What should be reported?

All adverse reactions that might be related to the use of medicines, vaccines, herbal products or cosmetics.
Report adverse drug reactions (ADRs) on any of the following:

- All suspected reactions for new drugs including minor ones.
- All serious and/ or unexpected reactions for well- known drugs.
- Any increased in frequency of a given reaction.
- All suspected ADRs associated with drug-drug, drug- food, drug- herb or food supplement interactions.
- All reactions in special populations such as pregnant and breastfeeding women, children and elderly.
- When suspected ADRs are associated with drug withdrawals.
- Any other situation where you believe it needs to be reported.

Who can report?

All health care professionals including physicians, dentists, pharmacists, nurses patients, as well as others should report ADRs to the National Pharmacovigilance and Drug Safety Center.

How to report ADRs?

Fill ADRs reporting form and send it to the Saudi Food and Drug Authority through the followings:
Online: www.sfda.gov.sa/npc
E-mail:npc.drug@sfda.gov.sa
Call NPC at + 966 11 2038222
Ext-2317-2356- 2354 or 5785
Toll Free Number: 8002490000
Fax: +966 11 2057662

Mail:

National Pharmacovigilance and Drug Safety Center
Vigilance and Crisis Management Excutive Directorate
Saudi Food and Drug Authority -Drug Sector
3292 Northern Ring Road AlNafal District
Riyadh 13312 - 6288
Kingdom of Saudi Arabia

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

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Guide for **Adverse Drug** Reactions Reporting

تيقظ
Saudi Vigilance
المركز الوطني للتيقظ والسلامة الدوائية
National Pharmacovigilance and Drug Safety Center

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Introduction:

Medicines play an important role in improving the health and promoting the well-being of every individual. ADRs are serious problems and classified as one of major causes of death in many countries. In addition, hospitalization due to ADRs in some countries is about 10%. Treating ADRs imposes a high financial burden on health care systems. Fortunately, most of ADRs are preventable by effective pharmacovigilance system.

What is Pharmacovigilance?

Pharmacovigilance is defined as "The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems".

What is an adverse drug reaction (ADR)?

ADR is defined as "a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man".

What is a side effect?

Side effect defined as "any unintended effect of a pharmaceutical product occurring at doses normally used by a patient which is related to the pharmacological properties of the drug".

What are the advantages of ADRs reporting system?

- Reduces drug-related problems leading to better treatment outcome.
- Improves the quality of care offered to patients.
- Improves patient confidence in professional practice.
- Is a cost effective method of monitoring the safety of medicinal products through out its lifetime.
- Remains the primary method of data collection used in most countries.
- Is an easy and fast way to submit an urgent health related issues.
- Provides feedback information on drug related problems reported nationally and internationally.

What are the consequences of ADRs under-reporting?

Under-reporting may delay the recognition of new ADRs leading to the perception that injuries from ADRs are less common than they really are.

Will reporting have any negative consequences on you as a healthcare professional and your patient?

Sometimes you as a healthcare professional fear that reporting ADRs may reflect negatively on your competence or put you at risk of litigation. Therefore you and your patient's identity are held in strict confidence by SFDA and protected to the fullest extent of law, and will not be used in any way against you. The information obtained from your report shall be used to promote safe use of medicines in Saudi Arabia.