MINISTRY OF HEALTH MALAYSIA

GUIDELINE ON REPORTING OF MEDICINE SHORTAGE AND DISCONTINUATION IN MALAYSIA

August 2025

PREFACE

This guidance document is issued by the Director of Pharmaceutical Services under Regulation 29, Control of Drugs and Cosmetics Regulations 1984.

This document is intended to provide general guidance. Although great care has been taken in compilation and preparation of this publication to ensure the accuracy, National Pharmaceutical Regulatory Agency (NPRA) cannot in any circumstances accepts liability for any errors or omission in this document, or any action/decision taken or not taken as a result of using this document. 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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ABBREVIATIONS

The following abbreviations are used in this document:

DCA	Drug Control Authority
NIP	National Immunisation Programme
NEML	National Essential Medicines List
NPRA	National Pharmaceutical Regulatory Agency
PRH	Product Registration Holder

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1. BACKGROUND

Ensuring a consistent supply of essential medicines is a critical component of any healthcare system. Medicine shortages disrupt patient care, delay treatments, and pose increased health risks, particularly for vulnerable populations.

In May 2022, Malaysia experienced a significant medicine shortage crisis involving 54 active ingredients and affecting 1,384 pharmaceutical products, including six (6) antibiotics. This crisis, resolved by 1st July 2023, underscored the growing need for an effective and coordinated approach to monitoring, reporting, and managing medicine shortages to safeguard public health.

The purpose of this guideline is to provide clear and actionable instructions for Product Registration Holders (PRH) to detect, report, and manage current and anticipated medicine shortages efficiently as well as to report discontinuation of a product. It aims to strengthen Malaysia's capacity to mitigate supply disruptions and reduce their impact on patients.

Accurate and timely monitoring and reporting of medicine shortages are critical. Access to real-time data on medicine availability enables healthcare systems to anticipate future crises and implement swift interventions to mitigate risks. Transparency in reporting also ensures that alternative treatments can be identified early, minimizing disruptions to patient care.

Globally, countries like the United States, Australia, and those within the European Union, have established robust mechanisms to monitor and report medicine shortages through regulatory agencies such as the United States Food and Drug Administration (USFDA), Therapeutic Goods Administration (TGA) and European Medicines Agency (EMA). These systems provide valuable lessons and templates for Malaysia to adopt and adapt to its local context.

Malaysia's healthcare system can greatly benefit from a structured approach to addressing medicine shortages. By incorporating global best practices and tailoring them to Malaysia's unique needs, this guideline outlines the essential steps for PRH to report and manage medicine shortages and discontinuations. Early and detailed communication between PRH and NPRA plays a pivotal role in mitigating the impact of supply disruptions, ensuring continuity of care, and safeguarding public health.

By implementing this guideline, Malaysia will enhance its ability to manage medicine shortages, reduce associated risks, and improve patient outcomes.

2. OBJECTIVE

This document serves as a guide for the PRH to report current and anticipated medicine shortages as well as discontinuations in Malaysia.

3. DEFINITION

Medicine
Biologics (including vaccines), New Drug Products & Generics containing Poisons for human use registered with the Drug Control Authority (DCA).

Medicine shortage
An occurrence of insufficiency in the medicines supply to meet the normal public health usage or demand within Malaysia for a period of three (3) months and above.

Medicine discontinuation
Medicines that are no longer available in the local market as a result of one of the following situations:

a) The medicines were previously marketed in Malaysia, remain registered with the DCA but no longer marketed by the PRH; or
b) The medicines' registration status is not renewed and is allowed to lapse by the PRH; or
c) The medicines' registration status is cancelled by the DCA upon the request of the PRH (voluntary withdrawal); or
d) The medicines' registration status is revoked (cancelled or suspended) by the DCA due to concerns related to the medicine's safety, quality, efficacy, or failure to comply with registration requirements.

PRH are required to submit notification (please refer to Section 4) for all the situations listed above. However, for situation (c), the PRH must submit an official withdrawal application letter to NPRA. Upon approval, the PRH can proceed to submit the medicine discontinuation notification through NPRA's website. For situation (d), the medicine discontinuation notification must be submitted upon receiving the cancellation or suspension letter from NPRA.

National Essential Medicine List (NEML)
A list of fundamental medicines designed to meet the healthcare needs of the majority of the population. Its primary goal is to ensure the accessibility and affordability of essential medicines for the Malaysian community. Adapted from the World Health Organisation (WHO) Model List of Essential Medicines, the NEML consists of locally registered medicines selected based on national needs. It serves as a guide for

healthcare facilities to develop their own essential medicines list tailored to their specific requirements.

The current list of NEML is published in Pharmaceutical Services Programme's website: www.pharmacy.gov.my

National Immunisation Programme (NIP)
A program managed by the Ministry of Health Malaysia, designed to ensure equitable access to vaccines, focused on the systematic delivery of immunisations to prevent and control vaccine-preventable diseases.

The current list of vaccines under NIP is published on the Family Health Development Division's website:
https://hq.moh.gov.my/bpkk/index.php/pages/orang-awam/kesihatan-kanak-kanak-2.html

Orphan Medicine
As defined in the Malaysian Orphan Medicines Guideline, an orphan medicine is a medicinal product that is primarily intended to treat, prevent or diagnose a rare disease. Rare disease refers to a life-threatening and/or chronically debilitating rare condition as listed in the Malaysian Rare Disease List.

The current list of approved orphan medicine is published in NPRA's website:
https://npra.gov.my/index.php/en/informationen/new-products-indication/orphan-medicines-approved.html

Period of shortage
The shortage period is defined as beginning on the expected date when the supply of the medicine in Malaysia falls short of, or is expected to fall short of, the usual public health usage or demand. It ends on the day before the supply is anticipated to return to levels that meet the normal public health usage or demand within the country.

4. GENERAL GUIDANCE FOR PRODUCT REGISTRATION HOLDERS

4.1 Scope of implementation

The implementation of reporting medicine shortage and discontinuation is mandatory. It applies to medicines (as defined above).

4.2 Requirements for reporting a medicine shortage or discontinuation

The PRH are required to notify NPRA in the event of:

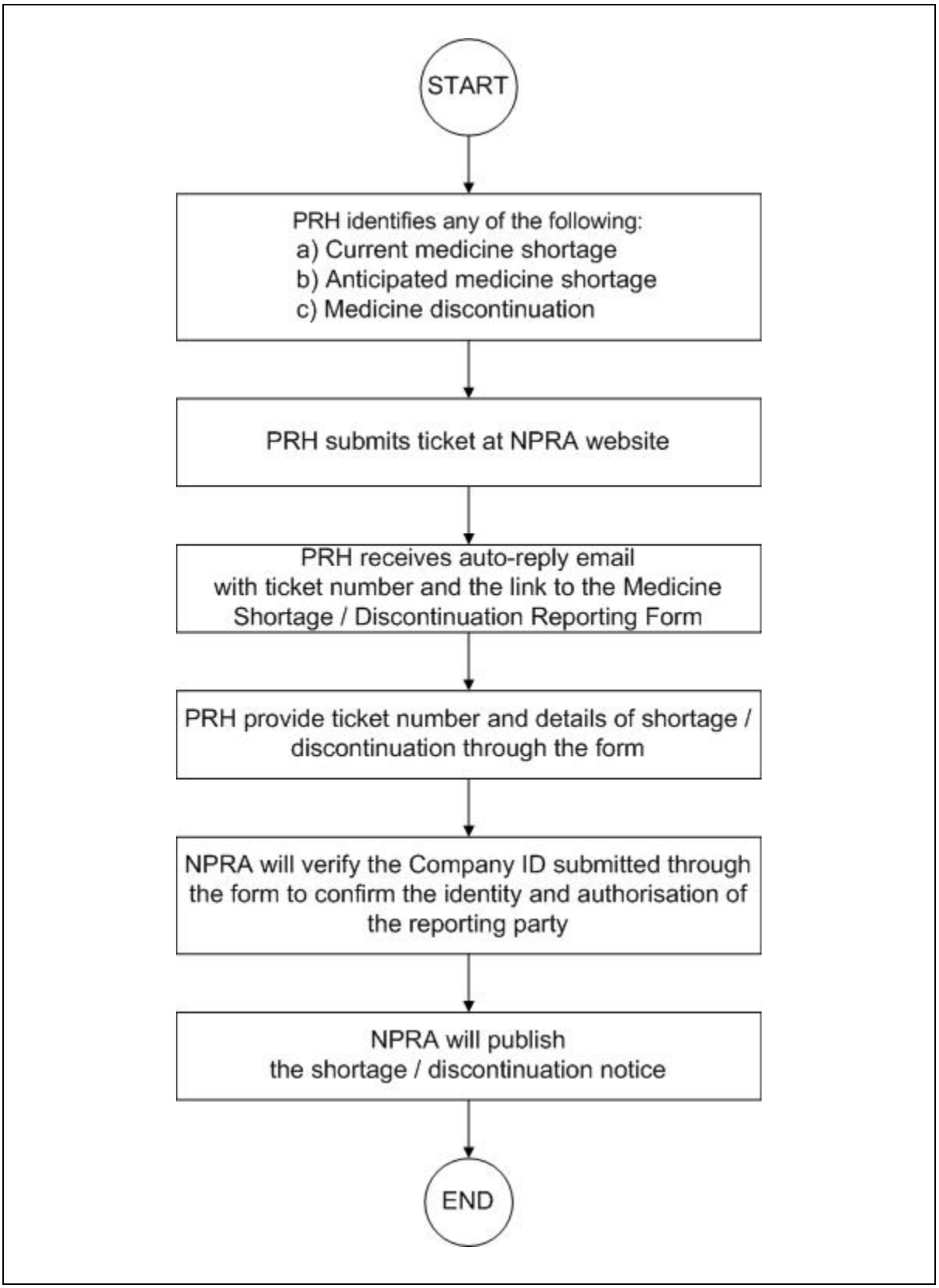
a) Current medicine shortage
b) Anticipated medicine shortage
c) Medicine discontinuation

4.3 Procedure for reporting medicine shortage or discontinuation

Below is the general procedure for reporting medicine shortage or discontinuation. The flow is illustrated in Diagram 1.

i. The PRH identifies a medicine shortage or discontinuation.
ii. The PRH submits a ticket through the NPRA website. In the ticket submission, state the following information:
    - Priority: High
    - Subject: Medicine shortage / Medicine discontinuation
    - Message: I want to submit medicine shortage notice / I want to submit medicine discontinuation notice
    - No attachment is needed for the ticket submission
iii. The PRH will receive an auto-reply email containing the ticket number and a link to the Medicine Shortage / Discontinuation Reporting Form.
iv. The PRH submits the ticket number and completes the form with relevant details regarding the medicine shortage or discontinuation, including the Company ID (linked to the QUEST system) as well as the name and IC number of the company's active token holders for verification purposes.
v. After NPRA confirms the identity and authorisation of the reporting party, NPRA will publish the shortage or discontinuation in the Medicine Shortage and Discontinuation Database with a suitable mitigation plan.

Diagram 1: Flow for reporting medicine shortage or discontinuation

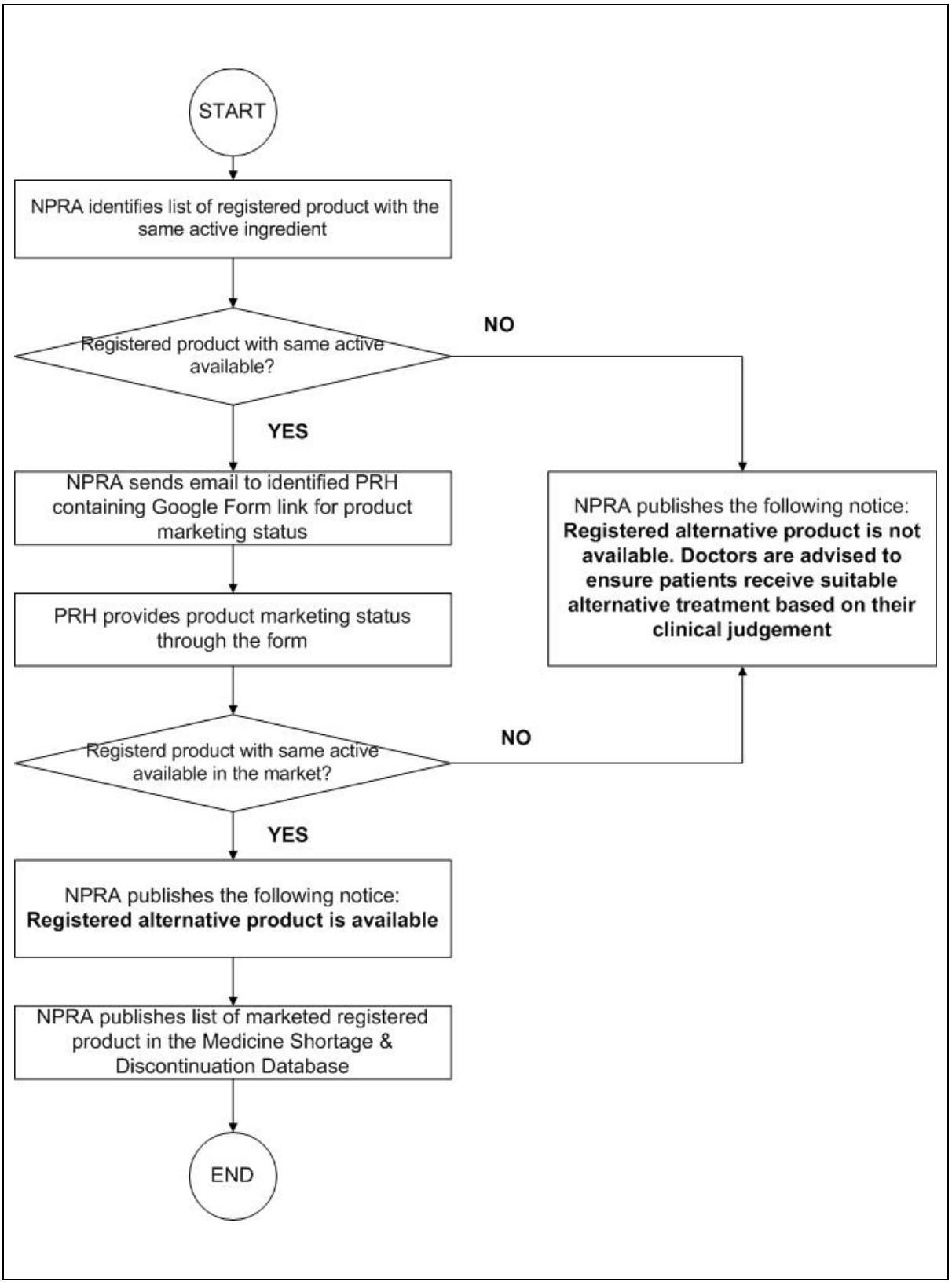


4.4 NPRA's action upon receiving report of medicine shortage and discontinuation

Below is the general procedure after receiving a report of medicine shortage and discontinuation. The flow is illustrated in Diagram 2.

i. The NPRA identifies a list of registered products with the same active ingredient as the affected medicine.
ii. The NPRA will notify the other PRH with the same active ingredient to update their product marketing status in the Product Marketing Status Form.
iii. The PRH must submit the product marketing status through the form.
iv. The NPRA will display products with the same active ingredient as the affected medicine in the Medicine Shortage and Discontinuation Database, under 'List of Alternative Products'.
v. The PRH may update the marketing status of the product at any time using the same form, and the current marketing status will be displayed on the website.

Diagram 2: Flow upon receiving report of medicine shortage and discontinuation



4.5 Information required from the PRH reporting for medicine shortage or discontinuation

During reporting of medicine shortage or discontinuation, the PRH of the affected medicine is required to provide the following information:

4.5.1 Medicine shortage

a) Ticket tracking ID
b) Shortage status
    - Current
    - Anticipated
c) PRH information
    - Contact person
    - Phone number
    - Email address
    - Company ID (from QUEST account)
    - Name and IC number of active token holder
d) Product information
    - Product name
    - Registration number (MAL no.)
    - Active ingredient
    - Product Registration Holder
    - Manufacturer
    - Dosage form
    - Strength
    - Package size
    - ATC Product Code
e) Shortage detail
    - Reason for shortage
    - Detailed description of issue
    - Shortage impact rating (Critical / Non-critical)
    - Justification for impact rating
    - Supply impact start and end date
    - Current inventory levels until stock depletion (in months)
    - Registered alternative products with the same active ingredient (If available)
f) Mitigation plans
    - Describe actions taken by the PRH to prevent or mitigate shortage
    - Proposed solutions (if any)

4.5.2 Medicine discontinuation

a) Ticket tracking ID
b) Shortage status
    - Current
    - Anticipated
c) PRH information
    - Contact person
    - Phone number
    - Email address
    - Company ID (from QUEST account)
    - Name and IC number of active token holder
d) Product information
    - Product name
    - Registration number (MAL no.)
    - Active ingredient
    - Product Registration Holder
    - Manufacturer
    - Dosage form
    - Strength
    - Package size
    - ATC Product Code
e) Discontinuation details
    - Reason for discontinuation
    - Discontinuation effective date
    - Current inventory levels until stock depletion (in months)

4.6 Mandatory reporting timeframe

PRHs are required to report a shortage or discontinuation at least six (6) months in advance. However, if six (6) months' notice is not possible, the notification must be submitted as soon as practicable thereafter.

4.7 Impact assessment

The impact of medicine shortages or discontinuation is assessed based on their criticality to public health and healthcare delivery. The criteria for determining whether a shortage has a critical or non-critical impact are outlined below, considering factors such as national programs, patent status, and supply chain dependencies.

4.7.1 Critical Shortage Impact Rating

A medicine is considered to have a **critical** shortage impact rating if any of the following criteria are met:

a) The medicine is used for the NIP
b) The medicine is listed in the NEML
c) The medicine is an Orphan Medicine
d) The medicine has an active patent status
e) The medicine has a single PRH
f) The medicine is supplied to both government and private healthcare facilities
g) The medicine is supplied exclusively to government healthcare facilities

4.7.2 Non-Critical Shortage Impact Rating

A medicine is considered to have a **non-critical** shortage impact rating if any of the following criteria are met:

a) The medicine is not listed in the NIP, NEML, or as an Orphan Medicine
b) The medicine does not have an active patent status
c) The medicine is supplied exclusively to private health facilities
d) The medicine is supplied exclusively to retail pharmacies

The impact assessment will be reviewed by NPRA, and the PRH may subsequently be contacted for further information, if required.

4.8 Supply management options

The PRH is required to provide information on the supply management actions planned or implemented to address the shortage.

Actions that can be considered include, but are not limited to:

- controlled supply to prevent stockpiling
- working to expedite the next shipment
- suggestion of an available substitute medicine
- suggest alternative products which may be imported via the special exemption

4.9 Mitigation plan by the reporting PRH

To mitigate a shortage of the reported medicine, the PRH may submit a request for the following measures:

a) To import, sell and distribute a registered product in Malaysia with different country label, i.e. immediate label and/or outer carton;
b) To request a priority review for a product currently under evaluation for registration or variation;
c) To import an unregistered product under the exemption provided in Regulation 15(6) of the Control of Drugs and Cosmetics Regulations 1984

A written formal request shall be submitted to:

- the Director of NPRA for items (a) and (b)
- the Deputy Director General of Health (Pharmaceutical Services) for item (c).

4.10 Mitigation plan by other than the reporting PRH of the affected medicine

To mitigate a shortage of the reported medicine, the applicant may request for the following measures:

a) To import an unregistered product by a person other than the PRH, provided the product is the same as a registered product, in accordance with Regulation 7(2)(a) of the Control of Drugs and Cosmetics Regulations 1984;
b) To import an unregistered product under the exemption provided in Regulation 15(6) of the Control of Drugs and Cosmetics Regulations 1984;

A written formal request shall be submitted to the Deputy Director General of Health (Pharmaceutical Services).

4.11 Mitigation plan by the National Pharmaceutical Regulatory Agency (NPRA)

When a medicine is reported to be in shortage, NPRA may display the following mitigation plan on the Medicine Shortage and Discontinuation Database on the website:

a) Registered alternative products are available; or
b) Registered alternative product is not available. Doctors are advised to ensure patients receive suitable alternative treatment based on their clinical judgement.

NPRA may also display a list of available medicines containing the same active ingredient. However, only registered medicines that are available in the market will be displayed in the Medicine Shortage and Discontinuation Database as alternative

products to the affected medicine.

Upon identifying medicines containing the same active ingredient with the affected medicine, NPRA will send a notification to the relevant PRH via email to obtain information on the marketing status of the product. PRHs are required to provide the following information through the Product Marketing Status Form within three (3) working days.

The PRHs with medicines containing the same active ingredient as the affected medicine are required to provide the following information:

a) Product Registration Holder
b) Email address
c) Product name
d) Registration number (MAL no.)
e) Active ingredient
f) Manufacturer
g) Strength
h) Is the product currently marketed in Malaysia? (Yes / No)

The PRH may update the marketing status of the product at any time using the same link and the current status will be displayed on the website.

4.12 Communication between the reporting Product Registration Holder (PRH) and the National Pharmaceutical Regulatory Agency (NPRA)

When the PRH reports a medicine shortage or discontinuation through the NPRA website, a unique ticket number will be assigned. This ticket number will need to be included in the medicine shortage or discontinuation form. Additionally, it can be used to submit any necessary corrections, updates, or additional information related to the reported shortage or discontinuation. If an error is identified after submission, the PRH can refer to the initial confirmation email received upon ticket submission and click the provided link to access the ticket status. Any amendments or additional details can be communicated directly through the message box within the ticketing system.

5 MEDICINE SHORTAGE & DISCONTINUATION DATABASE

5.1 Published Information

Anyone can view the medicine shortage or discontinuation information published in the Medicine Shortage & Discontinuation Database displayed on the NPRA website.

The status of a shortage or discontinued medicine will be displayed as detailed below:

a) An anticipated shortage will appear as 'Anticipated' in the Database until it is resolved or progresses to a current shortage.
b) Current shortages notified to the NPRA will appear as 'Current'.
c) Once the shortage is resolved and the notification is updated, the status will appear as 'Resolved' for an additional three (3) months.
d) Discontinuations will remain in the database from the date of notification until one (1) year after the effective discontinuation date.

The following information will be published in the Medicine Shortage and Discontinuation Database on the NPRA website:

a) Status (Current, Anticipated, Resolved)
b) Product name
c) Product Registration number (MAL no.)
d) Active ingredient
e) Product Registration Holder
f) Manufacturer
g) Dosage form
h) Strength
i) ATC Product Code
j) Types of disruption (Shortage / Discontinuation)
k) Reason for shortage / discontinuation
l) Supply impact start and end date
m) Mitigation plan by PRH of the affected product
n) Mitigation plan by NPRA
o) List of available alternative registered products with the same active ingredient

5.2 Timeline for Publishing Shortages and Alternatives

All current shortages and discontinuations will be immediately published after NPRA's review of the notification. This helps ensure timely and consistent communication to all our stakeholders. However, the list of available alternative registered products with the same active ingredients will appear within five (5) working days after the notification.

6 REGULATORY OR LEGAL ACTION

The Deputy Director-General of Health (Pharmaceutical Services) may provide assistance through the form of formal reminder letters or warning letters. However, legal actions based on the current enforceable act can be pursued depending on the severity of the offence (Table 1), where there is a history of repeated offences with mandatory reporting or where actual or potential public health risk may result from the offence. Investigations will be conducted if there is a complaint of medicine shortage by a healthcare provider. Sale of Drugs Act 1952 and its Regulations include penalty provisions ~~to~~ for PRH that fail to comply with the mandatory reporting requirements.

Table 1: Severity of The Offence

Nature of Offense	Offence Severity	Actions Towards PRH
One off or isolated alleged breach of mandatory reporting obligations	Low	A reminder letter will be issued to the PRH regarding their failure to comply with mandatory reporting requirements. The letter will include relevant information and guidance to support future reporting. PRHs may contact the Authority to dispute or discuss the alleged breach. A response acknowledging receipt of the letter is required within seven (7) days.
Alleged ongoing breaches where the PRH has been made aware of their obligations and has continued non-compliance with reporting obligations.	Medium	A reminder letter will be issued to the PRH regarding their failure to comply with mandatory reporting requirements. The letter will include information and guidance to support future reporting. The PRH may contact the Authority to dispute or discuss the alleged breach. A response is required within seven (7) days, outlining the remedial actions the PRH intends to undertake.
Continued alleged reporting breaches and/or breaches that are more serious in nature such as for critical medicine shortages.	High	A formal warning letter will be issued to the PRH, requiring a response within two (2) days outlining any remedial actions they intend to take to address their non-compliance with reporting obligations.

Nature of Offense	Offence Severity	Actions Towards PRH
		Failure to respond may result in legal investigation and/or enforcement action against the PRH.
Extensive non-compliance to mandatory reporting that raises public health concerns or undermines the Authority's mandatory reporting requirement for drug shortages with possible public health implications.	Extreme	Initiate an investigation to assess grounds for potential legal action against the PRH.

Table 2: Authority's Approach to Reporting Offences.

Offence Severity			
Low	**Medium**	**High**	**Extreme**
Provide ongoing compliance support by issuing a reminder letter that includes clear educational content and guidance materials	Issue a reminder letter containing targeted education and guidance to assist the PRH in achieving and maintaining compliance	Issue a formal warning letter to the PRH, notifying them of the offence and outlining the enforcement actions available to the Authority	The Authority may initiate legal proceedings, which may result in significant financial penalties being imposed on the responsible PRH of the affected product

7 REFERENCES

7.1 Therapeutic Goods Administration Australia – Shortages
https://www.tga.gov.au/safety/shortages

7.2 European Medicines Agency - Public Information on Medicine Shortages
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/public-information-medicine-shortages

7.3 The United States Food and Drug Authority
https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages

8 APPENDICES

8.1 Steps to report medicine shortage

Submit a ticket through the NPRA website. In the ticket submission, state the following information:

- Priority: High
- Subject: Medicine shortage / Medicine discontinuation
- Message: I want to submit medicine shortage notice / I want to submit medicine discontinuation notice
- No attachment is needed for the ticket submission

The PRH will receive an auto-reply email containing the ticket number and a link to the Medicine Shortage / Discontinuation Form.

The PRH submits the ticket number and completes the form with relevant details regarding the medicine shortage or discontinuation, as follows:

NO.	REPORTING ENTITY INFORMATION	SELECTION OPTION
1.	**Ticket Tracking ID**	
2.	**Product Registration Holder (PRH)** (Company name according to SSM and registered in QUEST system as the product token holder)	
3.	**Manufacturer** Manufacturing company name listed in the QUEST System for the affected product	
4.	**Contact Person** Reporter's name (Person In-charge) representing PRH of the affected product	
5.	**Phone Number** Number that can be contactable by the authority either office or HP Number, e.g. 60123456789	
6.	**Email Address** Official email address for the further correspondence	
7.	**Company ID (from QUEST account)** From QUEST3+ system (Membership Utilities > Company Profile > Company ID)	
8.	**Name of Active Token Holder**	
9.	**IC / Passport No. of Active Token Holder**	
10.	**Product Name**	

NO.	REPORTING ENTITY INFORMATION	SELECTION OPTION
	Product name as registered in the QUEST system database	
11.	**Product Registration Number** Registration number with QUEST system database, e.g. MAL12345678AZC	
12.	**Active Ingredient** Active ingredient registered with QUEST system database, e.g. Metformin	
13.	**Strength** Strength registered with QUEST system database for the affected product, e.g. 500mg	
14.	**Dosage Form** Dosage form registered with QUEST system database for the affected product, e.g. Tablet	
15.	**Package Size** Available packaging sizes registered with QUEST system database for the affected product, e.g. Tablet	
16.	**ATC Product Code**	
17.	**Type of disruption**	• Discontinuation • Shortage
18.	**Shortage Status**	• Current • Anticipated • Resolved
19.	**Reason for Shortage** Select at least one that apply	• Manufacturing Issues • Quality Problems • Regulatory Matters • API Shortage • Increased Demand • Others
20.	**Detailed Description of Issue** Please state detail explanation of the issue causing this event of disruption	
21.	**Shortage Impact Rating**	• Critical • Non-Critical
22.	**Justification for Impact Rating** Please briefly state your justification	
23.	**Supply Impact Start Date** Please state the estimated date that the supply is impacted	
24.	**Supply Impact End Date**	

NO.	REPORTING ENTITY INFORMATION	SELECTION OPTION
	Please state the estimated date that the supply is expected to be recovered	
25.	**Current Inventory Levels Until Stock Depletion (months)** State the estimated months left for the products will completely unavailable from company inventory, e.g. 12 months	
26.	**Alternative Products Available (If any)** Please state the alternative product registered and available in the market with the same active ingredient under the same PRH	• Yes • No
27.	**If yes, list the alternatives** Please provide the product name & registration number of all the products registered in QUEST system database	
28.	**Describe Actions Taken by the PRH to Prevent/ Mitigate Shortage** Please elaborate the actions taken by PRH	
29.	**Proposed Solutions (if any)** Please elaborate suggestion of any actions required to be taken by the authority perspective	
30.	**Consent** I verify the information provided is accurate and complete to the best of my knowledge.	

8.2 Steps to report medicine discontinuation

Submit a ticket through the NPRA website. In the ticket submission, state the following information:

- Priority: High
- Subject: Medicine shortage / Medicine discontinuation
- Message: I want to submit medicine shortage notice / I want to submit medicine discontinuation notice
- No attachment is needed for the ticket submission

The PRH will receive an auto-reply email containing the ticket number and a link to the Medicine Shortage / Discontinuation Form.

The PRH submits the ticket number and completes the form with relevant details regarding the medicine shortage or discontinuation, as follows:

NO.	REPORTING ENTITY INFORMATION	SELECTION OPTION
1.	**Ticket Tracking ID**	
2.	**Product Registration Holder (PRH)** (Company name according to SSM and registered in QUEST system as the product token holder)	
3.	**Manufacturer** Manufacturing company name listed in the QUEST System for the affected product	
4.	**Contact Person** Reporter's name (Person In-charge) representing PRH of the affected product	
5.	**Phone Number** Number that can be contactable by the authority either office or HP Number, e.g. 60123456789	
6.	**Email Address** Official email address for the further correspondence	
7.	**Company ID (from QUEST account)** From QUEST3+ system (Membership Utilities > Company Profile > Company ID)	
8.	**Name of Active Token Holder**	
9.	**IC / Passport No. of Active Token Holder**	
10.	**Product Name** Product name as registered in the QUEST system database	

NO.	REPORTING ENTITY INFORMATION	SELECTION OPTION
11.	**Product Registration Number** Registration number with QUEST system database, e.g. MAL12345678AZC	
12.	**Active Ingredient** Active ingredient registered with QUEST system database, e.g. Metformin	
13.	**Strength** Strength registered with QUEST system database for the affected product, e.g. 500mg	
14.	**Dosage Form** Dosage form registered with QUEST system database for the affected product, e.g. Tablet	
15.	**Package Size** Available packaging sizes registered with QUEST system database for the affected product, e.g. Tablet	
16.	**ATC Product Code**	
17.	**Type of disruption**	• Discontinuation • Shortage
18.	**Reason for Discontinuation** Select at least one that apply	• Manufacturing Issues • Quality Problems • API Shortage • Reduced Demand • Regulatory Matters • Others
19.	**Discontinuation Effective Date** Please fill in the date expected for the product that will be discontinued	
20.	**Current Inventory Levels Until Stock Depletion (months)** State the estimated months left for the products will completely face out from company inventory, e.g. 12 months	
21.	**Consent** I verify the information provided is accurate and complete to the best of my knowledge.	

8.3 Steps to report / update marketing status of a product

PRHs are required to provide the following information in the following Product Marketing Status Form :

NO.	REPORTING ENTITY INFORMATION	SELECTION OPTION
1.	**Product Registration Holder (PRH)** (Company name according to SSM and registered in QUEST system as the product token holder)	
2.	**Manufacturer** Manufacturing company name listed in the QUEST System for the affected product	
3.	**Product Name** Product name as registered in the QUEST system database	
4.	**Active Ingredient** Active ingredient registered with QUEST system database, e.g. Metformin	
5.	**Product Registration Number** Registration number with QUEST system database, e.g. MAL12345678AZC	
6.	**Strength** Strength registered with QUEST system database for the affected product, e.g. 500mg	
7.	**Is the product currently marketed in Malaysia?**	• Yes • No