MDA/GD/0067
January 2024
First Edition

MEDICAL DEVICE GUIDANCE DOCUMENT

MEDICAL DEVICE POST MARKET INFORMATION EXCHANGE FOR ASEAN MEMBER STATES

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Contents Page

National Preface

The development of Guideline on Medical Device Post Market Information Exchange for ASEAN Member States was actively worked towards by Malaysia, as a member state of ASEAN. In order to further monitor post-market surveillance among ASEAN Member States, Malaysia consents to adopt this guideline following its ratification at the Twelfth Meeting of the ASEAN Medical Device Committee (AMDC), held at Bandar Seri Begawan, Brunei Darussalam, on September 12–13, 2023.

This guideline is identical corresponding to the Guidelines on Medical Device Post Market Information Exchange for ASEAN Member States, as are to be accessed via the ASEAN website at https://asean.org.

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.

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Preface

This document is produced to ASEAN Member States (AMS) and intended to provide general guidance. There are no restrictions on the reproduction or use of this document; however, incorporation of this document, in part or in whole, into another document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the ASEAN Medical Device Committee (AMDC) or the ASEAN Secretariat. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. Neither the medical device regulatory authority of AMS nor the ASEAN Secretariat accept liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. If you need any legal or professional advice, you should consult your own legal or other relevant professional advisers.

In the event of any contradiction between the contents of this document and any written law, the latter shall take precedence.

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MEDICAL DEVICE POST MARKET INFORMATION EXCHANGE FOR ASEAN MEMBER STATES

1 Introduction

It is necessary to protect public health and patient safety by ensuring that all medical devices to be placed in the market meet appropriate standards of safety, quality and performance, and that they are used safely. This document is made pursuant to the ASEAN Medical Device Directive (AMDD) for post market alert and the need for information exchange among AMS.

This guidance document has been adapted from IMDRF/NCAR WG/N14FINAL:2022 (Edition 3) - *Medical Devices: Post Market Surveillance National Competent Authority Report Exchange Criteria and Report Form*.

2 Scope and application

This guidance provides guidance on exchange of post market information among AMS.

3 References

The references are as follows:

i. ASEAN Medical Device Directive (AMDD)

ii. IMDRF/NCAR WG/N14FINAL:2022 (Edition 3) - Medical Devices: Post Market Surveillance National Competent Authority Report Exchange Criteria and Report Form

4 Terms and definitions

For the purpose of this document, the terms and definitions given in ASEAN Medical Device Directive (AMDD).

5 Requirements on exchange of post market information

In order to facilitate the AMS in implementing the post market surveillance activities, AMDC agreed that all AMS are allowed to exchange post market information, including information relating to significant concerns or potential trends that individual authorities have observed in their jurisdictions.

5.1 The concerns or potential trends that individual authorities have observed in their jurisdictions are as according to the following:

5.1.1 Events leading or highly likely to lead to unanticipated public health threat

Reportable events, associated with a medical device that have led or are highly likely to lead to unanticipated serious public health threat and fulfil the following criteria:

a. Death of a patient, user or other person;
b. Serious injury of a patient, user or other person; or
c. No death or serious injury occurred but the event might lead to death or serious injury of a patient, user or other person if the event recurs. Some jurisdictions refer to these events as near incidents.

Notes:
1.The interpretation of "serious" in the context of serious public health threat may be difficult to assess and should be determined in consultation with a medical practitioner when appropriate.
2.Post market report from any AMS should not be used for advising of single incidents, unless those incidents have a clear implication for public health.

Examples:
a) A contaminated eye rinsing solution is used during eye surgery. The possible outcome is serious vision impairment or blindness. The issue was not identified until testing was conducted following several reports of patients having infection and visual problems. The size of the concerned batch is such that the contaminated solution is likely to be distributed in different geographical areas/regions.
b) A spinal disc prosthesis is inserted between two cervical vertebrae to treat the pain and numbness associated with the collapse of the disc space. Cases of implanted patients suffering from paralysis several months following surgery have been reported. The investigation concluded that the root cause of the paralysis is mechanical failure of the disc, resulting in the disc moving out from between the vertebrae. Subsequent investigation shows that there is no warning for when the disc might break. Advice provided is that all implanted patients should have the disc replaced.
c) An IVD product owner had identified a problem with his HIV test which can result in the generation of false negative results. The problem is not detected by the device control and therefore the incorrect false negative result could be given to medical staff and the patient. The device is widely used across the world, and in some jurisdictions, it is used for testing prior to blood / organ donation.

5.1.2 Observations from national trend analysis

A trend noticed by an AMS is circulated to the other AMSs when:

a) The frequency of the event associated with the device is significantly higher than the frequency recorded in the product owner's file or significantly higher than the frequency observed with similar devices; and
b) The event has led or is highly likely to lead to a serious public health threat.

Examples:
a) The review of data from a national registry, complemented by adverse event data indicates a potential concern regarding high revision rates for hip prosthesis that have Metal on Metal (MoM) articulations. The consequence for implanted patients can be permanent impaired mobility and/or the need for surgical re-intervention to avoid further impairment.
b) Review of adverse event data and literature for a specific atrial septal occluder device indicated an increase in tissue erosion compared with other devices in this category. This type of device failure has not been seen in similar devices to treat this condition. This erosion can require immediate interventional surgery to remove the device and repair the erosion.

5.1.3 Request and/or share of information

5.1.3.1 An AMS may request and/or share information about a specific device or class/group of devices concerning:

a) An adverse event;

b) An increased seriousness or frequency to what was previously reported to the AMS;

c) Major weaknesses and/or major deviations regarding a product owner's Project Management System (PMS) / Quality Management System (QMS); and

d) Regulatory status changes of a device(s).

The consequences of which:

a) Have led or are highly likely to lead to serious public health threat; and

b) May affect other jurisdictions.

5.1.3.2 The concerned AMS can ask whether other AMSs have similar experience and what actions were initiated or are being discussed to address the issue, e.g. recalls or Field Safety Corrective Actions (FSCA).

Examples:

a) An AMS has received an increasing number of reports for thrombosis in association with a particular Left Ventricular Assist Device (LVAD). These devices are used in very ill patients who depend on these devices for survival. If the LVAD is stopped or slowed because of thrombosis the patient requires immediate treatment such as thrombolytics or surgical intervention to avoid patient death. The root cause is not identified.

b) The AMS requests information and assistance if other jurisdictions have encountered this issue and have any additional information that might be useful in determining a root cause.

c)Several reports have been received of embolus, which has led to or could lead to the death of the patient during an operation, for devices delivering fibrin to seal the gut during surgery. It is unclear whether the device or the drug is responsible for the observed event. The competent authority circulates the report and requests information from other competent authorities regarding any reported adverse events associated with fibrin and embolus.

d) An AMS notes a series of field actions that have been conducted by a product owner. The field actions all relate to one specific device that is used both in the High Dependency Unit setting and palliative care settings. The large number of field actions and the manner in which the product owner has managed the identified issues raise questions about the product owner's quality management system. The competent authority seeks information from other authorities relating to their experience with the product owner and the product.

e) An AMS restricts the importation of a medical device(s) due to concerns about device safety that could result in a serious public health threat.

5.2 The exchange of post market information among AMS shall be reported based on the reporting template as attached in ANNEX A. The report shall be submitted to the ASEAN Secretariat which shall circulate it to all AMS. All information in the report shall be treated confidential and shall accordingly be managed or disclosed in accordance with Article 16 of the AMDD.

The ASEAN Secretariat, in ensuring/maintaining the quality and consistency of the circulated report, shall respect confidentiality arrangements of information among AMS. Except for the circulation of the report, no confidential information shall be disclosed by the ASEAN Secretariat.

5.3 The explanation on how to fill up the reporting template can be referred in ANNEX B of this document.

Annex A

(normative)

REPORTING TEMPLATE FOR EXCHANGE OF POST MARKET INFORMATION AMONG AMS

Completed forms shall not be released to any other party. All information contained in this form is considered confidential.

1. Report Number: <reference number>

☐ New
☐ Amended

2. PURPOSE of the EXCHANGE:

☐ Share Information
- ☐ Events leading or highly likely to lead to unanticipated serious public health threat.
- ☐ Observations from national trend analysis
- ☐ Share of Information as outlined in Clause 5.1.3

☐ Request Information
☐ Summary of query findings

DETAILS OF INITIATING COUNTRY

3. Authoring Country:	<name of country>		
4. Contact Person:	<name of contact person>	**5. Designation:**	
6. E-mail:	<email address>	**7. Telephone:**	<telephone number>
8. Circulated:	<date circulated - dd/mm/yyyy>		

DEVICE DETAILS

9. Generic name / kind of device:

10. Nomenclature Type:	**11. No / Code:**

12. Medical Speciality Area:

13. Trade Name and Model:	
14. Device also marketed as (trade name), if known:	
15. If Applicable, UDI No.:	**16. Software version (If Applicable):**
17. Serial number(s):	**18. Lot / batch number(s):**

Regulated Parties

19. Product Owner:	**20. Authorised Representative:**	**21. If Applicable, CAB / Notified Body No.:**
Country:	**Country:**	
Full Address:	**Full Address:**	
Contact:	**Contact:**	
Telephone:	**Telephone:**	
Email:	**Email:**	

BACKGROUND INFORMATION AND REASON FOR THIS REPORT

22. <background of report >

Is the Investigation of the report Complete : ☐ Yes ☐ No

Attachments : ☐ Yes ☐ No

(… include information on relevant manufacturing sites)

QUESTIONS AND RESPONSES (If Applicable)		
23. Deadline for response: <dd/mm/yyyy>		
Question	**Answer**	**Rationale / Remarks**
24.		

ADDITIONAL RATIONALE AND REMARKS
25.

DETAILS OF RESPONDING COUNTRY			
26. Responding Country:	<name of country>		
Contact Person:	<name of contact person>	**Telephone:**	<telephone number>
E-mail:	<email address>	**Fax**	<fax number>

FINAL SUMMARY / COMMENTS
27.

ANNEX B

(informative)

INSTRUCTIONS FOR FILLING UP REPORTING TEMPLATE FORM

B.1 GENERAL

1. The form should be completed in English.

2. The point of contact identified in Field 3 of the report form is considered to be the author of the report. The author is responsible for:
   i. ensuring that the report is issued in accordance with exchange criteria as mentioned in this guidance;
   ii. the accuracy, completeness and relevance of the content; and
   iii. the scope of its distribution.

3. Reports should not to be used for advising of single incidents, unless those incidents have a clear implication for public health. In such cases, the implied recommendation is for other AMSs to be aware and take such local actions they find appropriate.

4. If the report involves a specific product owner's device, then the product owner or authorized representative may be consulted regarding the reports content and distribution of the device prior to it being sent to ASEAN Secretariat – preferably by providing a copy for the product owner or authorized representative to comment on. This will help to ensure the accuracy, particularly the technical content, of the report. An appropriate timeframe for receiving product owner's comments should be communicated.

FIELD:

Number	Explanatory notes
1	Use the rules for numbering reports (use the ISO 3166 for country codes) which incorporates a two-letter code of the issuing country to fill in this item. For example: MY-2005-10-19-002 is a report from Malaysia sent 19 October 2004 and is the 2nd report for 2005. Each new report should be given a unique report number. If a report relates to a previously exchanged report ensure that the “Amended” box has been checked.
2	Check the box associated with the purpose of the exchange.
3-5	Identify person and organization sending the report. This should be the single point of contact, previously identified to the ASEAN Secretariat.
6-7	Telephone and e-mail of person in (3) above.
8	Add the date this report has been circulated
9	Kind of device or generic descriptor
10	Identify the nomenclature system used (e.g. Global Medical Device Nomenclature [GMDN] etc.).
11	Number or code to identify the device based on the nomenclature system.
12	State medical speciality area. No/Code of medical speciality areas are as follows: 1- Anaesthesia; 2- Cardiovascular; 3- Chemistry; 4- Dental; 5- Ear, nose and throat; 6- Gastroenterology/urology; 7- General and plastic surgery; 8- General hospital; 9- Haematology; 10- Immunology; 11- Microbiology; 12- Neurology; 13- Obstetrics and gynaecology; 14- Ophthalmology; 15- Orthopaedics; 16- Pathology; 17- Physical medicine; 18- Radiology; 19- Clinical toxicology; and 20- Paediatrics 21- Other (Please specify)
13	Trade name/ brand name and model number
14	List the marketed trade name(s) in other countries, if different.
15	State UDI information.
16-18	If there are many lot/ batch numbers or serial numbers (i.e., more than 3 or 4), a detailed list should be appended to the bottom of the report.
19	Product owner of device - full address, including country, phone number(s) and email.
20	Identify the natural or legal entity in reporting country who is responsible for placing the subject device on the market where the incidents occurred, full address, including country, phone number(s) and email.

21	Indicate name of Conformity Assessment Body / Notified Body involved, if applicable.
22	Provide a description of what has happened, including consequences to patients or users. With reference to the criteria for reporting (Clause 5), describe the reason for the report and why you want to inform other AMSs about these events. Such information will lead to a better understanding by the recipient on what is considered to be appropriate follow-up. Identify any investigation taken by the product owner and also whether there has been any regulatory, legal or company-initiated action taken in advance of sending out the report. Indicate if the investigation of the report is complete or not. Check either the 'Yes' or 'No' boxes to indicate whether there are any attachments associated with this report.
23	Indicate a date for which the sending AMS would like to receive responses from recipients of the report.
24	List questions under the heading 'Questions'. Number the questions for ease in replying.
25	Add any information that is relevant and will assist the receiver of the information to undertake action or to be able to answer the questions appropriately.
26	Provide the name of the AMS, the name of the person that the sending AMS can contact if they need to clarify any responses, a telephone number and an email address for the contact person.
27	This section is used by the sending AMS to inform other report members of the outcome of enquires related to a 'Request for Information' under the heading Purpose of the Exchange' (Field 2).

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