MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

Materiovigilance Programme of India (MvPI)

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

General Information

1. Date of Report :
2. Type of Report : Initial ☐ Follow up ☐ Final ☐ Trend ☐
3. Reporter Reference for MDMC only: • Centre • Location • Month-Year • Case No.

Reporter Details

1. Type of Reporter : (a) Manufacturer ☐ (b) Importer ☐ (c) Distributor ☐ (d) Healthcare Professional ☐
   (e) Patient ☐ (f) Others ☐ specify
2. In case, where the reporter is not 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 :

Device Category

Medical Device	In Vitro Diagnostics (IVD)	Medical Equipments / Machines
I. Therapeutic ☐ Diagnostic ☐ Both ☐ Preventive ☐ Assistive ☐	I. Kits ☐	I. Therapeutic ☐ Diagnostic ☐
II. Implantable device ☐ Non-Implantable device ☐	II. Reagents ☐	II. Therapeutic & Diagnostic ☐
III. Invasive ☐ Non-Invasive ☐	III. Calibrator ☐	III. Preventive ☐
IV. Single use device ☐ Reusable device ☐ Reuse of manufacture marked Single use device ☐	IV. Control Material ☐	IV. Assistive ☐
V. Sterile ☐ Non Sterile ☐	V. Others ☐	V. Imaging ☐
VI. Personal use / Homecare use ☐	VI. IVD electronic reader/ Analyzer ☐	VI. Invasive ☐ Non-Invasive ☐
		VII. Others ☐

Instruction for use Section A-F

- ***If Medical Devices/Equipments/Machines : Please fill all the sections i.e. A, B, C, D, E & F***
- ***If in Vitro Diagnostics (IVD) : Please fill sections i.e. A (except 6, 7, 8, 13, 14 & 16), B (except 1, 2, 6 & 8), D, E, & F***

(A) Device Details

Device Name / Trade Name / Brand Name:

Details	Name	Address
Manufacturer		
Importer		
Distributor		

1. a) Is the device notified/regulated in India : Yes ☐ No ☐

   b) Device Risk Classification as per India MDR 2017 : A ☐ B ☐ C ☐ D ☐
2. License No. (Manufacture/Import) :
3. Catalogue No. :
4. Model No. :
5. Lot / Batch No. :
6. Serial No. :
7. Software Version :
8. Associated Devices / Accessories :
9. Nomenclature Code if applicable; GMDN/UMDNS :
10. UDI No. (If applicable) :
11. Installation Date :
12. Expiration Date :
13. Last preventive maintenance date (dd/mm/yyyy) :
14. Last calibration date (dd/mm/yyyy) :
15. Year of manufacturing :
16. How long was device/Equipment/Machine in use :
17. Availability of device for evaluation : Yes ☐ No ☐

    If no, was the device destroyed ☐ Still in use ☐ return to manufacturer or importer/distributor ☐
18. Is the usage of device as per manufacturer claim /Instruction for use/user manual: Yes ☐ No ☐

    If no specify usage
19. For devices not regulated / notified in India : Regulator / Regulatory status in country of origin

(B) Event Description

1. Date of Event / Near miss incident:
2. Date of Implant/Explant (If applicable):
3. Location of Event:

   Hospital Premise ☐ Manufacture/Distributor premise ☐

   Home ☐ Others ☐
4. Device Operator:-

   Healthcare Professional ☐ Patient ☐ Others ☐

   Problem noted prior to use/near miss event ☐
5. 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) ☐
6. Is device in use after incidence : Yes ☐ No ☐
7. Serious event: ☐

   If serious, Tick the appropriate reason

   a) Death (DD/MM/YY) ☐ ...../...../.....

   b) Life Threatening ☐

   c) Disability or permanent damage ☐

   d) Hospitalization ☐

   e) Congenital anomaly /birth defect ☐

   f) Any other serious (Imp. medical event) ☐

   g) Required intervention to prevent / permanent Impairment / damage device ☐
8. Non serious event ☐
9. Whether other medical devices were used at same time with above device if yes, please specify name(s)/use(s)

10. Detail description of Event:-

For manufacturer/authorized representative use only

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	Year	No. of Similar Adverse Events	Total No. Supplied	Frequency of Occurrence (%)
11. Frequency of occurrence of similar Adverse Event in India in past 3 years				
12. Frequency of occurrence of similar Adverse Event in 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 ☐ Others ☐
5. Weight :
6. Other relevant history, including pre-existing medical conditions

7. Patient Outcomes:

   a) Recovered Date (DD/MM/YY) ☐ ...../...../.....

   b) Not yet recovered ☐

   c) Death (DD/MM/YY) ☐ ...../...../.....

   d) 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. :

(E) Causality Assessment

1. Investigation action taken:

2. Root cause of problem (Applicable for follow up / final reports):

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Continue on Page 5

(F) Manufacturer/Authorized Representative Investigation & Action taken

1. Manufacturer/Authorized Representative device risk analysis report:

2. Corrective / preventive action taken:

Continue on Page 5

3. Device history review:

Continue on Page 5

Continue on Page 5

(B) Event Description (Continued)

10. Detail description of Event:-

(E) Causality Assessment (Continued)

1. Investigation action taken:

2. Root cause of problem (Applicable for follow up / final reports):

(F) Manufacturer/Authorized Representative Investigation & Action taken (Continued)

1. Manufacturer/Authorized Representative device risk analysis report:

2. Corrective / preventive action taken:

3. Device history review:

Where to report?

Duly filled Medical Device Adverse Event Reporting Form can be sent to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-20002, Tel-0120-2783400, 2783401 and 2783392, FAX:0120-2783311 or email to shatrunjay.ipc@gov.in Or Call on Helpline no. 1800 180 3024 to report Adverse event.

Partnering Organizations

Disclaimer

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event.