

FAQ ON THE REPORTING OF THERAPEUTIC PRODUCT DEFECTS AND RECALL OF THERAPEUTIC PRODUCTS

1. Why is product defect reporting necessary?

Under the Health Products (Therapeutic Products) Regulations 2016, any product defects affecting the safety, quality and efficacy that may cause potential harm to the patient or public health have to be reported to HSA.

The reporting of these product defects is necessary as it allows HSA to assess if proper investigation on the root cause of the defect has been conducted and if corrective actions taken are adequate and appropriate in order to mitigate health risks to patients and consumers.

2. Why does the company need to report critical defect to HSA within 48 hours upon becoming aware of the product defect?

A critical defect can pose a serious threat to the intended users or to public health and may lead to a patient's death or cause serious injuries. Therefore, it is important for the company to alert HSA expeditiously so that both parties can work in collaboration to mitigate the health risk to patients that may potentially arise from these critical defects.

An example of a critical defect is the mislabelling of high strength potassium chloride infusion with a low strength potassium chloride label. This may lead to a patient receiving an overdose of potassium chloride, which in the worst case scenario can lead to a heart attack within minutes.

The company should inform HSA of the defect with preliminary key information such as the classification of the defect, description of the defect, details of the affected product(s), company's preliminary assessment and immediate mitigation actions (if any), as required in the HSA's product defect reporting form.

3. **When does the clock start for product defect reporting and recalls? Does the clock start upon the local company being aware?**

For product defects reporting, the clock starts from the day immediately following the day that the **local** company becomes aware of the defect. For a recall, the clock starts within 24 hours (1 day) prior to the start of the intended recall in Singapore.

4. **Do the 48 hours timelines for reporting of critical defects and the 24 hours timelines for notification of recalls to HSA include weekends and public holidays?**

Both of the timelines exclude Sundays and public holidays. However, it should be noted that 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.

5. **To what extent is a defect considered reportable to HSA? Would dented carton or isolated incident of chipped tablet be reportable to HSA?**

A defect which pose a serious threat to the intended users or public health in Singapore, cause illness or affect the outcome of a person's medical treatment, or which significantly affect the quality of TP need to be reported to HSA.

Some common examples* of defects which do not fall within the above scope include:

1. Minor typographical errors on the product label not affecting critical information like the strength of the product, the dose, the name of the product etc.
2. Dented shipping carton and damage to secondary packaging
3. Isolated incidents of chipped tablets

*non-exhaustive list of examples

It is to be noted that the company needs to maintain records of all defects affecting TP that have been supplied to Singapore and these records should be made available upon HSA's requests.

The company may also 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 TP supplied in Singapore.

6. Do reports of product defect occurring in other countries need to be reported to HSA?

Reports of product defects occurring in other countries need not be reported to HSA unless the root cause of the defect has been determined to affect local batches or batches to be supplied to Singapore.

However, the company may still 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.

7. How are the timelines affected in the event that there is a reclassification of the product defect or recall by the company?

At any point of time that a reclassification of a reported product defect or recall has been made, the clock will restart from the time that the reclassification has been determined by the company.

8. Who is responsible for reporting product defect to HSA?

Every manufacturer, importer, supplier or registrant of a therapeutic product is responsible for reporting the defect to HSA within the stipulated timelines, upon becoming aware of any defect in the therapeutic product.

If there is a business arrangement between the registrant, importer, manufacturer and/or supplier to ensure that at least one party is responsible for reporting the product defect to HSA, it is acceptable that not all parties report the same defect to HSA. The party reporting the defect should keep the other

parties informed, and the appropriate records should be kept. If unsure whether the defect has been reported by the other party(ies), the company should report the defect to HSA.

9. **Are product complaints by patients / consumers regarded as product defects?**

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

10. **Do the defects in the following categories of TP need to be reported:**

- (i) unregistered therapeutic products which are supplied for patients' use in Singapore**
- (ii) therapeutic products which are compounded by pharmacies or healthcare institutions**
- (iii) therapeutic products undergoing application process in Singapore**
- (iv) therapeutic products used for local clinical trials?**

Yes, these defects have to be reported as follows:

- (i) Unregistered therapeutic products can be imported by a licensed importer or a healthcare institution licensee or holder of a pharmacy licence for patients' use. The person importing the unregistered therapeutic products is responsible for reporting the defect to HSA.
- (ii) Defects discovered or suspected in therapeutic products which are compounded by licensed pharmacy or healthcare institution should be reported to HSA by the respective pharmacy or healthcare institution who supply these products.
- (iii) If the occurrence of defects or suspected defects is found in

therapeutic product which is still undergoing the application process in Singapore, it is the TP registration applicant's responsibility to inform the Therapeutic Products Branch, upon receipt of information about a product defect. The Therapeutic Products Branch may need to review the full investigation report and/or any information that could potentially affect the risk-benefit assessment of the product to be registered. The information should be sent directly to HSA_TP_Enquiry@hsa.gov.sg.

- (iv) If the therapeutic product used for local clinical trials is an unregistered therapeutic product in Singapore, please report it to the Clinical Trials Branch at HSA_CT@hsa.gov.sg . For registered therapeutic products used for local clinical trials, please report to the Vigilance and Compliance Branch at HSA_Productdefect@hsa.gov.sg and indicate the reference number of the local clinical trial.

11. Does the company need to provide the full investigation report at the time of reporting of the product defect?

In general, for critical and non-critical defects with impact on products marketed in Singapore, a full investigation report would be requested by HSA and should be submitted upon completion of the company's investigation.

HSA understands that a thorough investigation could take a few weeks or more to complete. Company should prioritise the investigation, and avoid delays in the investigation and reporting process. The company can submit all available information initially and provide updates as soon as it is possible.

12. Is there a template or format for the investigation report?

There is no fixed template or format for the investigation report and the company can adopt their own template. For the required information of the investigation report, please refer to Section 3 of the [Guidance for Industry- Reporting of therapeutic products defects and recall of therapeutic products](#).

13. **If a patient developed a serious adverse reaction as a result of a product defect, does the company need to submit both an adverse effect report and a product defect report to HSA?**

Yes, the company needs to submit both an adverse effect report and a product defect report if a local patient had developed a serious adverse reaction to the therapeutic product as a result of consuming or using the defective product. Both forms can be submitted together to HSA_productdefect@hsa.gov.sg to facilitate the submission.

For more details on the reporting requirements for product defect and adverse events, please refer to the respective forms and guidance below.

Forms	Guidance	Sent to email
Product Defect Reporting Form	Guidance for Industry- Reporting of therapeutic products defects and recall of therapeutic products	HSA_productdefect@hsa.gov.sg <i>(The form will be channelled to the respective department handling the information.)</i>
Adverse Effect Reporting Form	Guidance For Industry: Post-Marketing Vigilance Requirements For Therapeutic Products	

14. **Should the company submit the defective product to HSA?**

The company need not submit the defective product unless requested by HSA for examination and/or independent testing.

15. **What is the difference between class and level of recall?**

The classification of recall is meant to reflect the severity of the defect and its impact on a person's health.

The level of recall describes the extent of the action required based on the

extent of distribution of the affected product and potential hazard to public health.

The decision on the appropriate class and level of recall would depend on the severity of the defect, the extent of the recall and necessity of promptness of communication to the affected population.

16. **Does the timelines stipulated by HSA include both the class and level of recall?**

The timelines are determined by the class of the recall. The timelines to complete a recall are just provided as a guideline for best practice. These timelines for recalls has been recommended by HSA in the best interest of public safety. However, if more time is required by the company, please inform HSA and provide the reason(s).

17. **Who, from the company, will HSA contact on matters relating to the product defect reported, and what are the responsibilities of this person?**

HSA will contact the person reporting the product defect, as indicated in the product defect form. This person should be able to respond promptly to any request from HSA for the provision of information necessary for the risk assessment of the product, e.g. sales data, list of purchasers, investigation report and communication materials.