MDA/GD/0055
16 April 2020
First Edition

MEDICAL DEVICE GUIDANCE DOCUMENT

NOTIFICATION FOR OBSOLETE AND DISCONTINUED MEDICAL DEVICE

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Contents

1. Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it, and/or to facilitate their business endeavour.

In this Guidance Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

CONTACT INFORMATION

For further information, please contact:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC
63000 Cyberjaya, Selangor
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200 Website:portal.mda.gov.my

NOTIFICATION FOR OBSOLETE AND DISCONTINUED MEDICAL DEVICE

1. Introduction

All medical devices must be registered before being imported, exported or placed in Malaysian market. However, there are obsolete and discontinued medical devices in healthcare facilities or any other facilities which are not registered and still being used.

Therefore, to impose certain controls to the establishments, healthcare facilities and any other facilities that still continue to use such medical devices, as well as ensure that medical services are uninterrupted, there is a need to develop a process to control these medical devices.

Malaysian regulatory controls include the requirements to safeguard the health and safety of patients, users and the public. All establishments which has obsolete or discontinued medical devices shall provide the notification to the Medical Device Authority (MDA).

This Guidance Document is intended to assist establishments in providing notification to the Authority for obsolete or discontinued medical device, in-line with the requirements of Circular Letter of Medical Device Authority No. 2 Year 2018, *Control of orphaned, obsolete and discontinued medical device in hospitals, healthcare facilities or any related facilities*.

It also specifies the responsibilities and obligations of the establishment when dealing with this type of medical device. The risk of using obsolete and discontinued medical devices is under the responsibility of establishments, users, healthcare facilities and any other facilities.

2. Scope and application

This guidance document specifies requirements for notification of obsolete and discontinued medical devices to the Authority.

This document applies to all products that fall within the definition of medical device, as defined in MDA/GD/0006, *Definition of Medical Device, including in vitro diagnostic (IVD) medical devices*.

3. Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations, the order and circular letter under it and the following terms and definitions apply.

3.1 applicant

Applicant can be either manufacturer or authorised representative.

3.2 authority

The Medical Device Authority established under Medical Device Authority Act 2012 (Act 738).

3.3 beyond economical repair (BER)

Beyond economical repair is when:

a) cost of repair exceeds depreciated value; or

b) accumulated maintenance cost plus the estimated cost of impending upcoming repairs exceeds the depreciated value of the equipment.

[Source: MS 2058, *Code of practice for good engineering maintenance management of active medical devices*]

3.4 discontinued medical device

An existing medical device in healthcare facilities institution or any other facilities that is no longer in distribution.

3.5 establishment

As defined in Section 2 of the Medical Device Act 2012 (Act 737)

3.6 government healthcare facility

Any facility used or intended for use to provide established healthcare services, maintained, operated or provided by the Government but excluding government healthcare facilities privatized or incorporated;

[Source: Private Healthcare Facilities and Services Act 1998, Act 586]

3.7 healthcare facility

Any premise in which one or more members of the public receive healthcare services, which includes:

a) medical, dental, nursing, midwifery, allied health, pharmacy, and ambulance services and any other services provided by healthcare professionals;

b) accommodation for the purpose of healthcare services provided;

c) any service for the screening, diagnosis, or treatment of persons suffering from, or believed to be suffering from, any disease, injury or disability of mind and body;

d) any service for preventive and promotion of health purpose;

e) any service provided by any healthcare para-professional;

f) any service for curing or alleviating abnormal conditions of the human body by the application of any apparatus, equipment, instrument or device or any other medical technology; or

g) any health-related services.

[Source: Private Healthcare Facilities and Services Act 1998, Act 586]

3.8 manufacturer

As defined in Section 2 of the Medical Device Act 2012 (Act 737).

3.9 medical device

As defined in Section 2 of the Medical Device Act 2012 (Act 737).

3.10 obsolete medical device

An existing medical device in a healthcare facilities, or any other facilities which is outdated, or no longer being manufactured for example due to design changes and evolution of new technologies.

3.11 person responsible

Person responsible is the person appointed / authorised by the establishment who is responsible for related legal obligations and implications under Act 737 and its subsidiary legislations, including making submission for application for establishment licensing and medical device registration. Responsible person has the overall control and authority to make decision. Depending on the setup of an establishment, example of a responsible person may include the chief executive officer, managing director or general manager for a company.

3.12 place in the market

As defined in Section 2 of the Medical Device Act 2012 (Act 737).

3.13 private healthcare facility

Any premises, used or intended for use in providing services healthcare or services related to health, such as hospital, hospice, ambulatory care center, home nursing care, maternity home, psychiatric hospital, home psychiatric care, community mental health centers, centers hemodialysis, medical clinics, private dental clinics and anything else healthcare premises or health-related premises other than as may be determined by the Minister from time to time by notification in the Gazette;

[Source: Private Healthcare Facilities and Services Act 1998, Act 586]

Private healthcare facilities include government healthcare facilities privatized or incorporated.

4. Criteria to be eligible as obsolete and discontinued medical device

4.1 The criteria for obsolete medical device for notification are:

The medical device is outdated, no longer being manufactured for example due to design changes or evolution of new technologies and applies for

a) Unregistered medical device that has been placed in the healthcare facilities or any other facilities before the implementation of Medical Device Act (Act 737); or

b) Any medical device that has been registered

4.2 The criteria for discontinued medical device for notification are:

The medical device is no longer in the distribution and applies for

a) Unregistered medical device that has been placed in the healthcare facilities or any other facilities before the implementation of Medical Device Act (Act 737); or

b) Any medical device that has been registered

5. Person responsible

Criteria for person responsible:

a) Shall be from top management:

   i) Person responsible shall have the overall control and have the authority to make decision;

   ii) Depending on the organisational structure of the establishment, person responsible may include Proprietor, President, Vice President, Director, Chief Executive Officer (CEO), Managing Director, General Manager or Manager;

b) Domiciled in Malaysia;

   i) Malaysian citizen;

   ii) Non-Malaysian, who has an employment pass or residential address in Malaysia.

6. Obligations of establishment

6.1 The applicant is responsible to confirm that the products are medical devices. Such products which do not meet the medical device definition are not eligible for this requirement.

6.2 The applicant is responsible to confirm that the products are obsolete and / or discontinued medical devices. Such products which do not meet the obsolete and / or discontinued medical device definition are not eligible for this requirement.

6.3 The applicant shall identify and provide notification to the Authority.

6.4 The applicant shall provide declaration of obsolete medical device by the manufacturer or declaration of discontinued medical device by the local manufacturer / authorised representative.

6.5 Establishment shall be responsible for post-market issues on any obsolete or discontinued medical device at least in accordance with the projected useful life of the medical device as determined by the manufacturer.

Note. The projected useful life of a medical device may be based on technical, legal, commercial or other consideration. Establishment may refer to ISO / TR 14969, *Quality management system – Guidance on the application of ISO 13485* for some of the consideration when defining the lifetime of their medical device.

7. Submission of Notification

7.1 Notification shall be submitted to the Authority by using the 'Notification of Obsolete and Discontinued Medical Device Form' in Annex A by email to Chief Executive Medical Device Authority at email address *ood.md@mda.gov.my* .

7.2 The form for 'Notification of Obsolete and Discontinued Medical Device' is published in the Authority website at *www.portal.mda.gov.my* .

7.3 Each notification submitted shall be for one medical device / medical device grouping only.

7.4 The explanations for filling in the application for notification form is presented in **Table 1**.

Table 1 notification of obsolete and discontinued medical device application

Particulars	Explanation	Supporting document
Part 1 Establishment Details		
a. Type of Establishment	Please indicate the type of your establishment: Manufacturer / AR / Distributor / Importer	Letter of Authorisation
b. Business Registration No.	Please provide business registration number of your company as issued by the Registrar of Company (ROC), *Lesen perniagaan* (Sabah) or *Sijil Pendaftaran Ordinan Nama-nama Perniagaan* (CAP64) (Sarawak)	Copy of Business Registration
c. Establishment Name	Please provide particulars and contact information of your establishment	-
d. MDA Establishment License No. (If applicable)	Please provide establishment license number of your company as issued by the Medical Device Authority (MDA)	Copy of Establishment License
e. Address	Please write full address of the company	-
f. City	Please write name of city	-
g. State	Please write name of state	-
h. Postcode	Please write postcode number	
i. Telephone No.	Please write general telephone number of the company	-

j. Fax No.	Please write fax number of the company	-

Particulars	Explanation	Supporting document
k. Company Website	Please write URL / web address of your company website	-
Part 2 Person Responsible Details		
a. Nationality	Please write person responsible nationality	-
b. NRIC / Passport No.	Please provide NRIC / passport number	Copy of NRIC / Passport
c. Full Name	Please write full name of the person responsible	-
d. Designation	Please write the designation of person responsible for medical device	Form 49; or letter of appointment of the person responsible signed by head of the establishment
e. Telephone No.	Please write direct phone line number	
f. Email	Please write email address of the person responsible	
Part 3 Contact Person Details (If contact person is not the same person as the person responsible)		
a. Nationality	Please write person responsible nationality	-
b. NRIC / Passport No.	Please provide NRIC / passport number	Copy of NRIC / Passport
c. Full Name	Please write full name of the person responsible	-
d. Designation	Please write the designation of contact person	Letter of authorization of the contact person signed by the person responsible
e. Telephone No.	Please write direct phone line number	-
f. Email	Please write email address of the person responsible	-
Part 5 Medical Device Details		
a. General information		
i) Medical Device Name	Please write the general name of medical device (e.g. wheelchair)	If the notification involves medical device grouping, please complete List of Configuration (LOC) in Appendix A. Submit Appendix A (if applicable)
ii) Brand	Please write the brand name of the medical device	
iii) Model No.	Please write the model number of the medical device	
iv) Serial No.	Please write the serial number of the medical device	
v) Intended purpose	Please provide description of medical device.	

vi) Medical Device Registration No. (If applicable)	Please provide registration certificate number of medical device as issued by the Medical Device Authority (MDA)	Copy of registration certificate
vii) Date of purchase/placement	Please state the date the medical device procured in the healthcare facility.	
Particulars	**Explanation**	**Supporting document**
viii) Beyond Economic Repair (BER) Yes/No?	BER medical device which is pending disposal.	
b. Detail of healthcare facilities and any other facilities (if applicable)		
i) Healthcare facilities and any other facilities Name	Full name of healthcare facilities and any other facilities	-
ii) Healthcare facilities and any other facilities Address	Please write full address of the healthcare facilities and any other facilities	-
iii) City	Please write name of city	-
iv) State	Please write name of state	-
v) Postcode	Please write postcode number	-
vi) Telephone No	Please write general telephone number of the healthcare facilities and any other facilities	-
vii) Email Address	Please write email address of the healthcare facilities and any other facilities	-
Part 6 Attestations & Declaration		
i) Signature	Attestation to be signed by person responsible for this application or appointed personnel by top management	-
ii) Name		-
iii) Designation		-
iv) Date		-
v) Company stamp		-

8. Administrative charge

Each notification shall be submitted together with a RM 300 per application, with the following conditions:

a) Administrative charge shall be paid through bank draft. CASH WILL NOT BE accepted. The Authority will not be responsible for the cash sent or brought to MDA.

b) The bank draft shall be made payable to “KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN” and sent to:

CHIEF EXECUTIVE
Medical Device Authority
Ministry of Health Malaysia

Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC
63000 Cyberjaya, Selangor, MALAYSIA
U/P: UNIT KHIDMAT PENGURUSAN

c) Name, Telephone No. of the applicant and application for 'Notification for obsolete and / or discontinued medical device' shall be written at the back of the bank draft but not in the table section.

9. Conditions of the Notification

Notification of obsolete and discontinued medical device shall be made by establishment:

a) Provision of inaccurate information or making false declaration shall render this notification null and void.

b) The establishment shall be required to attest that its medical device is obsolete or discontinued medical device according to the definition.

c) Obsolete and discontinued medical device shall not be sold/loaned/provided for free/donated/used in research to/by a third party.

Excluding:

i) for teaching/education which is not to be used on patient; required to inform MDA on change of location; or

ii) if the medical device is sold to a third party for the purpose of disposal as a scrap material or as e-waste.

d) The notification letter shall not be used for the purpose of promoting or advertising the device.

e) Applicant shall monitor the safety and performance of the medical device.

f) The risk of using obsolete and discontinued medical device is under the responsibility of the establishment, users, and healthcare facilities.

g) Applicant shall ensure that any incidents involving its medical device is properly recorded and reported to the Authority according to the Act 737 using MDA Feedback Management System (FEMES) at https://femes.mda.gov.my/ .

h) When the medical device is no longer safe and effective, it shall be removed and disposed in a safe manner and the Authority shall be notified as in Annex B.

i) Applicant shall establish and implement documented procedures and maintain records of reported problems or complaints relating to the safety and the performance of its medical device.

j) Applicant shall provide any document or record upon request and may be subjected to inspection by the Authority.

ANNEX A
(normative)

		PIHAK BERKUASA PERANTI PERUBATAN *Medical Device Authority* KEMENTERIAN KESIHATAN MALAYSIA *Ministry of Health Malaysia* Portal: www.mda.gov.my Email: mdb@mda.gov.my

BORANG PERMOHONAN BAGI NOTIFIKASI PERANTI PERUBATAN *OBSOLETE & DISCONTINUED*

NOTIFICATION OF OBSOLETE & DISCONTINUED MEDICAL DEVICE FORM

For MDA Office use			
Application serial No. :			
Particulars (Please tick X if completed)		**[Signature and Name]**	**Date**
	Application received		
	CE office		
	Head of Division		
	Evaluation Officer		

KETERANGAN *EXPLANATION*

Berdasarkan Surat Pekeliling PBPP Bilangan 2 Tahun 2018: Kawalan terhadap peranti perubatan 'orphaned', 'obsolete' dan 'discontinued' di Hospital atau Institusi Kemudahan Kesihatan. Establismen yang mempunyai peranti perubatan *obsolete* atau *discontinued* hendaklah mengenalpasti dan memberikan notifikasi kepada Pihak Berkuasa Peranti Perubatan (PBPP).

In accordance with Circular Letter of Medical Device Authority No. 2 Year 2018: Control of orphaned, obsolete and discontinued medical device in hospital or healthcare facilities institution. Establsihment which have obsolete or discontinued medical devices shall identify and provide the notification to the Medical Device Authority (MDA)

Sila lengkapkan maklumat di ruangan yang disediakan *All field are mandatory unless stated otherwise*

NOTIFICATION FOR: (Please tick X the boxes)

- ☐ **OBSOLETE MEDICAL DEVICE**
- ☐ **DISCONTINUED MEDICAL DEVICE**

PART 1 ESTABLISHMENT DETAILS		
a.	Type of Establishment:	
b.	Business Registration No.:	
c.	Establishment Name:	
d.	MDA Establishment License No.:	
e.	Address:	
f.	City:	

g.	State:	
h.	Postcode:	
i.	Telephone No.:	
j.	Fax No.:	
k.	Company Website:	
PART 2 PERSON RESPONSIBLE DETAILS		
a.	Nationality:	
b.	NRIC / Passport No.:	
c.	Full Name:	
d.	Designation:	
e.	Telephone No.:	
f.	Email:	
PART 3 CONTACT PERSON DETAILS **(If contact person is not the same person as the person responsible)**		
a.	Nationality:	
b.	NRIC / Passport No.:	
c.	Full Name:	
d.	Designation:	
e.	Telephone No.:	
f.	Email:	
PART 4 MEDICAL DEVICE DETAILS		
** If the notification involves medical device grouping, please complete List of Configuration (LOC) in Appendix A		
a.	**GENERAL INFORMATION**	
	i. Medical Device Name:	
	ii. Brand:	
	iii. Model No.:	
	iv. Serial No.:	
	v. Intended purpose:	
	vi. Medical Device Registration No. (If applicable)	
	vii. Date of purchase:	

	viii. Beyond Economic Repair (BER): Yes/No?	
b.	**HEALTHCARE FACILITIES AND ANY OTHER FACILITIES DETAILS (if available)**	
	i. Healthcare facilities and any other facilities Name**:**	
	ii. Healthcare facilities and any other facilities Address**:**	
	iii. City	
	iv. State	
	v. Postcode	
	vi. Telephone No	
	vii. Email Address	

PART 5
ATTESTATIONS & DECLARATION

I, the undersigned, hereby attest and declare that:

The product indicated on this application is:

i) medical device according to the definition of "medical device" set out in Section 2, Medical Device Act 2012 (Act 737); and ii) obsolete and / or discontinued medical device according to the definition set out in Circular Letter of Medical Device Authority No. 2 Year 2018

I shall comply fully with the terms and conditions imposed in the Notification by the Authority.

I shall comply with any relevant competent authorities on any other law or regulations in Malaysia, if applicable (i.e. Atomic Energy Licensing Board, etc).

The information provided on this application is accurate, correct, complete and current to this date. I understand and acknowledge that it is an offence to make signs or furnish any declaration, or other document which is untrue, inaccurate or misleading as required by Section 76 of Medical Device Act 2012 (Act 737).

Signature: (person responsible or appointed personnel by top management)	
Name:	
Designation:	
Date:	
Company stamp:	

Please return this form to:

Chief Executive Medical Device Authority Email:
ood.md@mda.gov.my

APPENDIX A
LIST OF CONFIGURATIONS (LOC) OF OBSOLETE / DISCONTINUED MEDICAL DEVICE

Device Name and Brand Name(s) :

Brief description :

Intended Use of the device :

Medical Device Nomenclature :

GMDN Code :

Other Nomenclature Code if GMDN is not applicable :

UMDNS Code :

HS Code :

UDI Code :

Type of Medical Device (IVD) : **General Medical Device** ☐

☐ **In-Vitro Diagnostic**

Class & Classification Rule :
(according to First Schedule on Rules of Classification of Medical Device, MDR 2012)

Class & Classification Rule :
(according to First Schedule on Rules of Classification of Medical Device, MDR 2012)

Quantity :

List of lot/Batch No/Serial No. :

Grouping of Medical Device : ☐ **SINGLE** ☐ **SET** ☐ **IVD TEST KIT**

IVD CLUSTER ☐ **FAMILY** ☐ **SYSTEM** ☐

List of Configurations of Medical Device
***not applicable for single medical device**

(repeat as needed)

: Please provide medical device grouping list information as per **Grouping of Medical Device Table**

Grouping of Medical Device Table

No.	Name of device, constituent components, accessories, reagents and/or articles as per product label:	Device Identifier No.	Brief Description (including name, size, colours, variant, etc)	Intended Purpose *Mandatory for IVD Cluster

* Repeat as Needed
** This Appendix A is part of the notification to be submitted together with the Notification Application Form.

ANNEX B
(normative)

		PIHAK B ERKUASA PERANTI PERUBATAN *Medical Device Authority* KEMENTERIAN KESIHATAN MALAYSIA *Ministry of Health Malaysia* Portal: www.mda.gov.my Email: mdb@mda.gov.my

DISPOSAL OF OBSOLETE AND DISCONTINUED MEDICAL DEVICE NOTIFICATION FORM

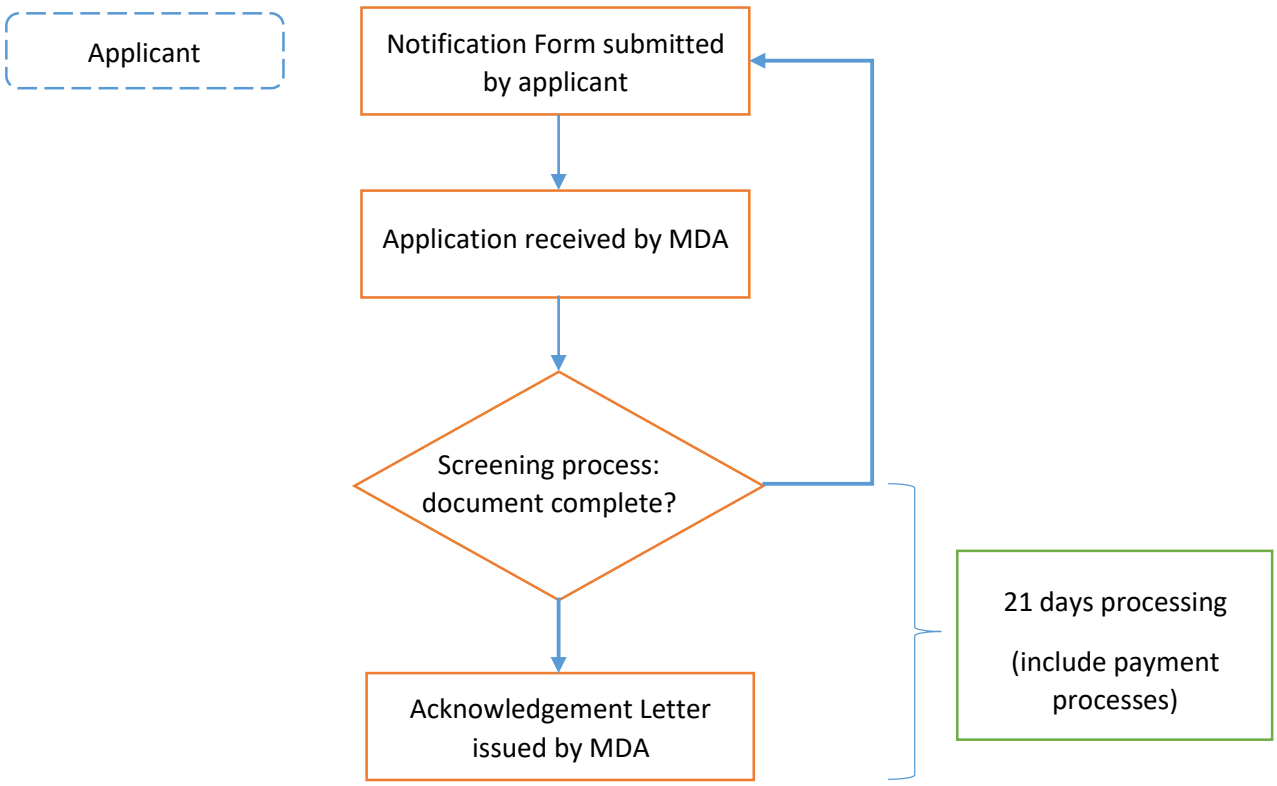
Please complete all information requested in this form		
Please state Notification letter reference number information:		
Name of Establishment		
PARTICULARS OF MEDICAL DEVICE(S) (Repeat as needed)		
Notification ID	Name of Device	Location(s)
1.		
2.		
3.		
4.		
5.		
DECLARATION **(Please read carefully & tick the boxes)**		
I, the undersigned, hereby declare that:		
☐	The obsolete and / or discontinued medical device(s) are properly disposed.	
☐	The information provided on this application is accurate, correct, complete and current to this date. I understand and acknowledge that it is an offence to make signs or furnish any declaration, or other document which is untrue, inaccurate or misleading as required by Section 76 of Medical Device Act 2012 (Act 737).	
Signature:		
Name:		
Designation:		
Establishment stamp: Date:		

Please return this form to:

Chief Executive Medical Device Authority
Email: ood.md@mda.gov.my

ANNEX C
(informative)

FLOWCHART OF APPLICATION FOR NOTIFICATION OF OBSOLETE AND DISCONTINUED MEDICAL DEVICE



MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II
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63000 Cyberjaya, Selangor
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T: (03) 8230 0300
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Website: https://portal.mda.gov.my