingredient used during manufacture of product

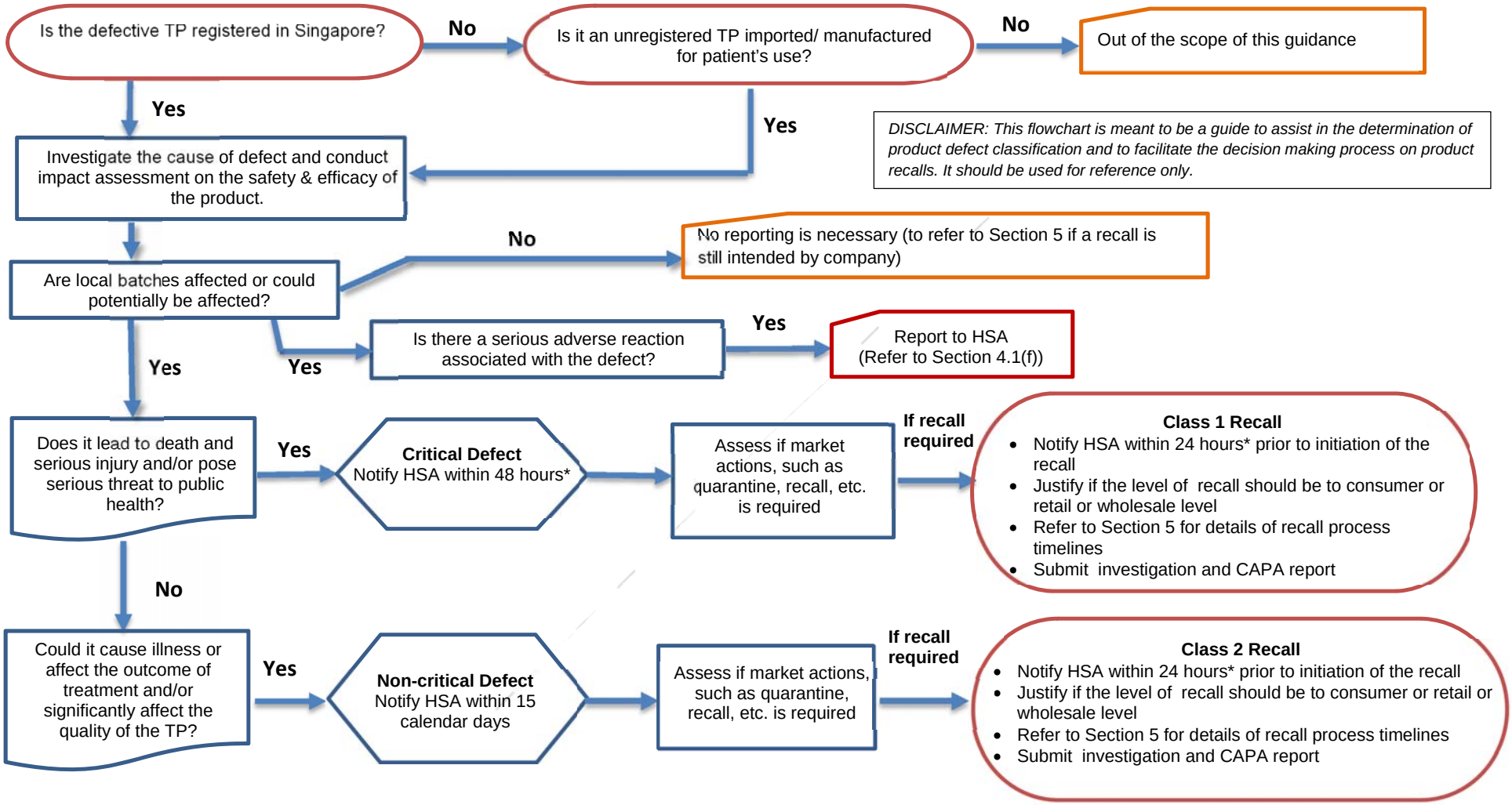
(2) Non-critical defect

Defects that do not meet the criteria of "critical defect" but may cause illness or affect the outcome of a person's medical treatment and/or significantly affect the quality of a TP.

Examples:

- Microbial contamination of non-injectable, non-ophthalmic product;
- Chemical/physical contamination;
- Non-compliance with specification (e.g. assay, stability, fill/weight, particulates, foul-smelling);
- Wrong expiry date
- Major label errors which may affect the safety and efficacy of the TP (e.g. error in the strength, dose, administration instructions, or name of product)

Annex II – Flowchart on Assessment of Product Defects and Product Recalls



*It does not include Sundays and public holidays.

Annex III – Product Defect Reporting Form

Instructions:

1. This form may take you 30 minutes to fill in. You will need to prepare certain information in order to complete the form.
2. You can refer to the HSA's guidance for industry – reporting of therapeutic product defects and recall of therapeutic products for details on the reporting requirements.
3. The information denoted (*) are mandatory to fill in.
4. If the space provided in the form is insufficient, please provide the information as an attachment.

This form is to be submitted to the Vigilance and Compliance Branch via email to **hsa_productdefect@hsa.gov.sg**.

1	**Summary of product defect notification**	
1.1	Product defect classification*	☐ Critical ☐ Non-critical
1.2	Is there a need for a product recall?*	☐ Yes ☐ No ☐ Not determined *If Yes, please complete the following (please attach a copy of the Dear Purchaser Letter):* Class of Recall: ☐ Class 1 ☐ Class 2 Level of Recall: ☐ Consumer ☐ Retail ☐ Wholesale Date of initiation of recall: _____
2	**Company and contact details**	
2.1	Date of notification to HSA*	
2.2	Company type*	☐ Registrant ☐ Importer ☐ Wholesaler ☐ Manufacturer ☐ Others (*please specify)*:_____
2.3	Name of company*	
2.4	Company address*	
2.5	Name of reporting person*	
2.6	Designation *	
2.7	Office tel.*	
2.8	Mobile tel.	

2.9	Fax				
2.10	Email*				
2.11	Signature of reporting person*				
2.12	Name of contact person *(if it is different from the reporting person)*				
2.13	Designation				
2.14	Office tel.				
2.15	Mobile tel.				
2.16	Fax				
2.17	Email				
3	**Product details** • Additional products can be provided as an attachment. • Please also attach the distribution list of the affected batch(es), if applicable.				
3.1	Name of product*				
3.2	Product licence number or other reference number				
3.3	Active ingredient(s)*				
3.4	Dosage form (s)*				
3.5	Strength (s)*				
3.6	Pack size(s)				
3.7	Manufacturer*				
3.8	Address of manufacturer				
3.9	Where is the product supplied to?	☐ Hospitals ☐ Medical or Dental clinics ☐ Nursing homes ☐ Retail pharmacies ☐ Retail shops ☐ Not marketed ☐ Others *(please specify)*:_____ If the product is supplied under a tender, please specify the tender period:_____			
3.10	Are the affected batch(es) supplied in Singapore?*	☐ Yes ☐ No			
3.11	If yes, provide batch number(s) affected and expiry date(s)	Batch no:		Expiry date:	
		Batch no:		Expiry date:	
		Batch no:		Expiry date:	

4	**Nature of defect(s)**	
4.1	Date of first detection of defect *	
4.2	If the defect is detected in Singapore, indicate the place of the first detection of the defect	☐ Hospital ☐ Medical or Dental clinics ☐ Manufacturer ☐ Nursing homes ☐ Patient / consumer ☐ Retail pharmacies ☐ Retail shops ☐ Others *(please specify)*:_____
4.3	If the defect is detected outside of Singapore, please state the country	
4.4	Details of the defect * *(please provide investigation and medical assessment if available. Investigation reports should provide justification on the defect classification)*	
4.5	Was there a local serious adverse reaction associated with the defect?	☐ Yes ☐ No ☐ Not known
4.6	If yes, was an adverse effect report submitted to HSA?	☐ Yes *(Date of submission of report to HSA):* _____ ☐ Pending ☐ Not known
5	**Actions taken / Proposed market actions** *(please attach CAPA report if needed)*	
5.1	Actions taken and proposed actions to be taken *(Include actions taken in overseas market for the affected product)*	
5.2	Other relevant information	

Attachment – Product details

		1	2	3	4	5
3.1	Name of product*					
3.2	Product licence number or other reference number					
3.3	Active ingredient(s)*					
3.4	Dosage form (s)*					
3.5	Strength (s)*					
3.6	Pack size(s)					
3.7	Manufacturer*					
3.8	Address of manufacturer					
3.9	Where is the product supplied?					
3.10	Are the affected batch(es) supplied in Singapore?*					
3.11	If yes, provide batch number(s) affected and expiry date(s)					

Annex IV – Product Recall Completion Form

Instructions:

1. This form may take you 30 minutes to fill in.
2. You will need the following information to fill in the form:
   - Details of recall, including import and sales data, batches recalled, quantity recalled etc.

   This form is to be submitted to the Vigilance and Compliance Branch via email to **hsa_productdefect@hsa.gov.sg**.

1 Details of company

1.1	Name of company	:	_____
1.2	Address of company	:	_____
1.3	Name of reporting person	:	_____
1.4	Designation	:	_____
1.5	Office tel.	:	_____
1.6	Mobile tel.	:	_____
1.7	Fax	:	_____
1.8	Email	:	_____
1.9	Signature of reporting person	:	_____
1.10	Date	:	_____

2 Details of recall

2.1	Class of the recall	:	_____
2.2	Level of the recall	:	_____
2.3	Date of recall initiation	:	_____
2.4	Date of recall completion	:	_____

3 Product details

- Additional products can be provided as an attachment.

3.1	Name of product	:	_____
3.2	Product licence number or other reference number *(please indicate relevant reference number for unregistered therapeutic product)*	:	_____
3.3	Active ingredient(s)	:	_____
3.4	Batch no: _____		Expiry date:_____
	Batch no: _____		Expiry date:_____
	Batch no: _____		Expiry date:_____
3.5	Quantity imported or manufactured in Singapore	:	_____
3.6	Quantity remaining in warehouse	:	_____
3.7	Quantity sold[#]	:	_____
3.8	Quantity recalled^	:	_____

[#] Please attach sales record.
^ Please provide names and addresses of purchasers and quantities recalled.

4. Action(s) taken on affected stock(s)

4.1 I confirm that the above recall has been completed on *(date)* _____and all recalled stocks have been planned for:

☐ Destruction*.

☐ Re-introduction into the market upon approval by the Authority.

☐ Other actions upon approval by the Authority. Please specify the actions to be taken:

_____

_____

* Approval is not required. Documentary proof of action taken is required to be submitted once the recalled products are destroyed.

Attachment – Product details

		1	2	3	4	5
3.1	Name of product					
3.2	Product licence number or other reference number					
3.3	Active ingredient(s)					
3.4	Batch number(s) affected and expiry date(s)					
3.5	Quantity imported or manufactured in Singapore					
3.6	Quantity remaining in warehouse					
3.7	Quantity sold					
3.8	Quantity recalled					
3.9	Action taken (pls specify: destruction / re-introduced / others)					

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact:

Vigilance and Compliance Branch
Post-Market Cluster
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way, #11-03 Helios
Singapore 138667
www.hsa.gov.sg
Tel: 6866 1111
Fax: 6478 9069
Email: HSA_productdefect@hsa.gov.sg
Website: www.hsa.gov.sg

HSA
Health Sciences Authority