GUIDE FOR ADR REPORTERS

DEFINITIONS:

(i) Time to onset of reaction: time interval between first dose (initiation) of the drug until first sign of the ADR.

(ii) Initial report: First submission of report to NPRA of a particular patient involving a particular ADR.

(iii) Follow-up report: Submission of further reports related to the same case to inform of additional information not mentioned previously or which occurred after the initial report. Please mention the date of initial report for reference.

1) IMPROVING THE QUALITY OF REPORTS

(Ref: MADRAC Bulletin August 2013)

The list below contains the frequently asked questions that NPRA poses to reporters during follow-up. You are encouraged to use this checklist to ensure your report is as complete as possible before submitting it.

Important Note:
*Please fill every section in the ADR form, stating **'none/nil'** if applicable. Even a dash would do.*

Is your report complete?

A Checklist for ADR reporters

Frequently missing information	✓
Any history of allergy (including drugs, food, etc.)?	
Any concomitant medications? *(Please state 'nil' if none)* • Date started and stopped for each medication • Please state 'cont' for any medication still continued after the ADR	
Any underlying illnesses?	
The specific indication of the suspected drug (e.g.: '*pneumonia due to S. Pneumoniae'*- not 'infection' or 'antibiotic').	
If the ADR reappeared after reintroducing drug (**rechallenge**), please describe the rechallenge fully (dose given, timing, brand used, etc.).	
Was any treatment given for the ADR, or if suspected drug was stopped, what alternative was given and patient's response? *(Please describe)*	
What is the latest/ current outcome for the patient? *(e.g. recovered)* If possible, follow-up patient periodically until final outcome is known. A follow-up report may be sent in to update the final outcome of the patient.	
Description of the specific type and location of skin reaction? *(Use the Cutaneous ADR form available on http://npra.moh.gov.my)*	
Do keep your own record of details enabling you to contact the patient/ trace the case notes later on if necessary *(e.g. IC number, patient name and phone number).*	

DISCLAIMER: The list above is not exhaustive and additional information requested may vary depending on safety issues that arise.

Additional information necessary for specific ADR cases

(Ref: MADRAC Bulletin December 2013)

ADR cases involving:	Additional information	Rationale
All reports	Indication of suspected drug (as **specific** as possible) e.g.: '*pneumonia due to S. Pneumoniae'*- not 'infection' or 'antibiotic'; *'lower back pain'*- not 'painkiller' or 'NSAID'	To increase quality of reports submitted to WHO and assist causality assignment
Paediatric patients	Body weight	To distinguish ADR from drug toxicity/ inefficacy
Skin reactions	Specific description of reaction (type and location of rash) - *attach the Cutaneous ADR classification form available on http://npra.moh.gov.my*	For more accurate causality assignment
Serious skin reactions (e.g. SJS, TEN, DRESS)	Designation of doctor who provided final diagnosis	Diagnosis should be confirmed by a dermatologist
Brand-switching	Name and MAL number of **both** brands involved	To identify brand/ batch problems
Drug use in pregnancy, post-delivery, breastfeeding or off-label use	Please mention this in the 'Relevant Medical History' section	To increase available data on such cases, where clinical trials are not carried out
Suspected Drugs:		
Allopurinol	1. Specific indication 2. Category of prescriber 3. Renal function of patient 4. If prescribed for asymptomatic hyperuricaemia: - Name, address and tel. no. of primary prescriber	- Allopurinol is not indicated for the treatment of asymptomatic hyperuricaemia. - Approved prescriber category: A/KK
Antibiotics	Please state if patient was given an ADR/ allergy card and counselling	To avoid risk of patient being given the same drug repeatedly
Antidiabetics	Baseline and latest blood glucose readings	To differentiate ADRs from disease exacerbations
Antihypertensive agents	Baseline and latest blood pressure readings	
Corticosteroid	Indication (e.g. asthma, SLE)	
ADR cases involving:	**Additional information**	**Rationale**
Antineoplastic agents	- List concomitant medication - Premedication(s) and administration time	Presence of concomitant medication will affect causality assignment
Noradrenaline	Other concomitant inotropes and medication	
Paracetamol	State the colouring agent and flavouring agent	To identify ADRs due to the excipient rather than active ingredient
Oral Antihistamines		
Statin causing skin reaction	Specify if reaction is related to photosensitivity	To identify specific type of skin reaction
Vancomycin	Rate of infusion and dose	To distinguish ADR from side effect of drug

*SJS: Stevens-Johnson syndrome; TEN: Toxic epidermal necrolysis;
DRESS: Drug reaction with eosinophilia and systemic symptoms

2) LABORATORY TESTING FOR SUSPECTED ADULTERATED PRODUCTS (REGISTERED PRODUCTS ONLY)

The NPRA may conduct laboratory testing to identify adulterants in registered product samples, including traditional products and health supplements.

In order for laboratory testing to be conducted, a **sufficient amount** of sample and certain information are required. The following is a simple guide on sending product samples for laboratory testing when an **adverse drug reaction occurs and adulteration is suspected**.

1. Fill in the adverse drug reaction (ADR) reporting form for healthcare professionals [or Consumer Side Effect Reporting Form (ConSERF) for consumers who wish to report directly to the NPRA]. Please include as many details as possible to ensure the report is useful.

   Important details:
   - Name and contact details of patient
   - Details of the ADR
   - Details of any concomitant medicines/ other products taken and underlying illnesses
   - Product name and label
   - Where it was obtained
   - Indication for which the patient was taking the product
   - Suspected adulterant (e.g. antihistamine, steroid) based on product indication and ADR
   - Name and contact details of reporter

2. Submit the completed form together with the product sample. Preferably samples should be sent in the **original packaging**, or at least with **clear pictures** of the product from all angles. This is because the label information may be required for further investigations (e.g. to identify fake products).

   Please send as much sample quantity as possible. The quantities listed below are for the screening of **one suspected** adulterant only. Therefore, the quantity should be multiplied based on the number of suspected adulterants.

   Minimum quantities required for testing of one suspected adulterant are as follows:

Minimum sample quantity required for laboratory testing for adulterants

Dosage Form	Minimum amount for one test	Total amount for confirmatory result
Tablet/ Capsule/ Pill	10g or 20 dosage forms	30g or 60 dosage forms
Liquid	40ml/ 40g	120ml/ 120g
Powder	10g	30g
Cream	10g	30g
Candy	10 candies	30 candies

3. Please **contact us** if you have any questions:

   The Pharmacovigilance Section,
   Centre for Post-Registration of Products & Cosmetic Control,
   National Pharmaceutical Regulatory Agency (NPRA).

   Tel: 03-7801 8465 / 7801 8466
   Email: fv@npra.gov.my

3) VIGIACCESS™ BY THE WHO

(Ref: MADRAC Bulletin April 2015)

Access information on global ADR reports at
www.vigiaccess.org

- ***Wondering if there have previously been any similar ADR reports for a particular drug?***
- ***Looking for general ADR data for your presentation?***

Check VigiAccess™.

VigiAccess™ is a public gateway that allows anyone to access information on reported cases of adverse events related to over 150,000 medicines and vaccines, as sourced from the WHO international database of ADRs (VigiBase®). VigiBase® currently contains data on over 10 million reports dating back to 1968, from more than 120 countries which participate in the WHO Programme for International Drug Monitoring.

However, it is important to note that information on suspected ADR **should NOT be interpreted** as meaning that the medicinal product in question, or the active substance(s), generally causes the observed effect or is unsafe for use. Any robust conclusion with regard to benefits and risks of a specific medicinal product always **requires detailed evaluation and scientific assessment** of all available data. The balance between benefit and risk of a specific medicinal product also varies between individual patients.

VigiAccess™ presents search results by active ingredient(s), with a breakdown by type of ADR, geographical distribution, age group, patient sex, and the number of reports per year. Great care has been taken to ensure privacy of the patient and reporter is protected.

4) ADR REPORTS INVOLVING ANTITUBERCULOSIS DRUGS

(Ref: MADRAC Bulletin December 2015)

The NPRA has received hundreds of **ADR reports** involving the four anti-TB drugs (isoniazid, rifampicin, pyrazinamide, and ethambutol), of which almost 80% reported the use of combination products containing all four drugs in one tablet. However, **very few reports** detailed the stepwise rechallenge of anti-TB drugs which was performed after the ADR occurred. Information on rechallenge and final outcome of the patient is vital to compare the safety profiles between brands, combination products and single active ingredient products.

Besides making sure that the report is completely filled in, here are several **points to ponder** when reporting adverse events for anti-TB drugs:

Reports involving serious ADRs requiring urgent attention	An initial report may be submitted first, then a follow-up report sent in after a final outcome is known.
	Follow-up report should include details on dechallenge/ rechallenge, final outcome and the final antituberculosis therapy given (Note: Please include date of initial report or attach a copy of initial report for reference purposes).
Reports involving mild to moderate ADRs	If it does not involve a serious ADR, please follow-up the patient until the final outcome is attained before submitting the report.
	Do include details of the final antituberculosis therapy given.
If **stepwise rechallenge** is performed, please report the following:	Time of rechallenge.
	Dose of the drug(s) rechallenged.
	Reactions observed.
	Treatment of adverse reaction and action taken.
	Outcome of the rechallenge
Adverse Reaction Description	Describe the adverse events in sequence with a notable time frame.
	If it involves skin adverse reactions, please use the Cutaneous ADR Classification Form.
	If it involves hepatic enzyme anomalies, please include the liver function test results.
Drug details	Specify the product brand name and registration number (MAL no).
	Include the dosage, frequency and duration.
Other important details	Additional sheets may be attached if necessary to describe further details.
	Reporter details and contact number should be included in case further information is required.

The NPRA thanks you for reporting suspected ADRs. These reports are an essential part of ensuring the safe use of medicines as well as the safety of patients in Malaysia. If you have any questions, please contact us at 03-7883 5447/5450 or send an email to fv@npra.gov.my.