GLOBAL FORM

Adverse Drug reaction (ADR) Reporting form for health care professionals (Providers) (HCP)

Suspect Drug Details		
Suspected Drug:	Indication:	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: _____

Patient *At least one of the below patient information is needed e.g. gender or age or age group, etc.*

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

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

Serious ☐

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

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

Signature/stamp of reporter:_______________________________________ Date (DD/MMM/YY): / /

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This form can be used by :

- Physician
- Pharmacist
- Dentist
- Nurses
- Other healthcare providers

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How to report:

- Fill out the reporting form.
- Attach additional information, if needed.
- Use a separate form for each product.

Please submit completed forms to:

Pharmacovigilance Department
Dr.Nabil Khuris-DSO
Mr. Mouath Ali Alsaeedi D-DSO
Email : QPPV@jalpharma.com
Fax : +9671683048
P.V Mobile phones:
+9671683047 (24hrs/ 7 days a week)
+967777710967 (24hrs/ 7 days a week)
+697777353722 Dr. Nabil Khuris DSO (24hrs/ 7 days a week)
+967737377642 Mouath Al-saeedi D-DSO (24hrs/ 7 days a week)

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