General Instructions for the Healthcare professionals

Notes

Dates
If exact dates are unknown, give the closest date as you can.

Report even if:
You're unsure whether the product caused the adverse reaction, you need report it.
If you do not have some of the information at the point of reporting,
Use **Uk (Unknown)** for no information currently. However, we will appreciate if you can provide us with the complete information later.

What to report
We encourage all types of suspected ADRs reporting whether they are known, unknown, serious, or nonserious, frequent, or rare regardless of an established causal relationship between a drug and the reaction. ADRs related with the use of allopathic medicines, vaccines, traditional medicines, medical devices, contrast media, etc., can be reported.

Time to onset of reaction:
Time interval between first dose (initiation) of the drug until first sign of the ADR.
Initial report:
First submission of a report to KMCA of a particular patient involving a particular ADR.
Follow-up report: Submission of further reports linked to the same case to additional information not stated earlier or which occurred after the initial report has been submitted. Please include the number of initial reports for reference.

Patient Demographic

The patient's identity is held in strict confidence and will be quoted in correspondence with the reporter.
The information can be used to identify duplicate reporting.
Age at time of event - Provide the best estimate of the patient's age. Please enter only numeric.

Details of Adverse Reaction

Description of ADR - Describe the nature of adverse drug reaction, its localization, severity, and characteristics.
If the ADR reappeared after reintroducing drug (rechallenge), please describe the rechallenge fully (dose given, timing, brand used, etc.) under section 'Adverse Reaction Description'.

Drug Details

Name (brand &/or ingredient name), dose, frequency, route, start date, end date & indication (batch numbers are important)

Reporter Information

Any information provided in this form will be handled confidentially. The identities of the health care professional, patient or any other person reporting will be held in strict confidence and fully protected. All reports will be assessed, and causality analysis decided by KMCA in due course.
It is the ultimate responsibility of KMCA to decide how to act on the information. It is also the responsibility of the KMCA to decide whether the incidences of reports will require further evaluation of drug performance. The KMCA will further provide the relevant pharmaceutical company with a summary of its findings and subsequent decision regarding intervention.

For more information, contact us at **+964-7516308879** or send an email to (adr@kmcakrg.org)

Thank you for taking time to provide this information.