AE FORM

Version Number: V2.0
Effective Date: 10-Nov-2016
This version replaces: V1.0
Parent Document:
Form Title: **Healthcare Providers Adverse Event Reporting Form**

Please submit the ADR by email to pharmacovigilance@jamjoompharma.com

Suspect Drug Details	
Suspected Drug: Indications:	Start date (DD/MMM/YY): / /
Total daily dose/route: Batch number:	Stop date (DD/MMM/YY): / /
Second Suspect Drug Details (if relevant)	
Suspected Drug: Indication:	Start date (DD/MMM/YY): / /
Total daily dose/route: Batch number:	Stop date (DD/MMM/YY): / /

Reporter

Name: Profession:

Institution:

Address:

Tel: Fax: Email:

Additional information

Patient Please fill the below mentioned patient information.

Patient Initials: Gender: ☐ F ☐ M Date of Birth (DD/MMM/YY): / / Age (Y/M/D):

Height cm Weight: kg Pregnancy: ☐ no ☐ yes If yes, pregnancy week:

Description of adverse drug reaction(s) Continue on separate sheet if more than 2 reactions	
1.	Date of onset (DD/MMM/YY) / /
	Time to onset (D/H/MIN) / /
	Resolution date (DD/MMM/YY) / /
	Causality: Related ☐ Unrelated ☐ Unknown ☐
	Did the reaction reappear after reintroduction of drug?
	Yes ☐ No ☐ Unknown ☐ Not applicable ☐

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2.	Date of onset (DD/MMM/YY) ____/____/____ Time to onset (D/H/MIN) _____/_____/_____ Resolution date (DD/MMM/YY) _____/_____/_____ Causality Related ☐ Unrelated ☐ Unknown ☐ Did the reaction reappear after reintroduction of drug? Yes ☐ No ☐ Unknown ☐ Not applicable ☐

Action Taken with suspect drug

☐ Product discontinued due to AE ☐ Dose Increased ☐ None
☐ Dose Decreased ☐ Other (please specify):

Patient's Outcome

☐ Recovered without sequelae* Date (DD/MM/YY) ____/____/____
☐ Recovered with sequelae Date (DD/MM/YY) ____/____/____ Specify sequelae* ____
☐ Ongoing
☐ Improved, but not yet recovered
☐ Death Date of death (DD/MM/YY) ____/____/____ Autopsy: ☐ yes ☐ no
☐ Unknown *Sequelae: a morbid condition following or occurring as a consequence of another condition or event.

Seriousness: Was the event serious or non serious? (please indicate below)

Serious ☐

☐ Patient died
☐ Persistent or significant disability/incapacity
☐ Congenital anomaly/birth defect
☐ Other reasons (please specify):
☐ Initial or prolonged hospitalisation
☐ Life threatening
☐ Other medically important condition

Non Serious ☐

Relevant Medical History (continue on separate sheet if required)

Concomitant disease(s), pregnancy, relevant laboratory results	Known since (i.e. onset date)
1.	
2.	
3.	

Relevant Concomitant drug(s)/Indication (continue on separate sheet if required)	**Total daily dose/route**	**Start date/Therapy duration**
1.		
2.		
3.		

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Additional Comments