PHARMACOVIGILANCE GUIDELINES

What is Pharmacovigilance?
Pharmacovigilance is defined as the science and activities concerned with the detection, assessment, understanding and prevention of adverse reactions to medicines (i.e. adverse drug reactions or ADRs). The ultimate goal of this activity is to improve the safe and rational use of medicines, thereby improving patient care and public health.

What is an Adverse Drug Reaction (ADR)?
The {Drug Regulatory Authority} defines an Adverse Drug Reactions (ADR) or adverse reaction as a response to a medicine used in humans or animals, which is noxious and unintended, including lack of efficacy, and which occurs at any dosage and can also result from overdose, misuse or abuse of a medicine.

Why is Pharmacovigilance important?
When a medicine is released onto the market there is still a great deal that is unknown about the safety of the product. Once marketed the medicines are used by patients who have many different diseases, who are using several other drugs and who have different traditions and diets which may affect the way in which they react to a medicine. Different brands of medicines may differ in the manner in which they are produced and the ingredients that are used. The adverse drug reactions and poisonings associated with traditional and herbal remedies also need to be monitored in each country. The information we receive on the adverse effects of drugs in other countries may not be relevant or applicable to {Country}’s citizens. In some cases, adverse effects to certain drugs may only occur in {Country}’s citizens.

In order to prevent unnecessary suffering by patients and to decrease the financial loss sustained by the patient due to the inappropriate or unsafe use of medicines, it is essential that a monitoring system for the safety of medicines in {Country} is supported by doctors, pharmacists, nurses and other health professionals in the country.

The {Drug Regulatory Authority} and the Department of Health’s Essential Drug Programme are committed to improving drug safety through adverse drug reaction monitoring in {Country}. Through the {Drug Regulatory Authority}’s national pharmacovigilance programme, adverse reactions should be reported on a daily basis.

What is the Size or Severity of the ADR Problem in {Country}?
While no studies have comprehensively assessed the burden of adverse drug reactions on health care, it is likely that the problem is considerable in {Country}. Studies conducted in developed countries have consistently shown that approximately 5% of hospitalised patients are admitted into hospital as a result of an ADR and 6-10% of in-patients will experience a serious ADR during hospitalisation. Even these startling figures don’t represent the whole picture. These studies generally excluded ADRs caused by overdose, drug abuse, or therapeutic failures. The cost to most countries for managing adverse drug reactions is considerable.

Who should report Adverse Drug Reactions?
All health care workers, including doctors, dentists, pharmacists, nurses and other health professionals are requested to report all suspected adverse reactions to drugs
(including vaccines, X-ray contrast media, traditional and herbal remedies), especially when the reaction is unusual, potentially serious or clinically significant. It is vital to report an adverse drug reaction to the Drug Regulatory Authority’s Pharmacovigilance programme even if you do not have all the facts or are uncertain that the medicine is definitely responsible for causing the reaction.

**What will happen to my Adverse Drug Reaction or Product Quality Report?**

*(Insert your draft flow diagram here and explain it briefly)*

The information obtained from your reported reactions promotes the safe use of medicines on a local and national level. Your reported case will be entered into the national adverse drug reaction database and analysed by expert reviewers. A well-completed adverse drug reaction/product quality form submitted by you could result in any of the following:

- additional investigations into the use of the medication in the country
- educational initiatives to improve the safe use of the medication.
- appropriate package insert changes to include the potential for the reaction reported by you
- changes in the scheduling or manufacture of the medicine to make the medicine safer

Therefore, the purpose of ADR reporting is to reduce the risks associated with drug prescribing and administration and to ultimately improve patient care and safety.

**What are the benefits of these reports for me and for my patients?**

*{Insert your response here}*  

**Will reporting have any negative consequences on the health worker or the patient?**  
This adverse drug reaction report does not constitute an admission that you or any other health professional contributed to the event in any way. The outcome of the report, together with any important or relevant information relating to the reaction you have reported, will be sent back to you as appropriate. The details of your report will be stored in a confidential database. The names of the reporter or any other health professionals named on a report and the patient will be removed before any details about a specific adverse drug reaction are used or communicated to others. The information obtained from your report will not be used for commercial purposes. The information is only meant to improve our understanding of the medicines we use in the country.

**How do I know if a patient’s condition is an ADR?**

1. **Take a Proper History and do a proper examination**
   - A full drug and medical history should be done
   - Can this adverse be explained by other causes e.g. patient’s underlying disease, other drug/s, over-the-counter medicines or traditional medicines; toxins or foods
• It is essential that the patient is thoroughly investigated to decide what the actual cause of any new medical problem is. A drug-related cause should be considered, especially when other causes do not explain the patient's condition.

2. Establish time relationships

• some reactions occur immediately after being given a medicine while other reactions take time to develop)
• The time from the start of therapy to the time of onset of the suspected reaction must be logical.

3. Do a thorough physical examination with appropriate laboratory investigations

• Few drug produce distinctive physical signs
• Exceptions include fixed drug eruptions, steroid-induced dermal atrophy, acute extrapyramidal reactions
• Lab tests are especially important if the drug is considered essential in improving patient care or of the lab test results will improve management of the patient
• try to describe the reaction as clearly as possible and where possible provide an accurate diagnosis

4. Effect of Dechallenge and Rechallenge should be determined. (when necessary)
Dechallenge = withdraw of drug
- resolution of suspected ADR when the drug is withdrawn is a strong, although not conclusive indication of drug-induced disease.
- In cases where a withdrawal reaction is experienced, a dechallenge is when the drug is again given to the patient.
- “Positive” dechallenge = improvement of reaction when dechallenge occurs

Rechallenge = reintroducing the drug after a dechallenge.
- this is only justifiable when the benefit of re-introducing the drug to the patient outweighs the risk of recurrence of the reaction. This is rare. In some cases the reaction may be more severe on repeat exposure.

5. Check the known pharmacology of the Medicine.
- Is the reaction known to occur with the particular drug as stated in the package insert or other reference?
- If the reaction is not documented in the package insert, it does not mean that the reaction cannot occur with that particular medicine.

Causality Classification
In order to assess the likelihood that the suspected adverse reaction is actually due to the medicine, the WHO has provided a list of causality assessment criteria for deciding on the contribution of the medicine towards the adverse event. These criteria are defined as follows:

WHO Definitions for Causality Assessment

Certain:
- Clinical event, lab test abnormality with plausible time relationship to drug intake
- Cannot be explained by concurrent disease or other drugs /chemicals
- Response to dechallenge- plausible
- Event must be definitive pharmacologically / immunologically
- Positive rechallenges (if performed).

Probable/ Likely:
- Clinical event, lab test abnormality with reasonable time relationship to drug intake
- Unlikely to be to concurrent disease, drugs / chemicals
- Clinically reasonable response to withdrawal (dechallenge)
- Rechallenge not required

Possible:
- Clinical event lab test abnormality with reasonable time relationship to drug intake
- Could also be explained by concurrent disease or other drugs or chemicals
- Information on drug withdrawal may be lacking or unclear

Unlikely:
• Clinical event, lab test with improbable time relationship to drug intake
• Other drugs, chemicals or underlying disease provide plausible explanations

Inaccessible / unclassifiable:
• Insufficient / contradictory evidence which cannot be supplemented or verified

Conditional / unclassified
• More data is essential for proper assessment or additional data are under examination

In most cases there is some level of uncertainty as to whether the drug is directly responsible for the reaction. Many of the questions above may remain unanswered or may be contradictory, however this should not dissuade you, from reporting the reaction to the {National Pharmacovigilance Programme}. A well-documented report which includes information about all the above-mentioned questions can provide us with the first signal of a previously unknown problem.

What types of reactions should be reported to the {Drug Regulatory Authority}’s Pharmacovigilance Programme?

Report adverse drug reactions such as:
• all ADRs to newly marketed drugs or new drugs added to the Essential Drugs List
• all serious reactions and interactions
• ADRs which are not clearly stated in the package insert.
• unusual or interesting adverse drug reactions
• all adverse reactions or poisonings to traditional or herbal remedies

What Product Quality Problems should I report?
Report Product Quality Problems such as:
• suspected contamination
• questionable stability
• defective components
• poor packaging or labelling
• therapeutic failures

What should I know about the {Drug Regulatory Authority}’s Pharmacovigilance Programme?

The {Drug Regulatory Authority} has a responsibility to ensure the safety, efficacy and quality of all medicines used by the {Country} public. Therefore it is the responsibility of the MCC to monitor the performance of these medicines once they are marketed. Essential drugs are particularly important as they are used by a large percentage of the population.

The MCC’s national pharmacovigilance programme, which is co-ordinated by the {Drug Regulatory Authority} offices, presently has one national pharmacovigilance centre in {place of institution}. The {Country Pharmacovigilance Programme} housed within {Institution Name} is responsible for monitoring the safety of all registered medicines in {Country}.

These units are responsible for collecting, evaluating and communicating the findings of ADR reports to the {National Pharmacovigilance Committee}. This committee advises the Council on how to prevent or minimise the risk of these adverse
reactions in {Country}. The {Drug Regulatory Authority} may communicate their findings and recommendations to the appropriate organisations or individuals. These include but are not limited to health professionals, pharmaceutical manufacturers, the Essential Drugs Programme or other directorates within the Department of Health, other public health institutions, the media and the public.

**How can I prevent ADRs from occurring in my patients?**

Some ADRs are unavoidable and cannot be prevented. However, most ADRs can be prevented by following the basic principles of rational use of medicines that are described as follows:

Some ADRs are unavoidable and cannot be prevented. However, most ADRs can be prevented by following the basic principles of rational use of medicines as follows:

1. **Use few drugs, whenever possible**
2. **Use drug that you know well**
3. **Do not change therapy from known drugs to unfamiliar one without good reasons.**
4. **Use text books and other reference material providing information on drug reactions and interactions.**
5. **Take extra care when you prescribe drugs known to exhibit a large variety of interactions and adverse reactions (anticoagulants, hypoglycemic, and drug affecting the CNS) with careful monitoring of patients with such reactions.**
6. **Beware of the interaction of drugs with certain food stuffs, alcohol and even with house hold chemicals.**
7. **Review all the drug used by your patients regularly, taking special notice with those bought without prescription .(Over the counter, herbal preparations).**
8. **Be particularly careful when prescribing to children, the elderly, the pregnant and nursing women, the seriously ill and patients with hepatic and renal diseases. Careful ongoing monitoring is also essential in these patients is essential.**
9. **If your patients show signs or symptoms not clearly explained by the course of their illness, think of adverse drug reaction.**
10. **If you suspect an adverse reaction, consider stopping the drug or reduce the dosage as soon possible and please notify the adverse drug reaction to {Pharmacoviglance Programme Co-ordinator} at the {drug regulatory authority}.**

**How do I report an adverse drug reaction to the {Drug Regulatory Authority}’s Pharmacovigilance Programme?**

An Adverse Drug Reaction/Product Quality Form is enclosed in this book. Adverse drug reaction forms for you and your institution can be obtained by contacting the {National Pharmacovigilance Programme} or {Other. Contract Addresses} are as follows:
The adverse drug event/product quality form should be completed in as much detail as possible and returned to the following addresses.

{INSERT ADDRESS}

Requests for ADR forms and ADR information may also be obtained from:

The {Country Pharmacovigilance Programme}

Thank you for supporting the {Drug Regulatory Authority}'s Pharmacovigilance Programme! Information supplied by you will contribute to the improvement of drug safety and therapy in {Country}.

What are my functions within the national pharmacovigilance programme?
{Insert functions of various organisations and individuals drafted over the weekend here.}