

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India) Ministry of Health & Family Welfare, Government of India Directorate, New Delhi, India www.mhfr.gov.in							FOR AMC/NCC USE ONLY			
A. PATIENT INFORMATION							AMC Report No. _____			
1. Patient Initials _____		2. Age at time of Event or Date of Birth _____		3. M ☐ F ☐ Other ☐			Worldwide Unique No. _____			
				4. Weight _____ Kgs			12. Relevant tests/ laboratory data with dates _____			
B. SUSPECTED ADVERSE REACTION							13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.) _____			
5. Date of reaction started (dd/mm/yyyy) _____							14. Seriousness of the reaction (Yes ☐ No ☐ ☐ Death (dd/mm/yyyy) ☐ Congenital anomaly ☐ Life threatening ☐ Required intervention to prevent permanent impairment/damage ☐ Hospitalization/Prolonged ☐ Disability ☐ Other (specify) _____			
6. Date of recovery (dd/mm/yyyy) _____										
7. Describe reaction or problem _____										
C. SUSPECTED MEDICATION(S)							15. Outcomes ☐ Recovered ☐ Recovering ☐ Not recovered ☐ Fatal ☐ Recovered with sequelae ☐ Unknown			
S.No	B. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication
								Date started	Date stopped	
i										
ii										
iii										
iv										
5. No. as per C	9. Action Taken						10. Reaction reappeared after reintroduction			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										
11. Concomitant medical product including self medication and herbal remedies with therapy dates (Exclude those used to treat reaction)							D. REPORTER DETAILS			
17. Causality Assessment: Additional information: _____							16. Name and Professional Address: _____ Pin: _____ E-mail: _____ Tel. No. (with STD code): _____ Occupation: _____ Signature: _____			
							18. Date of this report (dd/mm/yyyy): _____			
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 of the product caused or contributed to the reaction.										

How To Report Adverse Drug Reaction

**Mansour Adam Mahmoud, Brian
Godman, Ahmed Awaisu, Ahmed
Ibrahim Fathelrahman, Hisham
Aljadhey, Joseph O. Fadare, Johanna
Catharina Meyer, Fahad Saleem**

How To Report Adverse Drug Reaction:

Guideline for Postmarketing Reporting of Adverse Drug Reactions, [docket No. 85D-0249], 1985 **Report of Joint Commission of Prescription Drug Use** Joint Commission on Prescription Drug Use, 1980 Guidelines for Reporting of Adverse Drug Reactions, 1988 Reporting Adverse Drug Reactions Council for International Organizations of Medical Sciences, 1999-01-01 *Medication Safety and Interventions to Reduce Patient Harm in Low- and Middle-Income Countries* Mansour Adam Mahmoud, Brian Godman, Ahmed Awaisu, Ahmed Ibrahim Fathelrahman, Hisham Aljadhey, Joseph O. Fadare, Johanna Catharina Meyer, Fahad Saleem, 2023-02-07 **Contrast Media** Henrik S. Thomsen, Judith A. W. Webb, 2014-01-10 This is the third edition of a very successful book that originally emerged from the work of a committee set up by the European Society of Urogenital Radiology in 1994 to consider the safety of contrast media used for diagnostic imaging The new edition not only fully updates the previous edition but also includes new chapters on complex topics such as pediatric issues and practical aspects of off label contrast media use Comprehensive consideration is given to the many different safety issues relating to iodine based contrast media gadolinium based contrast media microbubbles for ultrasound and barium sulfate The text includes chapters on both acute and delayed non renal adverse reactions and on renal adverse reactions All of the questions frequently raised in radiological practice are addressed This book presented in a handy easy to use format provides an invaluable unique and unparalleled source of information **Interagency Coordination in Drug Research and Regulations** United States. Congress. Senate. Government Operations, 1962 **Best Practices for Hospital and Health-System Pharmacy 2013-2014** American Society of Health-System Pharmacists, 2013-10-01 ASHP position statements and more than 70 guidance documents of varying scope provide ongoing advice to managers and practitioners to help improve the medication use process patient care and safety and patient outcomes and quality of life New or revised material in this edition includes Clinical Practice Guidelines for Antimicrobial Prophylaxis in Surgery Clinical Practice Guidelines for the Management of Pain Agitation and Delirium in Adult Patients in the Intensive Care Unit ASHP Therapeutic Position Statement on the Role of Pharmacotherapy in Preventing Venous Thromboembolism in Hospitalized ASHP Guidelines on Compounding Sterile Preparations ASHP Guidelines on Home Infusion Pharmacy Services ASHP Statement on the Pharmacy Technician s Role in Pharmacy Informatics ASHP Statement on the Pharmacist s Role in Substance Abuse Prevention Education and Assistance Drug Safety Evaluation Shayne Cox Gad, 2016-12-01 This practical guide presents a road map for safety assessment as an integral part of the development of new drugs and therapeutics Helps readers solve scientific technical and regulatory issues in preclinical safety assessment and early clinical drug development Explains scientific and philosophical bases for evaluation of specific concerns including local tissue tolerance target organ toxicity and carcinogenicity developmental toxicity immunogenicity and immunotoxicity Covers the development of new small and large molecules generics 505 b 2 route NDAs and biosimilars Revises material to reflect new drug products small

synthetic large proteins and cells and tissues harmonized global and national regulations and new technologies for safety evaluation Adds almost 20% new and thoroughly updates existing content from the last edition *Interagency Coordination in Drug Research and Regulation* United States. Congress. Senate. Committee on Government Operations, 1963

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