



Republic of the Philippines
DEPARTMENT OF HEALTH
Office of the Secretary



ADMINISTRATIVE ORDER
No. 2025- 0030

DEC 26 2025

SUBJECT: Implementing Guidelines for the Post-Marketing Alert System (PMAS) Requirements, Annex 5 of the ASEAN Medical Device Directive (AMDD)

I. RATIONALE

Republic Act (RA) No. 3720, otherwise known as the “Food, Drug, Device, and Cosmetic Act” as amended, and RA No. 9711, otherwise known as the “Food and Drug Administration (FDA) Act of 2009,” and its Implementing Rules and Regulations (IRR), were enacted to protect and promote the right to health of the Filipino people by ensuring the safety, efficacy, and quality of health products, including medical devices.

Under Sections 4 (i), (k), and (l) of RA No. 3720 as amended by RA No. 9711, the FDA is mandated: (i) to require all manufacturers, traders, distributors, importers, exporters, wholesalers, retailers, consumers, and non-consumer users of health products to report to the FDA any incident that reasonably indicates that said product has caused or contributed to the death, serious illness or serious injury to a consumer, a patient, or any person; (k) after due process, to order the ban, recall, and/or withdrawal of any health product found to have caused the death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive, and to require all concerned to implement the risk management plan which is a requirement for the issuance of the appropriate authorization; and (l) to strengthen the post market surveillance system in monitoring health products as defined in this Act and incidents of adverse events involving such products.

The Philippines, as a signatory to the ASEAN Medical Device Directive (AMDD) in 2014, adheres and commits to its provisions and its Annexes on the regulation of medical devices. With this, the government signed the Instrument of Ratification of the AMDD on 18 November 2020. The AMDD entered into force for the Philippines on 4 March 2021 in accordance with Article 22 of the said Agreement.

Consistent with the foregoing, the Philippines, through the FDA of the Department of Health (DOH), hereby issues the implementing guidelines for the adoption of the Post-Marketing Alert System (PMAS) Requirements provided under Annex 5 of the AMDD. Specifically, these guidelines will provide the post-marketing rules concerning the (1) importation and/or distribution records, (2) complaint records, (3) adverse event reporting criteria and format, and (4) field safety corrective action reporting format for medical devices in the country.

II. OBJECTIVE

This Order aims to adopt the PMAS Requirements provided under Annex 5 of the AMDD as the mandatory guidance on the post-market obligations of all manufacturers, traders, retailers, and distributors (e.g., importers, exporters, or wholesalers) of medical devices in the Philippines.

III. SCOPE AND COVERAGE

This Order shall cover all medical devices, including in-vitro diagnostic (IVD) medical devices, and shall apply to all manufacturers, traders, retailers, and distributors (importers, exporters, or wholesalers) of medical devices in the Philippines.

IV. DEFINITION OF TERMS

The terms used in this Order shall have the meaning as defined in RA 9711 and its IRR, AMDD, and related laws and regulations. However, for clarity and purposes of these guidelines, the following terms are defined as follows:

- A. **Adverse Event (AE)** – refers to either a malfunction or a deterioration in the characteristics or performance of a supplied medical device or use error, which either has caused or could have caused or contributed to death, or injury to health of patients or other persons.
- B. **Distributor/Importer/Exporter** - refers to any establishment that imports or exports raw materials, active ingredients, and/or finished products for its own use or for wholesale distribution to other establishments or outlets. If the distributor/importer/exporter sells to the general public, it shall be considered a retailer.
- C. **Distributor/Wholesaler** - refers to any establishment that procures raw material, active ingredients, and/or finished products from a local establishment for local distribution on a wholesale basis.
- D. **Field Safety Corrective Action (FSCA)** - refers to any action taken by a product owner to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device. This may include the return of a medical device to the product owner or its representative; device modification which may include: retrofit in accordance with the product owner's modification or design change; permanent or temporary changes to the labelling or instructions for use; software upgrades including those carried out by remote access; modification to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the device. device exchange; device destruction; advice given by product owner regarding the use of the device.
- E. **Manufacturer** - in relation to a health product, refers to an establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formulating, filling, packaging, repackaging, altering, ornamenting, finishing and labeling with the end in view of

its storage, sale or distribution; Provided, That the term shall not apply to the compounding and filling of prescriptions in drugstores and hospital pharmacies. A trader shall be categorized as a manufacturer.

- F. **Marketing Authorization Holder (MAH)** - refers to the owner of the permission embodied in a document granted by the FDA to a natural or juridical person who has submitted application to implement the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and/or, where appropriate, the use, testing, promotion, advertising, or sponsorship of health products. The authorization can take the form of a permit, a license, a certificate of registration, of compliance, or of exemption, or any similar document. The MAH is responsible and accountable for the safety, efficacy and quality of the health products approved by the FDA to be in the market.
- G. **Medical Device** - refers to any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material, or other similar or related article intended by the manufacturer to be used alone, or in combination, for human beings for one or more of the specific purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; preventing infection; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body. This device does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means but which may be assisted in intended function by such means.
- H. **Non-consumer User** - refers to personnel and workers who use radiation devices for medical and non-medical applications, and radioactive substances inside medical devices in the conduct of their profession or in the course of their work. It may also refer to users of other health products who are members of a certain class of profession or workers where the use of such health products may have an effect on health that requires regulations as determined by the FDA.
- I. **Post-Marketing Alert System** - refers to a mechanism or process established by regulatory authorities or agencies to monitor and respond to safety-related issues and incidents associated with medical devices after they have been approved or cleared for market distribution. This system aims to ensure ongoing patient safety and product effectiveness by promptly identifying and addressing any potential risks, adverse events, or performance concerns that may arise following the commercialization of a medical device.
- J. **Post-marketing Surveillance** - refers to activities involved in safety, efficacy, and quality monitoring of health products. This shall also include among others adverse events reporting, product safety update reporting, collection and testing of health products in the market.
- K. **Retailers** - refers to any establishment which sells or offers to sell medical device directly to the general public.

- L. **Trader** - refers to any establishment, which is a registered owner of a health product and procures the raw materials and packing components and provides the production monographs, quality control standards and procedures, but subcontract the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products.

V. GENERAL GUIDELINES

- A. The current version (AMDD 2015) of the PMAS Requirements provided under Annex 5 of the AMDD shall be adopted as the mandatory regulatory guidance on (1) the post-market surveillance system for all medical devices, and (2) the post-marketing obligations of all manufacturers, traders, retailers, and distributors (e.g., importers, exporters, or wholesalers) of medical devices in the Philippines, insofar as it is not in conflict with existing national laws and regulations on post-market surveillance of medical devices.
- B. All manufacturers, traders, retailers, and distributors (e.g., importers, exporters, or wholesalers) of medical devices in the Philippines shall comply with the PMAS Requirements provided under Annex 5 of the AMDD indicated under Annex A of this Order, and other subsequent FDA Circulars on PMAS.
- C. The Center for Device Regulation, Radiation Health and Research (CDRRHR) of the FDA of the DOH shall lead the adoption and implementation of the PMAS Requirements provided under Annex 5 of the AMDD, including its promulgation and compliance monitoring of all manufacturers, traders, retailers, and distributors (e.g., importers, exporters, or wholesalers) of medical devices in the country, pursuant to RA No. 9711 and its IRR.
- D. All supplements and revisions relating to the PMAS Requirements provided under Annex 5 of the AMDD shall be automatically adopted insofar as the provisions and/or requirements are consistent with existing national laws and regulations. The CDRRHR of the FDA in DOH shall likewise release supplemental issuances on the same if deemed necessary.
- E. The timeline for the evaluation of the post-marketing alerts such as AE report, FSCA report and complaints received by the FDA-CDRRHR shall be based on the relevant provisions of RA No. 11032 otherwise known as the "Ease of Doing Business and Efficient Delivery of Government Services Act of 2018."
1. Seven (7) working days from receipt of the post-marketing alert for the initial assessment. If further information or clarification is required from the submitter, the FDA-CDRRHR shall notify the submitter.
 2. Twenty (20) working days for the comprehensive risk assessment, considering factors such as device type, intended use, patient population, and available scientific evidence. Based on the risk assessment, the FDA-CDRRHR shall decide on the appropriate regulatory action, which may include recall, market suspension, safety advisory, labeling changes, or further investigation.

Compliance monitoring of post-marketing alert shall be based on the existing guidelines or procedures of concerned FDA offices such as the CDRRHR, Regional Field Offices, and FDA Laboratories.

- F. The adopted PMAS Requirements provided under Annex 5 of the AMDD, its supplements and revisions shall be made accessible at the FDA website through the following web link: <https://www.fda.gov.ph>.

VI. TRANSITORY PROVISION

All medical devices MAH shall be given one (1) year transition period to comply with the AMDD Annex 5 starting from the effectivity date of this Order.

VII. REPEALING CLAUSE

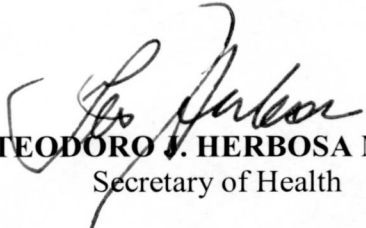
All administrative orders, rules and regulations and administrative issuances or parts thereof inconsistent with the provision of this order are hereby repealed or modified accordingly.

VIII. SEPARABILITY CLAUSE

In the event that any part, sections or provision of this guideline is declared invalid or unconstitutional by a competent court of jurisdiction, the other provisions of this guideline, insofar as they are separable from the invalid ones, shall remain in full force and effect.

IX. EFFECTIVITY

This Order shall take effect fifteen (15) days after its publication in the Official Gazette or in any newspaper of general circulation and upon filing with the Office of the National Administrative Register of the University of the Philippines Law Center.


TEODORO J. HERBOSA M.D.
Secretary of Health

ANNEX A

ANNEX 5 of the ASEAN Medical Device Directive (AMDD)

Post Marketing Alert System (PMAS) Requirements

1. INTRODUCTION

1.1. Purpose

This document aims to provide guidance on the post-market obligations of persons who place medical devices on the markets of ASEAN Member States.

1.2. Background

This document is intended to provide guidelines on the following post-market alerting system requirements:

- Importation and/or distribution records
- Complaint records
- Adverse event (AE) reporting criteria and reporting format
- Field Safety Corrective Action (FSCA) reporting format

The Regulatory Authorities in the Member States may adopt the recommended post-market alerting system requirements in this Annex or prescribe their own post-market alerting system requirements.

Importation and/or Distribution records

Traceability is not only a requirement of an effective quality system but also the requirement of regulatory bodies around the world. Keeping proper and appropriate importation and/or distribution records is an important component of ensuring traceability of medical devices in the market.

Complaint records

An effective complaint handling system is an important part of any quality system. Any complaint received on a medical device should be evaluated and if necessary, thoroughly investigated and analyzed, and corrective actions should be taken. The results of the evaluation should lead to a conclusion regarding whether the complaint was valid, the causes of the complaint, and what actions were necessary to prevent further occurrences.

Dealers of medical devices in the Member State shall be required to:

- maintain records of complaint reports and of actions taken in response to these reports, and produce such records for inspection by the Regulatory Authority in that Member State as and when requested; and

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- establish and implement documented procedures to conduct effective and timely investigations of reported problems.

Adverse events

A number of post-marketing risk assessment measures to ensure the continued safe use of medical devices may be undertaken. These measures include reporting from healthcare professionals, mandatory reporting from medical device dealers, and exchange of regulatory information with other medical device regulatory agencies.

The mandatory reporting of AEs by medical device dealers is an important part of the post-market surveillance system. The objective of AE reporting and subsequent evaluations is to improve protection of the health and safety of patients, users and others by disseminating information that may reduce the likelihood of, or prevent repetition of AEs, or alleviate consequences of such repetition.

Field Safety Corrective Action (FSCA)

A FSCA is required when it becomes necessary for the product owner of the medical device to take action (including recall of the medical device) to eliminate, or reduce the risk of, the hazards identified.

A FSCA may still be necessary even when the medical device is no longer on the market or has been withdrawn but could still possibly be in use (e.g. implants).

A FSCA only applies to a medical device that has already been distributed by the product owner. It does not arise when a product owner is exchanging or upgrading medical devices in the absence of a safety risk or when removals from the market are for purely commercial reasons.

The product owner, physical manufacturer, authorized representative(s), importer and/or authorized distributor(s) in the Member State shall be responsible for performing and completing the FSCA in that Member State.

1.3. Scope

This document applies to all medical devices, including IVD medical devices.

1.4. Definitions

CUSTOMER COMPLAINT: any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market.

DEALER: any person, which could include the product owner, physical manufacturer, authorized representative or authorized distributor in a Member State, who has either manufactured, imported, placed on the market or put into service a medical device in that Member State.

FIELD SAFETY NOTICE (FSN): A communication sent out by a product owner or its representative to the medical device users in relation to a FSCA.

SERIOUS DETERIORATION IN THE STATE OF HEALTH: any of the following state or condition of a patient:

- a life-threatening illness or injury suffered by that person;
- a permanent impairment of a bodily function of that person;
- any permanent damage to any part of that person's body; or
- a condition requiring medical or surgical intervention to prevent any such permanent impairment or damage.

2. IMPORTATION AND/OR DISTRIBUTION RECORDS

2.1. Responsibility for keeping importation and/or distribution records

In accordance with the requirements of the Regulatory Authority of each Member State, dealers shall:

- establish and implement documented procedures for the maintenance of importation and/or distribution records;
- maintain an importation and/or distribution record of each medical device.

Importation and/or distribution records should be maintained for all medical devices, including low risk medical devices that may be exempted from product registration.

2.2. Necessity of importation and/or distribution records

Keeping importation and/or distribution records will facilitate the accountability and traceability of a medical device. This ensures that the medical device import and/or distribution channels in Member States are identifiable.

Importation and/or distribution records of the medical devices are required to:

- expedite any recalls of batches of the medical devices;
- identify the product owner of each batch of the medical devices;
- identify where each batch of the medical devices is supplied.

2.3. Information to be retained as importation and/or distribution records

The importation and/or distribution record should contain sufficient information to permit complete and rapid withdrawal of the medical device from the market, where necessary.

Information may include:

- name and address of initial consignee;
- identification and quantity of medical devices imported/shipped;
- date imported/shipped;
- any control number(s) used, including lot / batch / serial number of the medical device.

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2.4. Retention period for importation and/or distribution records

The importation and/or distribution record maintained with respect of a medical device should be retained for the longer of one of the following:

- the projected useful life of the medical device as determined by the product owner; or
- two years after the medical device is shipped.

NOTE: The projected useful life of a medical device may be based on technical, legal, commercial or other considerations. Product owners may refer to ISO/ TR 14969 Medical devices - Quality management systems - Guidance on the application of ISO 13485:2003 for some of the considerations when defining the lifetime of their medical device.

For medical devices that are imported for export only, it is two years after the date the medical device is shipped out of the Member State.

2.5. Records maintenance

Importation and/or distribution records should be maintained in a manner that will allow their timely retrieval.

2.6. Records of implant

The distribution record maintained should also contain a record of the information of the implant when supplied by a healthcare facility.

3. COMPLAINT RECORDS

The records on complaints related to a medical device may include the following information:

- the medical device brand name, medical device registration number, model/catalogue number or bar code, control/serial/ lot number and any other means of identification of the medical device;
- the name(s) and address(es) of the dealer;
- records pertaining to the problem investigation.

All actions taken by dealers in response to the problems and complaints must be kept on record. These actions include any communications with the reporter/complainant, the evaluation of the problem/complaint, and any steps taken to correct the problem or prevent the recurrence of the problem. Such steps might include increased post-market surveillance of the medical device, corrective and preventive action with respect to the design and manufacture of the medical device affected by the recall.

Attention should also be given to identifying the development of patterns or trends in problems with medical devices. The report of an isolated incident would assume much greater significance if other similar occurrences were reported.

3.1. Complaint handling procedure

Dealers should have in place a written procedure for complaint handling that outlines the steps to be taken once a complaint report is received for a medical device placed on the market or put into service in the Member State. The procedure should identify the personnel involved, and describe their functions and responsibilities.

In addition, the procedure should explain how to maintain records of the complaint reports, and where appropriate, how to assess these records and a reasonable time frame for completion of the investigation.

The procedure may contain the following:

- determination of whether there is a health hazard associated with the medical device;
- determination of whether the medical device fails to conform to any claim made by the dealer relating to its effectiveness, benefits, performance characteristics or safety;
- determination of whether the medical device fails to meet any legislative requirements;
- determination of the most appropriate preventive/corrective action; and
- justification when no action is taken, for example, in the case of receiving an unfounded or invalid complaint.

3.2. Retention of complaint records

Complaint records maintained with respect to a medical device should be retained for a period of five years on top of the projected useful life of the medical device as determined by the product owner. For example, if the projected useful life of the medical device is one year, the complaint records should be kept for six years.

4. ADVERSE EVENTS

4.1. Adverse event (AE) reportability criteria

As a general principle, there should be a pre-disposition to report rather than not to report in case of doubt on the reportability of an AE. Any AE, which meets the three basic reporting criteria listed below, is considered as a reportable AE. The criteria are that:

- an AE has occurred;
- the medical device is associated with the AE;
- the AE led to one of the following outcomes;
- a serious threat to public health;
- death of a patient, user or other person;
- serious deterioration in state of health, user or other person;
- 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.

An event or other occurrence relating to a medical device represents a serious threat to public health if one or more of the following occur:

- the event or other occurrence is a hazard arising from a systematic failure of the medical device that becomes known to the dealer of the medical device;
- the event or other occurrence may lead to the death of, or a serious injury to, a patient, a user of the medical device or any other person;
- the probable rate of occurrence of or degree of severity of harm caused by the hazard was not previously known or anticipated by the product owner of the medical device;
- it becomes necessary for the product owner of the medical device to take prompt action (including the recall of the medical device) to eliminate or reduce the risk of the hazard.

A serious deterioration in state of health can include:

- life-threatening illness or injury;
- permanent impairment of a body function or permanent damage to a body structure;
- a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

Not all AEs that should be reported involve a death or serious deterioration in health that actually occurred. The non-occurrence of an adverse effect might have been due to other fortunate circumstances or to the timely intervention of health-care personnel. In such cases, it is sufficient that either:

- an AE associated with a medical device happened, and the AE was such that, if it occurred again, it might lead to death or serious deterioration in health; or
- testing, examination of the medical device, information supplied with the medical device, or any scientific literature indicated some factor (e.g. a deterioration in characteristics or performance, or a shortcoming in the information) which could lead to an AE involving death or serious deterioration in health.

For IVD medical devices, it would be sufficient that:

- an AE associated with an IVD medical device occurred, and
- the AE might lead to death or serious deterioration in health if it happens again;
- for the adverse event to become reportable.

In assessing the type of AE, medical practitioner involved or other health-care professional should be consulted wherever practicable. All persons who place medical devices on the markets of Member States should be vigilant for any changes in trends or frequency of occurrences of AEs with regards to medical devices they deal in.

4.2. Adverse events involving IVD medical devices

Most IVD medical devices do not come into contact with patients and so it is not easy to establish direct harm to patients, unless the IVD medical device itself causes deterioration in the state of health in a patient. However, an adverse event involving an IVD medical device could result in indirect harm as a result of an action taken or not taken on the basis of an incorrect reading obtained with an IVD medical device.

There should always be a predisposition to report even though it may not be easy to establish that a serious deterioration in the state of a patient's health was the result of an erroneous test result

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obtained with an IVD medical device, or if the harm was the result of an error by the user or third party.

Information supplied by the product owner when inadequate, can lead users, patients or third parties to harm and should be reported. For self- testing IVD medical devices, where a medical decision may be made directly by the user who is the patient, insufficient information on the product presentation could lead to an incorrect use of the IVD medical device or a misdiagnosis. Hence, AEs involving IVD medical devices will most likely result from a consequence of a medical decision or action taken, or not taken, on the basis of result(s) provided by the IVD medical device.

Examples of these types of AEs include (non-exhaustive list):

- misdiagnosis;
- delayed diagnosis;
- delayed treatment;
- inappropriate treatment;
- transfusion of inappropriate materials.

AEs for IVD medical devices may arise due to (non-exhaustive list):

- shortcomings in the design or manufacture of the IVD medical device itself;
- inadequate instructions for use;
- inadequate servicing and maintenance;
- locally initiated modifications or adjustments;
- inappropriate user practice;
- inappropriate management procedures;
- inappropriate environment in which an IVD medical device is used or stored;
- selection of the incorrect IVD medical device for the purpose.

4.3. Adverse Event Reporting Timeline

All AEs should be reported immediately and

- not later than 48 hours for events that represent a serious threat to public health;
- not later than 10 days for events that has led to the death, or a serious deterioration in the state of health, of a patient, a user of the medical device or any other person;
- not later than 30 days for events where a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the medical device or any other person

The clock for reporting starts as soon as any personnel of the medical device dealers, including sales representatives, is made aware of the AE. If there is uncertainty about whether the AE is reportable, dealers should still submit a report within the timeframe stipulated.

Dealers should not unduly delay the reporting of AE(s) if information is incomplete. The initial report of an AE should contain as much relevant detail as is immediately available, but should not be delayed for the sake of gathering additional information.

Dealers of medical devices are to follow up with a final report within 30 days of the initial reports, detailing the investigation into the AE. If the final report is not available within 30 days, a follow-up report is to be submitted. Follow-up reports may be requested as and when necessary.

4.4. Reporting obligations

All dealers shall be required to report AEs involving medical devices, which they have placed on the market in the Member State.

Reports should be submitted using the prescribed format of the Regulatory Authority of the Member State, which may follow the ASEAN AE Report Form (Reference No. ASEAN-MDAR).

5. FIELD SAFETY CORRECTIVE ACTION (FSCA)

5.1. Determining the need for a field safety corrective action

The product owner of the medical device in question is responsible for determining the need for a FSCA. In accessing the need for an FSCA, the product owner should perform a risk assessment in accordance to the current ISO 14971. If the risk assessment performed by the product owner is deemed deficient by the Regulatory Authority of the Member State, the Regulatory Authority of the Member State may instruct the relevant companies and persons who placed the medical device in the market of the Member State to take additional measures to safeguard public health.

FSCA may be triggered when information from the product owner's post market surveillance (including product complaints, adverse incidents, etc) indicates an unacceptable increase in risk.

On occasions, the Regulatory Authority may advise product owners or their representative to implement a FSCA in relation to a medical device due to risk of serious injury or death to patients, users or others. Such risks are usually identified through adverse events reports or other means.

In certain cases it may be necessary to use precautionary measures in the interest of public health and restrict or prohibit medical devices subject to particular requirements. In other cases, for safety reasons, it may be necessary to remove a medical device from the market.

5.2. Notification of field safety corrective action

When the dealer decides to initiate a FSCA, they shall notify the Regulatory Authority.

The time frame for notification of an FSCA shall be prescribed by the Regulatory Authority of the Member State.

All notification and reports are to be submitted in the manner that the Regulatory Authority prescribes.

5.3. Information to be provided

When the need for an FSCA has been established, the dealer should gather all relevant information on incident reports, the medical device and its distribution, and the action proposed. Some information may not be available immediately (e.g. distribution chains, batch size etc). Notification to the Regulatory Authority in the Member State should not be delayed pending collation of these data.

Reports should be submitted using the prescribed format of the Regulatory Authority of the Member State, which may follow the ASEAN FSCA Report Form (Reference No. ASEAN-MDFR).

5.4. Closure of FSCA

On completion of a FSCA, the dealer should provide details to the Regulatory Authority of the Member State of the proposed corrective action to prevent recurrence of the problem that give rise to the FSCA.

The FSCA will only be closed when all appropriate corrective actions have been undertaken, subject to the concurrence of the Regulatory Authority of the Member State.

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