ALHAKEEM Company for Pharmaceutical and Medical Supply			
HCPS ADR-Reporting Form			
Form No.	AHKM-L4-22-01	**Issued date**	01/12/2024
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For VOLUNTARY reporting of ADRs by Healthcare Professionals

For VOLUNTARY reporting of Adverse Drug Reactions by health care professionals

Report #

To be filled in by MOH PV Department

B. Patient information*

1. Patient identifier initials

In confidence

2. Age at time of event: or Date of Birth: _____

3. Sex: ☐ M ☐ F

4. Weight_____Kgs

C. Suspected Adverse Reaction*

5. Date of reaction started (dd/mm/yy):

6. Date of recovery (dd/mm/yy):

7. Describe reaction or problem

12. Relevant tests/ laboratory data, including dates

13. Other relevant history, including pre-existing medical conditions (e.g., allergies, race, pregnancy, smoking alcohol use, hepatic/ renal dysfunction, etc.)

14. Seriousness of the reaction

☐ Death (dd/mm/yy)_____ ☐ Congenital anomaly
☐ Life threatening ☐ Required intervention to prevent permanent impairment/ damage
☐ Hospitalization-initial or prolonged
☐ Disability ☐ Other (specify)_____

15. Outcomes

☐ Fatal ☐ Recovering ☐ Unknown
☐ Continuing ☐ Recovered ☐ Other (specify)_____

D. Suspected medication(s)*

Sl No.	8. Name (brand and / or generic name)	Manufac-turer (If known)	Batch No. / Lot No. (If known)	Exp. Date (If known)	Dose Used	Route used	Frequency	Therapy dates (if unknown, give duration)		Reason for Use or prescribed for
								Date started	Date stopped	
i										
ii										
iii										
iv										

Sl. No. As per C	9. Reaction abated after drug stopped or dose reduced					10. Reaction reappeared after reintroduction				
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Unknown	NA	If reintroduced, dose
i										
ii										
iii										
iv										

11. Concomitant medical products and therapy dates including self medication and herbal remedies (exclude those used to treat reaction)

E. Reporter *

16. Name and Professional Address: _____

_____

_____

Pin code:_____ E-mail:_____

Cell No. / Tel. No. : _____

Speciality:_____ Signature:

17. Occupation	18. Date of this report (dd/mm/yy)

ADVICE ABOUT REPORTING

- **Report adverse experiences with medications**

- **Report serious adverse reactions. A reaction is serious when the patient outcome is:**
  - death
  - life-threatening (real risk of dying)
  - hospitalization (initial or prolonged)
  - disability (significant, persistent or permanent)
  - congenital anomaly
  - required intervention to prevent permanent impairment or damage

- **Report even if:**
  - You're not certain the product caused adverse reaction
  - You don't have all the details although point no. 1, 7, 8 & 16 are essentially required.

- **Who can report:**
  - Any health care professional (Doctors including Dentists, Nurses and Pharmacists).

- **Where to report:**
  - Duly filled in Suspected Adverse Drug Reaction Reporting Form can be sent directly to Pharmacovigilance office of Alhakeem Pharmaceuticals (PVAP).
  - Call on 00218920920053 to report ADRs or directly mail this filled form to pvap@alhakeem.ly

- **What happens to the submitted information:**
  - Information provided in this form is handled in strict confidence. The forms will be sent to mother company to carry out causality assessment of the reported cases. If approved, the case reports are sent back to PV office of Alhakeem. The received case reports are then forwarded to the pharmacovigilance department of the Libyan MOH to Finally submit the data to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
  - The reports are periodically reviewed by the PVAP. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.

Please return this form to:

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.
Submission ion of an ADR report does not have any legal implication on the reporter. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.