Paviour Obsessed with Quality	PAVIOUR PHARMACEUTICALS PVT. LTD. DELHI PHARMACOVIGILANCE DEPARTMENT

MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

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 : Pharmacist ☐ Nurse ☐
   Consumer ☐ Healthcare Professional ☐
   Others ☐ Specify

2. 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 ☐

Where to report?

Duly filled Medical Device Adverse Event Reporting Form can be send to Paviour Pharmaceuticals pvt.ltd, Regd. Office : 311-312, Suneja Tower-1, District Centre, Janakpuri, New Delhi-110058, Tel +011-41587181, 46539679 or email to drugsafety@paviour.org