MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

Materiovigilance Program of India (MvPI)

This form is intended to collect information on Medical Devices Adverse Event in India. The form is designed to be used by Manufacturer/Importer/ Distributor of Medical Devices and Healthcare Professionals with direct/indirect knowledge of Medical Devices Adverse Event

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 :
2. Type of Report : Initial ☐ Follow up ☐ Final ☐ Trend ☐
3. Report Reference No. for MDMC only : Centre Location Month - Year Case No.
4. Report Reference No. for MAH only :
   (For Reference No. Format, Kindly Refer to Instructions)

Reporter Details

1. Type of Reporter : Manufacturer ☐ Importer ☐
   Distributor ☐ Healthcare Professional ☐
   Others ☐ Specify
2. In case, Where the Reporter is not the Manufacturer, Fill the Following Details:-
   a) Has the Reporter Informed the Incident to the Manufacturer? Yes ☐ No ☐
   b) Is the Reporter also Submitting the Report on Behalf of the Manufacturer? Yes ☐ No ☐
3. Reporter Contact Information:
   a) Name :
   b) Address :
   c) Tel. /Mobile :
   d) Email :

Medical Device Category

Medical Device

I. Therapeutic ☐ Diagnostic ☐ Therapeutic & Diagnostic ☐
Assistive ☐ Preventive ☐ Imaging ☐

II. Implantable Device ☐ Non-Implantable Device ☐

III. Invasive ☐ Non-Invasive ☐

IV. Single Use Device ☐ Reusable Device ☐
Reuse of Manufacturer Marked Single Use Device ☐

V. Sterile ☐ Non Sterile ☐

VI. Personal use / Homecare Use ☐

In Vitro Diagnostics (IVD)

I. Kits ☐

II. Reagents ☐

III. Calibrator ☐

IV. Control Material ☐

V. IVD Electronic Reader/ Analyzer ☐

VI. Others ☐

(A) Medical Device Description

Common Medical Device Name :

Trade Name / Brand Name :

Details	Name	Address
Manufacturer		
Importer		
Distributor		

1. Device Risk Classification as per India MDR 2017 : A ☐ B ☐ C ☐ D ☐
2. Is the device refurbished : Yes ☐ No ☐

   If Yes then, Refurbishment was Performed By : OEM ☐ Others ☐
3. License No. (Manufacturer/Importer) :
4. Model No. :
5. Catalogue No. :
6. Lot / Batch No. :
7. Serial No. :
8. Software Version (If Applicable) :
9. Associated Devices / Accessories :
10. Nomenclature Code; GMDN/UMDNS (If Applicable) :
11. UDI No. (If Applicable) :
12. Installation Date (If Applicable) :
13. Expiration Date (If Applicable) :
14. Last Preventive Maintenance Date (dd/mm/yyyy) (If Applicable) :
15. Last Calibration Date (dd/mm/yyyy) (If Applicable) :
16. Year of Manufacturing :
17. How long the Device/Equipment/Machine was in Use :
18. Availability of Device for Evaluation : Yes ☐ No ☐

    If no, was the Device Destroyed ☐ Still in Use ☐ Return to Manufacturer or Importer/Distributor ☐
19. Is the Usage of Device as per Manufacturer Claim /Instruction for Use/User Manual : Yes ☐ No ☐

    If no Specify Usage

(B) Event Description

1. Date of Event/Near Miss Incident (DD/MM/YY)
2. Type of Event:
   - Adverse Event ☐
   - Product Problem (e.g., defects/ malfunctions) ☐
3. For Implantable Medical Devices Only:
   a) If Implanted, Give Date (DD/MM/YY)
   b) If Explanted, Give Date (DD/MM/YY)
4. Location of Event:
   Hospital ☐ Manufacture/Distributor Premises ☐
   Home ☐ Others ☐ Specify
5. Device Operator:-
   Healthcare Professional ☐ Problem Noted Prior to Use ☐
   Patient ☐ Others ☐ Specify
6. Device disposition / Current Location:
   a) Returned to Company ☐ If yes, Date
   b) Remains Implanted in Patient ☐
   c) Within the Healthcare Facility ☐
   d) At Patient Home ☐
   e) Destroyed ☐
   f) Others (Specify)
7. Is Device in Use After Incidence : Yes ☐ No ☐
8. Serious Event : Yes ☐
   If yes, tick the appropriate reason
   a) Death (DD/MM/YY) ☐
   b) Life Threatening ☐
   c) Disability or Permanent Damage ☐
   d) Hospitalization/Prolongation of Existing Hospitalization ☐
   e) Congenital Anomaly ☐
   f) Required Intervention to Prevent / Permanent Impairment / Damage Device ☐
   g) Other (Imp. Medical Event) ☐
9. Non Serious Event ☐
10. Whether Other Medical Devices were Used at Same Time With Above Device if yes, Please Specify Name(s)/Use(s)
11. Event Outcome and Reoccurrence Information
    a) Event Abated after use Stopped/ Reduced?
       Yes ☐ No ☐ Doesn't Apply ☐
    b) Event Reappeared after Reintroduction
       Yes ☐ No ☐ Doesn't Apply ☐

12. Detail Description of Event:-

Note: Do you have any relevant diagnostics test/laboratory data/pictures/videos related to the events Yes ☐ No ☐
If yes then kindly provide them while submitting the filled application form.

For Manufacturer/Authorized Representative Use Only

13. Frequency of Occurrence of Similar Adverse Event in India in Past 3 Years	Year	No. of Similar Adverse Events	Total No. Supplied	Frequency of Occurrence (%)
14. Frequency of Occurrence of Similar Adverse Event Globally in Past 3 Years	Year	No. of Similar Adverse Events	Total No. Supplied	Frequency of Occurrence (%)

(C) Patient Information, History & Outcome

1. Patient Hospital ID :
2. Patient Initial :
3. Age :
4. Gender : Male ☐ Female ☐ Transgender ☐
5. Weight :
6. Other Relevant History, including Pre-existing Medical Conditions, Treatment, Allergy
7. Patient Outcomes:
   a) Death (DD/MM/YY) ☐
   b) Recovered Date (DD/MM/YY) ☐
   c) Not yet Recovered ☐
   d) Stable ☐
   e) Others ☐
   Please Specify

(D) Healthcare Facility Information (if available)

1. Name :
2. Address :
3. Contact Person Name at the Site of Event :
4. Tel. No. /Mobile No. :
5. Email :

(E) Medical Device Adverse Event Assessment

1. Immediate Action Taken:

2. Suspected Root Cause of Problem:

3. In Your Opinion, Which of the Following Best Describe the Association between Suspected Medical Device(s) and Adverse Event?
)

a) Not related ☐ b) Possible ☐ c) Probable ☐ d) Related ☐

(F) For Manufacturer/Authorized Representative / License Holder Only

1. Investigation Needed? Yes ☐ No ☐

2. Investigation Action Taken with Timeline:

3. Root Cause of Problem (Applicable for follow up / final reports):

4. Corrective and Preventive action (CAPA) taken:

Where to report?

Duly filled Medical Device Adverse Event Reporting Form can be send to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-20002, Tel-0120-2783400, 2783401 and 2783392, or email to mvpi-ipc@gov.in, shatrunjay.ipc@gov.in Or Call on Helpline no. 1800 180 3024 to report Adverse event.

Partnering Organizations			