Instructions for filling the MDAE reporting form (Version 1.2)

Materiovigilance Programme of India (MvPI)

Disclaimer: Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event. Submission of a Medical Devices Adverse Event (MDAE) Report does not have any legal implication on the reporter.

Confidentiality: The patient/reporter's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the patient/reporter's identity in response to a request from the public.

PRIMARY INFORMATION

1. **Date of Report**: Enter the current date (the date on which reporter is filling the MDAE form).
2. **Type of Report**: Select the appropriate type of report (Initial, Follow-up, Final, Trend) by ticking the checkbox.
   - **Initial:** The first report that the reporter is submitting about an event.
   - **Follow up:** Additional information provided subsequent to a previous report (either initial or follow-up report).
   - **Final:** The last report the reporter intends to submit about an event. An initial report can also serve as the final report if the reporter possesses all the necessary information about the event.
   - **Trend:** The manufacturers/importer/distributors are required to monitor trends in the significant increase of adverse events. Any notable changes in the frequency or severity of events associated with devices must be reported. These reports are referred to as "trend" reports.
3. **Report Reference No. for MDMC only:** The details such as, Name of the MDMC, location, month, year and number of the report is to be entered.
4. **Report Reference No. for MAH only:** Reference number given to the event based on the numbering system adopted/followed by the Marketing Authorisation Holder/License Holder.

REPORTER DETAILS

1. **Type of Reporter**: Tick the appropriate checkbox (Manufacturer, Importer, Distributor, Healthcare Professional, Others). If "Others," specify the type.
2. **In case the Reporter is not the Manufacturer**:
   a). Indicate whether the incident has been reported to the manufacturer (Yes/No).
   b). Indicate whether the report is being submitted on behalf of the manufacturer (Yes/No).
3. **Reporter Contact Information**:
   Enter the name, address, telephone/mobile number, and email address of the reporter.

MEDICAL DEVICE CATEGORY

Select the applicable Medical Device categories:

I. Therapeutic, Diagnostic, Therapeutic & Diagnostic, Assistive, Preventive, Imaging
II. Implantable Device, Non-Implantable Device
III. Invasive, Non-Invasive
IV. Single Use Device, Reusable Device
V. Reuse of Manufacturer Marked Single Use Device
VI. Sterile, Non-Sterile
VII. Personal Use/Homecare Use

Select the applicable In Vitro Diagnostics (IVD) categories:

I. Kits,
II. Reagent
III. Calibrator
IV. Control Material
V. IVD Electronic Reader/Analyzer
VI. Others (specify)

A. Medical Device Description

Common Medical Device Name - This is the widely recognized or standard name used to identify a medical device in the industry.

Trade Name / Brand Name -This is the name given to a product by its manufacturer or marketer, used for branding and commercial purposes.

Provide details of Manufacturer / Importer / Distributor including name & address.

1. **Device Risk Classification as per India MDR 2017**: Tick the appropriate classification (A, B, C, D). Every device marketed in India is regulated and classified as per MDR 2017. Kindly visit www.cdsco.gov.in to see the classification of suspected medical device.
2. **Is the device refurbished**: Indicate Yes/No, if yes, specify whether refurbishment was performed by Original Equipment Manufacturer (OEM) or others (Specify).
   Refurbished Medical Devises: A refurbished medical device can be defined as a restored medical device rebuilt to meet safety and performance requirements that are comparable to its condition when new, without changing the intended use of the original device.

   Reference: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10225950/
3. **License No. (Manufacturer/Importer) -** The official number granted to a manufacturer or importer authorizing them to manufacture or import medical devices.
4. **Model No. -**The specific identifier for a particular version or design of a device manufactured by the manufacturer.
5. **Catalogue No. -** A unique number used in product catalogs to identify and order specific medical devices.

6. **Lot/Batch No. -** The identifier for a specific production batch of devices, used for tracking and quality control
7. **Serial No. -** A unique number assigned to an individual device for identification and traceability.
8. **Software Version (If Applicable) -**The specific version of software installed on a medical device, if the device includes software components.
9. **Associated Devices/Accessories** - Additional equipment or components that are used in conjunction with the primary medical device.
10. **Nomenclature Code (GMDN/UMDNS) (If Applicable)** - Global Medical Device Nomenclature (GMDN) and Universal Medical Devices Nomenclature System (UMDNS) terms are an international naming and grouping convention used to identify and consistently describe medical device.
11. **UDI No. (If Applicable) -** Unique Device Identification Number is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard.
12. **Installation Date (If Applicable) -** The date when the device was set up and made operational.
13. **Expiration Date (If Applicable) -** The date beyond which the device or its components should not be used.
14. **Last Preventive Maintenance Date (If Applicable) -** The most recent date when the device underwent scheduled maintenance to ensure proper functioning.
15. **Last Calibration Date (If Applicable) -** The most recent date when the device was calibrated to maintain accuracy and performance.
16. **Year of Manufacturing -** The year when the device was produced.
17. **How long the Device/Equipment/Machine was in Use -** The total time period that the Device/Equipment/Machine has been in use.
18. **Availability of Device for Evaluation**–It indicates whether the device is currently available for inspection and analysis (Yes/No). If no, indicate if the device was destroyed, still in use, or returned to the manufacturer/importer/distributor.
19. **Is the Usage of Device as per Manufacturer Claim /Instruction for Use/User Manual –**It indicates whether the device is being used according to the manufacturer's guidelines and instructions provided in the user manual. (Yes/No). If no, specify the usage.

B. EVENT DESCRIPTION

1. **Provide the date of the event/near-miss incident** - refers to specifying the exact date when an event or near-miss incident occurred. This date is crucial for tracking and addressing occurrences that might affect safety, quality, or operations.
2. **Specify the type of event (adverse event, product problem) –** refers to identify and categorize the nature of the incident, such as whether it is an adverse event or a product problem (issue with the product itself like defects/ malfunctions).

3. **For Implantable Medical Devices Only:**

   a) **If Implanted, Give Date (DD/MM/YY)**: The date when the implantable device was initially inserted into the patient body or body orifice, formatted as date/month/year.

   b) **If Explanted, Give Date (DD/MM/YY)**: The date when the implantable device was removed from the patient body or body orifice, formatted as date/month/year.

4. **Location of Event:**- specifies where the incident involving the device occurred. It includes:

   Hospital: The event took place within a hospital.

   Manufacturer/Distributor Premises: The event occurred at the location of the manufacturer or distributor.

   Home: The event happened at the patient's home.

   Others: Any other location not listed, with space to specify the exact location.

5. **Specify the device operator:** refers to the individual who used or handled the medical device. It includes:

   Healthcare Professional: A medical worker who operated the device.

   Patient: The person receiving treatment who used the device.

   Others: Any other individual or entity involved, with a space to specify who they are.

6. **Provide the device disposition/current location-**refers to the current status or location of a medical device. It includes:

   a) **Returned to Company**: If the device was sent back to the manufacturer, with an option to specify the date of return.

   b) **Remains Implanted in Patient**: If the device is still inside the patient.

   c) **Within the Healthcare Facility**: If the device is still at the healthcare facility where it was used.

   d) **At Patient Home**: If the device is with the patient at their home.

   e) **Destroyed**: If the device has been disposed of or destroyed.

   f) **Others (Specify)**: Any other status or location not listed above.

7. **Indicate if the device is in use after the incident (Yes/No) -** means to specify whether the device is still being used following the reported incident. Respond with "Yes" if it is in use or "No" if it is not.

8. **Serious events -** Indicates whether the incident is considered serious. If yes, specify the reason: tick the appropriate reason (death, life-threatening, disability or permanent damage, hospitalization/ prolongation of existing hospitalization, congenital anomaly, required intervention to prevent / permanent impairment, if others, then specify).

9. **Non-serious events -** refer to incidents that do not result in significant harm to the patient or user. These events typically do not lead to death, life-threatening, disability or permanent damage, hospitalization/ prolongation of existing hospitalization, congenital anomaly, required intervention to prevent / permanent impairment. Tick the appropriate checkbox.

10. **Whether Other Medical Devices were Used at Same Time With Above Device if yes, Please Specify Name(s)/Use(s) -** asks if other medical devices were used simultaneously with the device in question. If yes, provide details such as the names of the devices and their specific uses.

11. **Event Outcome and Reoccurrence Information**

    a) **Event Abated after use Stopped/Reduced?**

    - **Yes**: The event subsided after stopping or reducing use.
    - **No**: The event did not subside.
    - **Doesn't Apply**: The situation is not applicable.

    b) **Event Reappeared after Reintroduction?**

    - **Yes**: The event reoccurred after reintroducing the device.
    - **No**: The event did not reoccur.
    - **Doesn't Apply**: The situation is not applicable.

12. **Detail Description of Event**

    - Provide a detailed description of the event and describe the incident comprehensively, including what happened, how it occurred, and any relevant circumstances or observations.
    - Attach any relevant diagnostic tests, laboratory data, pictures, or videos related to the event (indicate Yes/No for availability).

For Manufacturer/Authorized Representative Use Only

13. **Frequency of Occurrence of Similar Adverse Event in India in Past 3 Years:**
    Provide details of similar adverse events in India in the past 3 years, including the number of events, total devices supplied, and frequency of occurrence (%).

14. **Frequency of Occurrence of Similar Adverse Event in Globally in Past 3 Years:**
    Provide details of similar adverse events in globally in the past 3 years, including the number of events, total devices supplied, and frequency of occurrence (%).

C. PATIENT INFORMATION, HISTORY & OUTCOME

Enter the Patient's hospital ID, Patient Initial (The name of the patient shall be abbreviated to contain the first letter of the patient's name. E.g. "Hardik Pandey" shall be abbreviated to "HP"), age, gender, weight, relevant medical history, and treatment details. Indicate the patient outcome (death, recovered, not yet recovered, stable, others).

D. HEALTHCARE FACILITY INFORMATION (IF AVAILABLE)

Provide the name, address, contact person's name, telephone number/ Mobile No., and email address at the site of the event.

E. MEDICAL DEVICE ADVERSE EVENT ASSESSMENT

1. **Immediate Action Taken**: -The prompt measures or steps carried out in response to the event to address the situation and mitigate any potential harm.
2. **Suspected Root Cause of Problem**: The preliminary identified reason or underlying factor suspected to have caused the issue or adverse event.
3. **In Your Opinion, Which of the Following Best Describe the Association between Suspected Medical Device(s) and Adverse Event? -** Describe the association between the suspected medical device(s) and the adverse event- Indicate the level of association (not related, possible, probable, and related). For the purpose of understanding the nature of the adverse event, the reporter is requested to provide any one of the options that is given below which best describes the relation of the adverse event and the suspected medical devices.

   a) Not related –Relationship to the device, comparator or procedures can be excluded when:

   i. the event has no temporal relationship with the use of the medical device, or the procedures related to application of the medical device;
   ii. the serious adverse event does not follow a known response pattern to the medical device (if the response pattern is previously known) and is biologically reasonable;
   iii. the discontinuation of medical device application or the reduction of the level of activation/exposure- when clinically feasible - and reintroduction of its use (or increase of the level of activation/exposure), do not impact on the serious adverse event;
   iv. the event involves a body-site or an organ that cannot be affected by the device or procedure;
   v. the serious adverse event can be attributed to another cause (e.g. an underlying or concurrent illness/ clinical condition, an effect of another device, drug, treatment or other risk factors);
   vi. the event does not depend on a false result given by the medical device used for diagnosis, when applicable;

   In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious adverse event.

   b) Possible -The relationship with the use of the medical device or comparator, or the relationship with procedures, is weak but cannot be ruled out completely. Alternative causes are also possible (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases where relatedness cannot be assessed, or no information has been obtained should also be classified as possible.

   c) Probable –The relationship with the use of the medical device or comparator, or the relationship with procedures, seems relevant and/or the event cannot be reasonably explained by another cause.

   d) Related –the serious adverse event is associated with the medical device, comparator or with procedures beyond reasonable doubt when:

   i. the event is a known side effect of the product category the device belongs to or of similar devices and procedures;
   ii. the event has a temporal relationship with medical device use/application or procedures;

iii. the event involves a body-site or organ that
   - the medical device or procedures are applied to;
   - the medical device or procedures have an effect on;

iv. the serious adverse event follows a known response pattern to the medical device (if the response pattern is previously known);

v. the discontinuation of medical device application (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of the level of activation/exposure), impact on the serious adverse event (when clinically feasible);

vi. other possible causes (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment) have been adequately ruled out;

vii. harm to the subject is due to error in use;

viii. the event depends on a false result given by the medical device used for diagnosis, when applicable;

In order to establish the relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious adverse event.

Reference : https://health.ec.europa.eu/system/files/2022-11/md_mdcg_2020-10-1_guidance_safety_reporting_en.pdf

F. FOR MANUFACTURER/AUTHORIZED REPRESENTATIVE / LICENSE HOLDER ONLY

Investigation Needed: (Indicate Yes/No.) – Here, Manufacturer/Authorized Representative / License Holder need to specify whether an investigation is required or not for a particular issue or situation. If "Yes," it indicates that further investigation is needed; if "No," it means no investigation is required.

Investigation Action Taken with Timeline: This refers to documenting the specific actions taken during an investigation and the corresponding dates or deadlines when these actions were carried out or completed.

Root Cause of Problem (Applicable for follow-up/final reports): This is a brief explanation of the underlying reason or primary factor that led to the issue or problem, as identified in follow-up or final reports.

Corrective and Preventive Action (CAPA) Taken: This refers to the measures implemented to address and rectify an identified issue (corrective action) and to prevent its recurrence in the future (preventive action).

SUBMISSION DETAILS

- The Medical Device Adverse Event Reporting Form can be submitted in soft copy to the Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, via email to mvpi-ipc@gov.in or shatrunjay.ipc@gov.in.
- Alternatively, hard copy of this form can be sent to the Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India Sector-23, Rajnagar, Ghaziabad-20002.

CONTACT US

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