MINISTRY OF HEALTH
BRUNEI DARUSSALAM

GUIDANCE FOR REPORTING OF MEDICINAL PRODUCT DEFECT, QUARANTINE AND RECALL IN NON MINISTRY OF HEALTH FACILITIES

1ST EDITION JULY 2022

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Adapted from:

1. Guideline on Good Storage Practice for Medicinal and Health Products, Department of Pharmaceutical Services, Ministry of Health, Brunei Darussalam, 2010.

2. Guidance for industry Product Defect Reporting and Recall Procedures for Therapeutic Products and Cells, Tissue and Gene Therapy Products by Health Sciences Authority Singapore, revised 1st March 2021.

   https://www.hsa.gov.sg/docs/default-source/hprg-vcb/product-defect-and-recall/guidance_defect-and-recall-reporting_1mar2021.pdf

3. Guidelines on Good Distribution Practice (GDP), National Pharmaceutical Regulatory Division, Ministry of Health, Malaysia, 2018

   https://npra.gov.my/images/Guidelines_Central/Guidelines_on_Regulatory/2018/GUIDELINE_ON_GDP_3rd_Edi_2018.pdf

4. A Guide to Defective Medicinal Products, Medicines & Healthcare Products Regulatory Agency, August 2021.

PREFACE

The purpose of this document is to provide guidance on reporting of product defect from **non Ministry of Health facilities** to the Licensed Manufacturer/ Licensed Wholesaler/ Licensed Importer/ Product Licence Holder in Brunei Darussalam and the handling of quarantine and recall of medicinal products in non Ministry of Health facilities.

Non Ministry of Health facilities are healthcare facilities that are not under the management of Ministry of Health such as private retail pharmacies, private hospitals, private clinics and other government agencies that handle medicinal products such as Ministry of Defence and Ministry of Culture, Youth and Sports.

SECTION A: MEDICINAL PRODUCT DEFECT

1. Introduction to Medicinal Product Defect

Medicinal Product (MP) are health products regulated under the Medicines Order 2007; and is intended for use in humans for therapeutic, preventive, palliative and diagnostic purposes.

A defective Medicinal Product is one which has quality issue concerns, which may compromise their safety and efficacy. These include defects which:

- Pose a *serious threat* to the intended users or public health in Brunei Darussalam
- May cause illness or affect the outcome of a person's medical treatment
- Significantly affect the quality of the MP
- Has or has possibly been adulterated or tampered with
- Is or is possibly an unwholesome health product
- Is or is possibly of inadequate quality or unsafe or inefficacious for its intended purpose
- Fails or could possibly fail to satisfy such other standards or requirements as may be prescribed.

2. Classification of Product Defects

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 MP.

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 Brunei Darussalam. In this guidance, a *serious threat* means a hazard that occurs in association with the use or administration of a MP and that may lead to the death of, or a *serious injury* to, any person. *Serious injury* refers to an incident that:

- May result in a person being hospitalised or prolong a person's existing stay in hospital
- May result in a person's disability or incapacity
- 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 MP.

Examples of critical and non-critical defects commonly associated with MPs are listed in Annex I. As the list of examples is non-exhaustive, Non Ministry of Health facilities may wish to clarify with Licensed Manufacturer/ Licensed Wholesaler/ Licenced Importer/ Product Licence Holder on specific cases/ scenarios not mentioned in Annex I.

3. Mechanism of Reporting of Medicinal Product Defects

Any medicinal product which have been supplied to non Ministry of Health facilities that showed any indications for product quality defect should be **reported to the Licensed Manufacturer/ Licensed Wholesaler/ Licensed Importer/ Product Licence Holder** using the **Medicinal Product Quality Reporting Form** in Annex II with information such as:

- Reporter details
- Medicinal Product details
- Quality report description
- Additional information (eg: storage conditions, seal still intact, etc)

It is preferable for the affected sample or picture to be sent with the form where possible (unless item is a cold chain product where the sample must be quarantined at detected site).

The Medicinal Product Quality Report is to be sent to Licensed Manufacturer/ Licensed Wholesaler/ Licensed Importer/ Product Licence Holder and cc to Pharmacovigilance Section, Department of Pharmaceutical Services, Ministry of Health in accordance with the following timelines:

- Critical defects to be reported **within 24 hours***;
- Non-critical defects to be reported **within 7 calendar days**.

(* Not including Sundays and public holidays)

The report will be investigated and outcome of investigation will be relayed to the reporter in due time.

The product in question will be continued to be regularly monitored for further reports. Regulatory action such as a product recall may be initiated if the defective medicinal product presented a risk to the intended user and/or the public.

The Licensed Manufacturer/ Licensed Wholesaler/ Licensed Importer/ Product Licence Holder will also make a report on the investigation of the product defect to Pharmacovigilance Section, Department of Pharmaceutical Services, Ministry of Health, Brunei Darussalam.

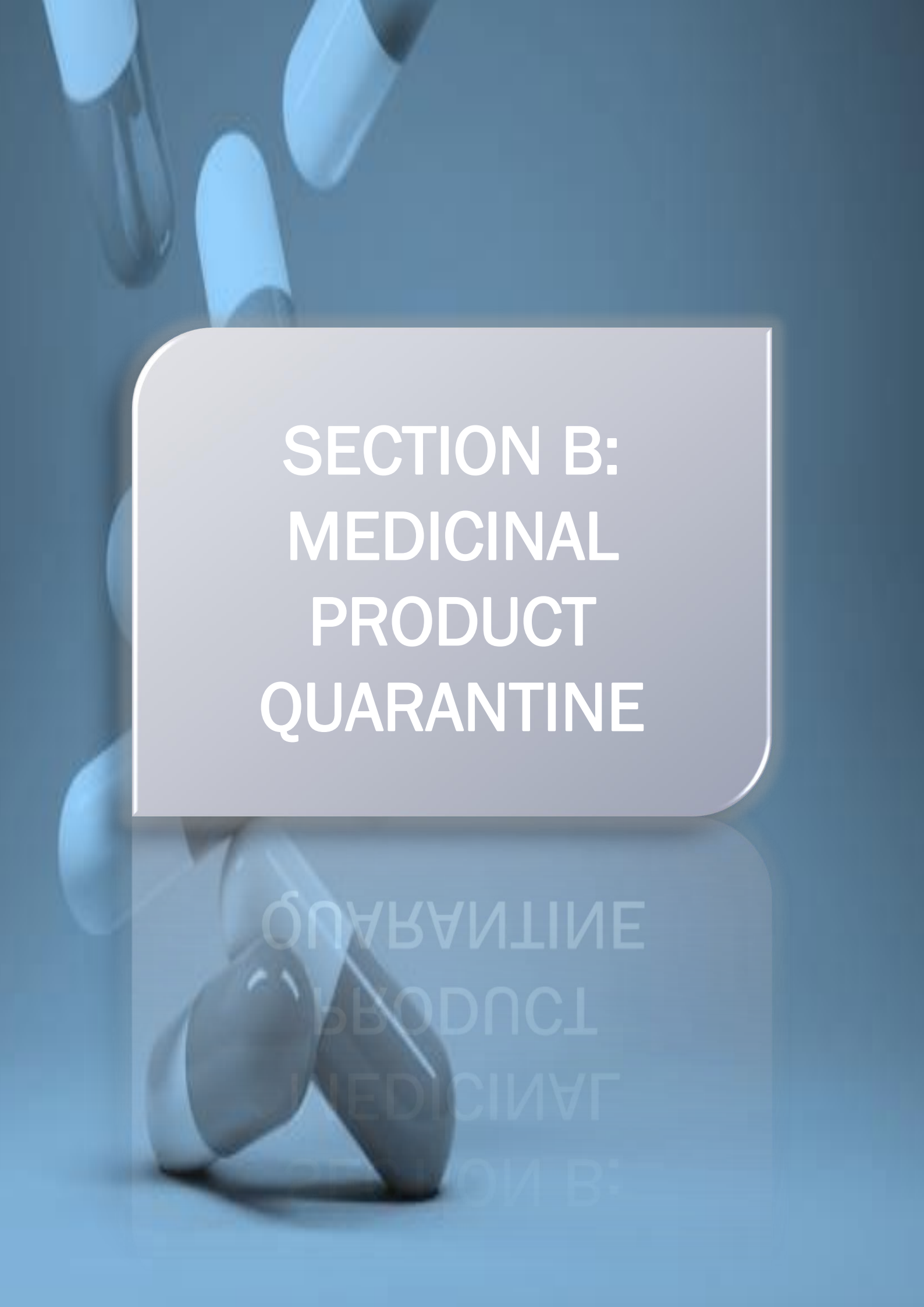
The outcome of investigation including corrective action (if required) from the manufacturer is to be relayed to the enduser and a copy given to Pharmacovigilance Section, Department of Pharmaceutical Services.

The Licensed Manufacturer/ Licensed Wholesaler/ Licensed Importer/ Product Licence Holder are also required to provide replacement of the same product to non Ministry of Health facilities. If this is not feasible, medicines of equivalent value or a credit note can be given as the replacement. Details of this arrangement will be between the particular facility and the Licensed Manufacturer/ Licensed Wholesaler/ Licensed Importer/ Product Licence Holder.

4. Reporting of Local Serious Adverse Reaction Related to A Product Defect

In addition to reporting the defect to the Licensed Manufacturer/ Licensed Wholesaler/ Licenced Importer/ Product Licence Holder, if non Ministry of Health facilities 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 serious adverse reaction is to be

submitted. This report can be submitted using the **Suspected Adverse Drug Reaction Report form or Adverse Events Following Immunisation (AEFI) reporting form (for vaccines)** and submit to the **Pharmacovigilance Section, Department of Pharmaceutical Services, Ministry of Health.** For more details on serious adverse reaction reporting such as the channels of reporting and timelines for reporting a SAR, please refer to the Brunei Darussalam Pharmacovigilance Guidelines June 2018.



SECTION B: MEDICINAL PRODUCT QUARANTINE

1. Introduction to Medicinal Product Quarantine

After the initial assessment of a defective product, a conclusion is usually made to further monitor the item. However, there are certain defects that may present an unknown risk to the intended user and/or public which may need to be investigated further or when a definite conclusion is difficult to make due to insufficient information. Therefore, for safety reasons, the defective product is to be taken out from the supply chain and keep in quarantine.

Information on MP for quarantine can be based on own investigation, advice from Ministry of Health or from the Licensed Manufacturer/ Licensed Wholesaler/ Licenced Importer/ Product Licence Holder.

2. Conducting Medicinal Product Quarantine in Non Ministry of Health Facilities

If the affected product is to be quarantined, the designated personnel will suspend all supply of the affected batch(es), collect all affected batch(es) and quarantine them in a safe designated area in their premises. This should be conducted promptly after issuance of a Quarantine Alert (if applicable). The designated quarantine storage areas should be clearly marked and the access should be restricted to authorise personnel. Any system (eg: computerised and bar coding system) replacing the physical separation should give equivalent assurance in segregation and restriction in accessibility.

The defective product will be quarantined while waiting detailed investigation report from the manufacturer as well as laboratory analysis report from Pharmacy Laboratory, Ministry of Health (if required). Based on the outcome of the investigation, the defective MP can either be released from quarantine and can be given out to the public or will lead to the initiation of a medicinal product recall.

SECTION C: MEDICINAL PRODUCT RECALL

1. Introduction to Medicinal Product Recall

Where a defective MP is considered to present a risk to the intended user and/or public, this may require the removal of the defective MP from the supply chain by recalling the affected batch(es).

A product recall may arise from a product quality or drug safety issue. It can also be due to substandard and falsified MP. This information may be obtained from investigations by Pharmacovigilance Section, Department of Pharmaceutical Services, Ministry of Health or are provided by the Licensed Manufacturer/ Licensed Wholesaler/ Licenced Importer/ Product Licence Holder.

Licensed Wholesaler/ Licenced Importer/ Product Licence Holder can initiate a voluntary recall based on information from their manufacturer or other regulatory agencies. The voluntary recall must be informed to Ministry of Health.

Licensed Manufacturer/ Licensed Wholesaler/ Licenced Importer/ Product Licence Holder may also initiate a recall of a MP 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).

In the event of a recall, Licensed Manufacturer/ Licensed Wholesaler/ Licenced Importer/ Product Licence Holder are advised to have back-up procedures and plans for anticipating scenarios where there may be potential disruption of product supply, particularly for MPs where there are no other available alternatives in Brunei Darussalam. This may include checking if unaffected batches are available and to source for an equivalent alternative brand.

2. Classification of Recall and Recall Timelines

A recall is classified as Class I, Class II or Class III depending on the potential hazard of the defect.

	Description	Notification to MOH and other facilities that were supplied with the MP	Examples
Class I	There is a reasonable probability that the use of or exposure to a product with **critical defect** may cause serious adverse health consequences or death.	Company must notify no later than 24 hours prior to the start of the intended recall.	- A label mix up on a life- saving drug - Microbial contamination of sterile injections or ophthalmic products - Wrong product
Class II	The use of or exposure to a product 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.	Company must notify no later than 72 hours prior to the start of the intended recall.	- A drug which is under strength but not used to treat life-threatening situations
Class III	Products that are unlikely to cause any adverse health reactions but withdrawal maybe initiated for other reasons	Company must notify no later than 14 days prior to the start of the intended recall.	- A container defect/faulty closure - Off taste - Disparities in colour - Missing batch number or expiry date

The recall process is recommended to be completed within **4 weeks**, unless otherwise justified.

Licensed Manufacturer/ Licensed Wholesaler/ Licenced Importer/ Product Licence Holder should notify their stakeholders including non-Ministry of Health facilities about the recall as soon as possible. To ensure prompt notification, Licensed Manufacturer/ Licensed Wholesaler/ Licenced Importer/ Product Licence Holder may consider disseminating the recall notice to their stakeholders via telephone and/or email first and follow-up with the letter / facsimile to confirm this notification.

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 4 levels of recall:

a) Level A (Consumer/Public)

- 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 patients/consumers who had been supplied with the affected batch(es), all points of sale/retail/pharmacy (Level B), wholesale/importer (Level C) and manufacturer (Level D).
- All wholesale and retail supply of the affected product or batch(es) should be suspended.
- 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. recall of a General Sales List medicine where it is not possible to contact patients/consumers who had been supplied with the affected product/batch(es), or recall of a product that had been widely supplied to consumers/patients).

- 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) Level B (All points of sale/retail/pharmacy)

- 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 points of sale (eg Hospitals, Clinics) including retail supply of the affected product or batch(es) should be suspended.
- Affected product or batch(es) are to be recalled from all points of sales and retail distributors including:
  - Government hospital pharmacies, wards and Health Centres;
  - Private hospital pharmacies, wards and clinics;
  - Retail pharmacies;
  - Medical, dental and other healthcare practitioners' establishments;
  - Other related healthcare institutions;
  - Other retail outlets, e.g. health food stores, supermarkets
  - Wholesale distributors
- All wholesalers shall be identified and are required to provide a list of all points of sale from the distribution records.
- Affected product or batch(es) are to be recalled also from wholesale/ importer (Level C) and manufacturer (Level D).
- The wholesaler or importer will be required to retrieve existing stocks from these points of sale/ retail/ pharmacy.
- 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) Level C (Wholesale/Importer)

- 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 such as visual inspections or other interventions by healthcare professionals before supply to patients, or in situations to prevent disruption in supply of a critical product.
- All wholesale supply of the affected product or batch(es) should be suspended.

- Affected product or batch(es) are to be recalled also from all wholesalers, all distributors, all third-party logistics providers holding the product for distribution to retailers, importers and manufacturers (Level D).
- The importer is responsible for contacting the wholesalers and arrange for retrieval of affected product from the importers or manufacturers.
- 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.

d) Level D (Manufacturer)

- Usually initiated when affected product is still with the manufacturer.

4. Conducting Medicinal Product Recall

Medicinal Product recalls may be initiated by:

- Ministry of Health through the Pharmacovigilance Section, Department of Pharmaceutical Services which arises from investigations from product defects, adverse drug reactions, post marketing surveillance or defective reports from reputable sources.
- Licensed Manufacturer/ Licensed Wholesaler/ Licenced Importer/ Product Licence holder as a result of reports of product defects from various sources such as from the original manufacturer and from regulatory agencies.

Licensed Manufacturer/ Licensed Wholesaler/ Licenced Importer/ Product Licence holder should communicate the affected medicinal product for recall through appropriate means (eg: e-mail to official MOH e-mail or official letter) **within 24 hours*** upon receipt of such information to Ministry of Health (especially if MP is bought by MOH) and also to other non MOH clients (if MP is purchased by them).

* Not including Sundays and public holidays.

A product recall information from Licensed Manufacturer/ Licensed Wholesaler/ Licenced Importer/ Product Licence Holder should include:

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

All products recalls should be conducted promptly and the affected product or batch(es) should be effectively removed from the distribution chain. Where MP recall affects a particular batch, consideration should also be given to determine whether other batches are also affected.

If the affected product is available in any of the non Ministry of Health facilities that the MP was supplied, the designated personnel will **suspend** all supply of the affected batch(es) and **collect** all affected batch(es).

The designated storage area for recalled products in the facility should be clearly marked and the access should be restricted to authorise personnel. Any system (eg: computerised and bar coding system) replacing the physical separation should give equivalent assurance in segregation and restriction in accessibility.

For non Ministry of Health facilities, all recalled products are to be sent back to the Licensed Manufacturer/ Licensed Wholesaler/ Licenced Importer/ Product Licence Holder with a cover letter with details of the affected product and quantity returned.

5. Communication with Endusers

5.1 Dear Purchaser Letter

A Dear Purchaser Letter is a letter issued by the Licensed Manufacturer/ Licensed Wholesaler/ Licenced Importer/ Product Licence Holder to its purchasers (such as hospitals, clinics, retail stores) 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 name, active ingredient, 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 anddate to acknowledge the recall and that they have followed through the recall instructions)

5.2 Dear Healthcare Professional Letter

A Dear Healthcare Professional Letter is issued to alert relevant healthcare professionals such as doctors, pharmacists and dentists. This is to notify about important new or updated information regarding major safety, quality and efficacy concerns related to the use of a product that presents potential risks to patients and/or public health.

A Dear Healthcare Professional Letter can be issued by the Ministry of Health and by the Licensed Manufacturer/ Licensed Wholesaler/ Licenced Importer/ Product Licence Holder.

The Dear Healthcare Professional Letter should include (but not limited to) the following information:

1. Purpose of letter;
2. Product details (brand name, active ingredient, affected batch number, product image, images to guide where to find the batch details if needed);
3. Description of the issue, reason for recall and any potential health hazard(s);
4. Actions required by patients;
5. Advisories for healthcare professionals on clinical management and monitoring of patients if any; and
6. Hotline number(s) (and operating hours) whereby healthcare professionals are able to contact should they have any additional questions relating to the recall.

For enquiries on this document, please contact:

Pharmacovigilance Section
Department of Pharmaceutical Services
Ministry of Health
Lot no 65943, Spg 433,
Lebuhraya Rimba
Kg Madaras
BB1514
Brunei Darussalam
Tel: 2393230/2393301 ext 201 / 207
E-mail: productdefect.pharmacy@moh.gov.bn

GLOSSARY

Adulterated product[1]

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 Ministry of Health.

Critical defect[1]

A defect is deemed as one that can pose a *serious threat* to the intended users or public health. A *serious threat* means a hazard that occurs in association with the use or administration of a MP and that may lead to the death of, or a *serious injury* to, any person. *Serious injury* refers to an incident that:

- May result in a person being hospitalised or prolong a person's existing stay in hospital;
- May result in a person's disability or incapacity; or
- May result in a congenital anomaly or birth defect.

Defective Medicinal Product[1]

Product which has quality issue concerns, which may compromise their safety and efficacy. These include defects which:

- Pose a *serious threat* to the intended users or public health
- May cause illness or affect the outcome of a person's medical treatment
- Significantly affect the quality of the MP
- Has or has possibly been adulterated or tampered with
- Is or is possibly an unwholesome health product
- Is or is possibly of inadequate quality or unsafe or inefficacious for its intended purpose; or
- Fails or could possibly fail to satisfy such other standards or requirements as may be prescribed.

Falsified[3]

Medicinal products that deliberately/fraudulently misrepresent their identify, composition or source.

Medicinal Product (MP)[2]

Health products regulated under the Medicines Order 2007; and is intended for use by, and in humans for therapeutic, preventive, palliative and diagnostic purposes.

The meaning of 'medicinal product' and related expressions as stated in the Medicines Order, 2007 (Part 1: Section 4):

(1) Subject to the following provisions of this section, in this Order "medicinal product" means any substance or article (not being an instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways:

(a) use by being administered to one or more human beings or animals for a medicinal purpose;

(b) use as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose.

(2) In this Order, "a medicinal purpose" means any one or more of the following purposes:

(a) treating or preventing disease;

(b) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;

(c) contraception;

(d) inducing anaesthesia;

(e) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

(3) Notwithstanding anything in subsection (1), in this Order “medicinal product” does not include any substance or article which is manufactured for use wholly or mainly by being administered to one or more human beings or animals, where it is to be administered to them:-

(a) in the course of the business of the manufacturer or on behalf of the manufacturer in the course of the business of laboratory or research established carried on by another person;

(b) solely by way of a test for ascertaining what effects it has when so administered; and

(c) in circumstances where the manufacturer has no knowledge of any evidence that those effects are likely to be beneficial to those human beings, or beneficial to, or otherwise advantageous in relation to, those animals, as the case may be, and which (having been so manufactured) is not sold, supplied or exported for use wholly or mainly in any way not fulfilling all the conditions specified in paragraphs (a), (b) and (c).

(4) In this Order, a “medicinal product” does not include:

(a) substances used in dental surgery for filling dental cavities;

(b) bandages and other surgical dressings, except medicated dressings where the medication has a palliative or curative function which is not limited to sterilising the dressings; and

(c) substances and articles of such other description or classes as may be specified by order made by the Minister).

(5) Where in accordance with subsections (1) to (4) a substance or article is a Medicinal product immediately after it has been manufactured, imported or exported as mentioned in subsection (1), or immediately after the first occasion on which it has been sold or supplied as mentioned in that subsection, then it shall not cease to be a medicinal product for the purposes of this Order by reason only that, at any subsequent time, it is sold, supplied, imported or exported for the use wholly or mainly in a way other than those specified in subsection (1).

(6) For the purposes of this Order, medicinal products are of the same description if:

(a) they are manufactured to the same specification; manufacturing methods and processes; equipment and manufacturing plant; and

(b)they are, are to be, sold, supplied, imported or exported in the same pharmaceutical form.

(7) For the purposes of this Order, a document, advertisement or representation shall be taken to be likely to mislead as the uses or effects of medicinal products of a particular description if it is likely to mislead as to any of the following matters:

(a) any purposes for which medicinal products of that description can with reasonable safety be used);

(b) any purposes for which such products cannot be so used; and

(c) any effects which such products when used, or when used in any particular way referred to in the document, advertisement or representation, produce or are intended to produce.

Non-critical defect[1]

A 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 MP.

Product recall[1]

Any action(s) taken by the Licensed Manufacturer/ Licensed Wholesaler/ Licenced Importer/ Product Licence holder of the MP to remove and or to retrieve the defective MP from the market or from any person to whom it has been supplied. The recall is performed because the MP:

- May be hazardous to health;
- May fail to conform to any claim made by its manufacturer or importer relating to its quality, safety or efficacy; or
- May not meet the requirements of the Medicines Order 2007.

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

Serious adverse reaction[1]

"Serious adverse reaction" means an adverse effect that is unintended and occurs in association with the use or administration of a product 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).

Substandard[3]

Also called 'out of specification' medicinal products. These are authorised medicinal products that fail to meet either their quality standards or specifications, or both.

Tampered product[1]

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[1]

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.

References in glossary:

1) Guidance for industry Product Defect Reporting and Recall Procedures for Therapeutic Products and Cells, Tissue and Gene Therapy Products by Health Sciences Authority Singapore, revised 1st March 2021.
2) Medicines Order 2007
3) Guidelines on Good Distribution Practice (GDP), National Pharmaceutical Regulatory Division, Ministry of Health, Malaysia, 2018

ANNEX

ANNEX 1

Examples of Defects Commonly Associated with Medicinal Products

This list is non-exhaustive. Healthcare personnel in non Ministry of Health may wish to clarify on specific cases/scenarios to the Licensed Manufacturer/ Licensed Wholesaler/ Licensed Importer/ Product Licence Holder.

(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) that may affect the safety and efficacy of the product with potential serious medical consequences;
- Microbial contamination of sterile injectable or ophthalmic product;
- Chemical contamination of product with serious medical consequences;
- Physical contamination with glass and/or metal particle of sterile injectable or ophthalmic product;
- 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 MP.

Examples:

- Microbial contamination of non-injectable, non-ophthalmic product;
- Non-compliance with specification (e.g. assay, stability, fill/weight, foul-smelling);
- Labelling of product with shorter shelf-life

ANNEX 2

Medicinal Product Defect Form for Non Ministry of Health Facilities to Licensed Wholesaler/ Licensed Importer/ Product Licence Holder

For office use only
Date received:
Ref:

BORANG LAPORAN KUALITI PRODUK UBAT /
MEDICINAL PRODUCT QUALITY REPORTING FORM

(1) MAKLUMAT PRODUK UBAT / *MEDICINAL PRODUCT DETAILS*

*Nama produk pada label / *Name of product on label*: _____

Bahan aktif / *Active ingredient*: _____ Pengilang / *Manufacturer*: _____

Saiz pak asal / *Original pack size*: _____ Jumlah produk terjejas / *Quantity of product affected*: _____

*Bac / *Batch number*: _____ Tarikh mansuh / *Expiry date*: _____

(2) BUTIRAN LAPORAN KUALITI / *QUALITY REPORT DESCRIPTION*

*Tarikh dan masa isu kualiti dikesan/ *Date and time quality issue was detected*:_____

*Sila beri penerangan ringkas berkaitan isu yang dilaporkan / *Please provide brief description about the reported issue*:

(3) KETERANGAN LANJUT MENGENAI PRODUK UBAT / *ADDITIONAL INFORMATION ON MEDICINAL PRODUCT*

Adakah *seal* pada produk sudah dibuka semasa menerima stok? ☐ Ya / *Yes* ☐ Tidak/ *No* ☐ Produk tidak mempunyai *seal* / *Product has no seal*
Was the seal on product broken when you received the stock?

Adakah stok produk dengan bac yang sama diperiksa? ☐ Ya / *Yes* ☐ Tidak/ *No*
Were other stocks of the same batch examined?

Jika ya, apa keadaan produk tersebut?/ *If yes, what is the product condition*?

_____

Adakah stok bac yang berlainan juga diperiksa? ☐ Ya / *Yes* ☐ Tidak/ *No* ☐ Tidak ada bac lain / *No other batches available*
Were stocks of a different batch also examined?

Jika ya, apa keadaan produk tersebut?/ *If yes, what is the product condition*?

_____

Kondisi penyimpan produk/ *Storage conditions of product*:

☐ Suhu bilik/ *Room temperature* (≤ 25°C)

☐ Suhu rangkaian sejuk/ *Cold-chain temperature* (2°C- 8°C)

☐ Kelembapan/ *Humidity* (≤ 60% relative humidity)

☐ Lain-lain/ *Others* _____

Sampel produk dihantar untuk siasatan lanjut?/ ☐ Ya / *Yes* ☐ Tidak/ *No*
Product sample submitted for further investigation?

(Nota: Jika produk adalah menggunakan rangkaian sejuk- sampel akan dikuarantin di peti sejuk di tempat ianya dikesan /*Note: If cold chain product- sample are to be quarantined at the refrigerator at the detected site*)

(4) MAKLUMAT PELAPOR / *REPORTER DETAILS*

*Nama pelapor / *Reporter's name*: _____

Jawatan / *Post*: _____ *Tempat bertugas / *Place of work*: _____

*No. telefon / *Tel. no.*: _____ E-mel / *E-mail*: _____

Tandatangan & cop rasmi /

Signature & official cop: _____Tarikh laporan/ *Date of reporting*:_____

GUIDANCE FOR REPORTING OF MEDICINAL PRODUCT DEFECT, QUARANTINE AND RECALL IN NON MINISTRY OF HEALTH FACILITIES

(FIRST EDITION, JULY 2022)