INDIAN MEDICAL ASSOCIATION PHARMACO VIGILANCE CELL

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ADVERSE DRUG EVENT REPORTING FORM
For VOLUNTARY reporting of Adverse Drugs Events by IMA Members

A. Patient information

1. Patient identifier (initials) _____ _____ _____
   First Last Age or Date of Birth
2. Sex F O M O Weight _____ kgs

B. Suspected Adverse Event

3. Outcome attributed to adverse event (Check all that apply): O Death _____ (dd/mm/yy)
   O Life-threatening O Hospitalization – initial or prolonged O Disability
   O Congenital anomaly O Required intervention to prevent permanent impairment/damage
   O Other_____
4. Dates of event starting _____ (dd/mm/yy) Dates of event stopping _____ (dd/mm/yy)
5. Describe event or problem : _____
   _____
   _____
6. Relevant tests/laboratory data, including dates : _____
   _____
7. Other relevant history, including pre-existing medical conditions (eg. Allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) : _____
   _____

C. Suspected medication(s)

8. 1. Brand and/generic name _____ Labelled strength_____
   Manufacturer _____ Dose _____ Frequency _____ Route used _____
   Lot # (if known) _____ Exp. Date (if known) _____ Therapy dates : From _____ To _____
   Diagnosis for use (separate indications with commas) _____
   Event abated after use stopped or dose reduced: Yes O No O Not applicable O
   Event reappeared after reintroduction: Yes O No O Not applicable O

   2. Brand and/generic name _____ Labelled strength_____
   Manufacturer _____ Dose _____ Frequency _____ Route used _____
   Lot # (if known) _____ Exp. Date (if known) _____ Therapy dates : From _____ To _____
   Diagnosis for use (separate indications with commas) _____
   Event abated after use stopped or dose reduced: Yes O No O Not applicable O
   Event reappeared after reintroduction: Yes O No O Not applicable O
9. Concomitant medical products and therapy dates including self medication & herbal remedies (exclude those used to treat event) _____
   _____

D. Clinical (if not the reporter)

10. Name and Professional Address _____
    _____ Pincode _____
    Tel. No. with STD Code: _____ Specialty _____

E. Reporter (See confidentiality section below)

11. Name and Professional Address _____
    _____ Pincode _____
    Tel. No. with STD Code: _____
12. Date of this report _____ Health Professional? Yes O No O Occupation _____
    (dd/mm/yy)
13. Also reported to : O No one else O Manufacturer O User facility O Distributor
14. If you do not want your identity disclosed to the manufacturer tick this box O

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme is not expected to & 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 event

This form completed in all respects may kindly be sent to the IMA Pharmaco vigilance cell as per communication details as above. For any further query or clarifications, please feel free to contact : **Dr. S.C.L.Gupta, Director, IMA Pharmaco Vigilance Cell; Mob.No.+91-9810003807**

For IMA office use only :
Date of receipt of Form _____ Report No. _____ Sign. _____