HOSPITAL SEGAMAT
Issue 03/2016

BULLETIN PHARMACY

ADVERSE DRUG REACTION REPORTING - THE HOW & THE WHY

Inside this issue:

Being part of the pharmaceutical field, the thalidomide tragedy in 1961 is no foreign case. Congenitally deformed infants were born as a result of exposure to an unsafe medicine promoted for use by pregnant mothers. This tragedy opened many eyes for the needs of pharmacovigilance to address drug safety issues. Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) was established under Drug Control Authority (DCA) to monitor adverse drug reaction (ADR) for drugs registered for use in Malaysia. ADR reported will be assessed to ensure the quality of the report before it is forwarded to the central WHO Global ICSR (individual case safety report) database.

WHAT DOES IT MEAN BY ADVERSE DRUG REACTION?

'A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function'.

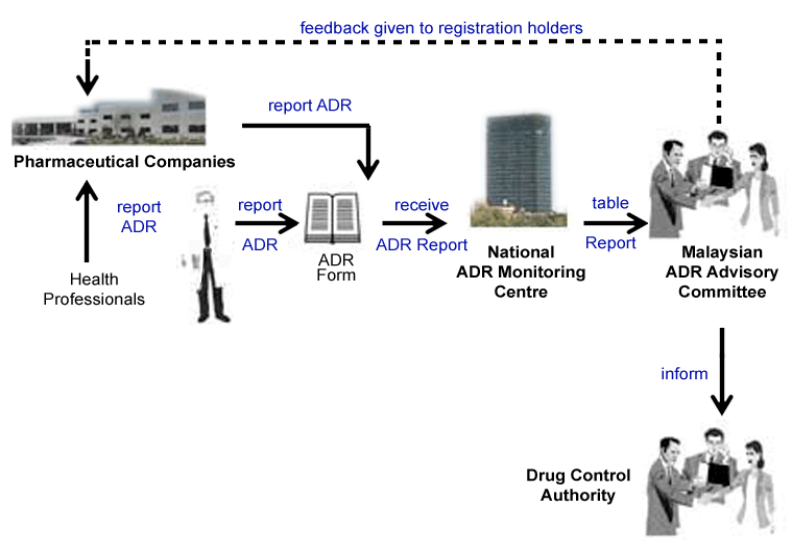
WHO, 1972

Reporting ADR is not as simple as reporting an event. The reporter should know 'The How' of providing quality report to ensure that the report can be assessed objectively to be entered into the ADR database. A comprehensive details should be provided to help the investigation team. In this article, we would lay out ways to fill ADR form for case report purpose.

The How

(Ref: MADRAC Malaysian Guidelines for the Reporting and Monitoring)

- The important information required for the submission of an initial report :
  - a named suspected drug
  - a suspected reaction
  - an identifiable patient
  - an identifiable reporter



Using trade name is encouraged but if it is not known, the generic name and the product registration number (MAL No.) should be given. Use common terminology to describe the adverse reaction.[1]

ADR Form Checklist

(Adapted from NPCB: Guide for ADR Reporters)

FREQUENTLY MISSING INFORMATION	/
Any history of allergy (including drugs, food, etc.)?	
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 npra.gov.mog.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).	

REPORT ON SUSPECTED ADVERSE DRUG REACTIONS

NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING

Email: fv@bpfk.gov.my Website: portal.bpfk.gov.my Tel: 03-7883 5550 Fax: 03-7956 7151

(Please report **all** suspected adverse drug reactions including those for vaccines, cosmetics and traditional products. Do not hesitate to report if some details are not known. **Mandatory fields** are marked with *, but please give as much other information as you can. Identities of Reporter, Patient and Institution will remain **Confidential**.)

REPORT No. *(for official use only)*: .....

PATIENT INFORMATION

I.C. No. / R/N / Initials	*Age	*Gender *(please tick)*	Wt (kg)	*Ethnic Group	*Please tick (if applicable):*
		Male ☐ Female ☐			☐ Initial Report ☐ Follow-up Report

***ADVERSE REACTION DESCRIPTION** (inc. sequence of adverse events, details of rechallenge, interactions)

Time to onset of reaction : ☐ mins/ hours/ days/ months/ years *(please circle)* Date start of reaction : DD / MM / YYYY Date end of reaction : DD / MM / YYYY

Reaction subsided after stopping drug / reducing dose : Yes ☐ No ☐ Unknown ☐ *N/A (drug continued) ☐

Reaction reappeared after reintroducing drug : Yes ☐ No ☐ Unknown ☐ *N/A (not reintroduced) ☐

Extent of reaction : Mild ☐ Moderate ☐ Severe ☐

Seriousness of reaction : Life threatening ☐ Caused or prolonged hospitalisation ☐ Caused disability or incapacity ☐ Caused birth defect ☐ *N/A (not serious) ☐

Treatment of adverse reaction & action taken :

Outcome : Recovered fully ☐ Recovering ☐ Not recovered ☐ Unknown ☐ Fatal ☐ Date & Cause of death:.....

Drug-Reaction Relationship : Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Unclassifiable ☐

***Suspected Drug :** *N/A: Not applicable

Product / Generic Name	Dose & Frequency Given	MAL and Batch No.	Therapy Dates		Indication
			Start	Stop	

Concomitant Drug *(please state 'NIL' if none)* :

Product / Generic Name	Dose & Frequency Given	MAL and Batch No.	Therapy Dates		Indication
			Start	Stop	

(Please attach additional sheets if necessary)

Relevant Investigations / Laboratory Data	Relevant Medical History (e.g.: hepatic / renal dysfunction, allergies, pregnancy status, etc)

Reporter Details

*Name : *Institution Name & Address :

Designation : *Tel No :

*Email Address : Date of Report : Signature : rev11/2015

Submission of a report does not constitute an admission that medical personnel or the products caused or contributed to the reaction. *Thank you for reporting.*

ADR reporting Form

Recently, life-threatening cutaneous drug reaction associated with allopurinol had drawn the attention of its drug safety for appropriate indication. In year 2012, Ministry of health had restrict the prescription of allopurinol which should **NEVER** been prescribe to asymptomatic gout. ADR reporting for allopurinol is mandatory which need a much more detail information to control its use. The details are portrayed below (Figure 1):

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

Figure 1

Before deciding whether reaction is due to a certain drug, the reporter should use the Naranjo Adverse Drug Reaction Probability Scale, or WHO-UMC causality assessment system to assess the causal relationship between an identified untoward clinical event and a drug.

For reports of cases with clinical manifestation of cutaneous adverse drug reaction, another form (Figure 2) should be attached together to further describe the type of skin reaction that happened.

CLINICAL MANIFESTATION OF ADVERSE DRUG REACTION

1. Type of cutaneous adverse drug reaction (please √)
   - You are allowed to choose more than one of the following.

1. Acneiform Eruption		9. Pruritus only	
2. Alopecia		10. Purpura	
3. Erythema multiforme		11. Toxic Epidermal Necrolysis	
4. Erythema nodosum		12. Stevens-Johnson Syndrome	
5. Fixed drug eruption		13. Urticaria / Angioedema	
6. Maculo-papular rash (exanthem)		14. Vasculitis	
7. Photosensitivity		15. Vesiculobullous reaction	
8. Pigmentary changes		16. Others :	

Figure 2

DOES ALL ADR NEED TO BE REPORTED?

The World Health Organization encourages reporting of **ALL** adverse drug reactions. Health professionals are requested to report adverse reactions to all identifiable drugs including traditional medicines

A serious adverse event or reaction is any untoward medical occurrence that at any dose:

- results in death,
- is life-threatening,
- requires inpatient hospitalization of prolongation of existing hospitalization,
- is a congenital anomaly/birth defect.

WHEN EVERYTHING HAS BEEN COMPLETED?

The National Adverse Drug Monitoring Centre
National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia
P.O. Box 319, Jalan Universiti
46730 Petaling Jaya

THE WHY (Ref: MADRAC Malaysian Guidelines for the Reporting and Monitoring)

OBJECTIVES OF ADR MONITORING

- To detect adverse reactions to drugs as early as possible especially serious, unknown and rare reactions
- To establish the frequency and incidence of adverse reactions, both the well-recognized and newly discovered reactions
- To identify risk factors that may predispose/ induce/influence the development, severity and incidence of adverse reactions e.g. genetic/racial factors, drug interactions, underlying conditions, etc.
- To maintain a database for sharing of information with regards to ADRs in this country

IMPACT OF ADR MONITORING

- Product registration holder can initiate steps to make changes to the product dossier/information leaflets/labels to create awareness on these findings
- Regulatory authority can take appropriate action in the interest of public health to minimize risk of ADRs to consumers
- Health professionals prescribe drugs rationally
- Public use products in an appropriate manner
- Make data available to analogous systems in other countries (via the WHO) to promote the growth of knowledge in this field worldwide

ADR REPORTING IS OUR RESPONSIBILITY

According to the latest ADR form which can be downloaded from the National Pharmaceutical Regulatory Agency (NPRA) website, all suspected ADR due to drugs, vaccine, cosmetics and traditional product should be reported.

"A licensed manufacturer, a licensed wholesaler, a licensed importer or the holder of a registration certificate in respect of any product shall inform the Authority of any adverse reactions arising from the use of the registered product immediately after he receives notice of such adverse reactions".

Sales of Drug Act, Control of Drug and Cosmetic Regulation 1984, Section 28

Out-Patient Pharmacy Services

Drive–Thru Pharmacy

Operating hour:
Sunday-Wednesday
(8am-5pm)
Thursday (8am-3.30pm)
Rest : 1-2pm
Service is not available during
Public Holidays and weekend

NEW SERVICES

Drive– Thru Pharmacy service (Farmasi Pandu lalu) established by Department of Pharmacy Hospital Segamat had started to operate in December 2015. This service is to provide fast and time saving medication collection service for patients and to avoid long waiting time and crowded phenomenon around outpatient pharmacy dispensary counter. Besides, finding parking is not an issue anymore after the service was launched especially during the peak clinic visit hour.

We are currently having 437 registered drive-thru patient benefits from this service as compared to 35 patient registered last year before the service started. We are hoping to have more in the near future!

Terms and Conditions:

1. Service only provided for **Continuation** medication collection.
2. Only for chronic disease patient with medication supply more than 1 month.
3. Please **REGISTER** with us at **OUTPATIENT PHARMACY COUNTER** HOSPITAL SEGAMAT! The first month medication supply must be done over the counter.
4. Please show the registered Drive-Thru card upon collection.
5. Collection can be done within 1 week from the "Next collection date" stated.
6. For enquiry please call: 07-9433333 (ext: 120) or Fax: 07-9434130

Out-Patient Pharmacy Services

Ubat Melalui Post (UMP)

UMP is a medication-by-post service promoted by KKM to provide continuation medication supply to the door-step of patient with standard charge. This service will especially ease the patient who have transport issue or staying far from the hospital or "klinik kesihatan". This service is a cooperation between Ministry of Health Malaysia with Malaysia Post Berhad

Criteria for UMP service:

1. Patient with stable chronic disease and understand about the drug treatment.
2. Patient should understand and follow the instruction of drug used.
3. For prescription with supply of more than 1 month.
4. First time collection need to be done over the pharmacy counter.
5. Only medication in tablet or capsule form and those that are not affected by humidity and temperature can be sent by post.
6. Non– psychotropic medications.

* For enquiry please call: 07-9433333 (ext: 120) or Fax: 07-9434130

Charges incurred for post Laju service (included GST 6%)

Post Area		Charge (RM)	
From	To	<500g	500-1000g
Peninsular Malaysia	Peninsular Malaysia	5.30	6.40
Sabah/ Sarawak	Sabah/ Sarawak	5.30	6.40
Peninsular Malaysia	Sabah/ Sarawak	8.50	10.60
Sabah/ Sarawak	Peninsular Malaysia	8.50	10.60

Medication will be Sent to the DOOR STEP.

Cash payment upon receiving or ONLINE bank in is acceptable!

REGISTERED with us at OUTPATIENT PHARMACY COUNTER

Hospital Segamat.

Source: Bahagian Perkhidmatan Farmasi http://www.pharmacy.gov.my/v2/sites/default/files/document-upload/pamphlet-ump1m-baru.pdf

Reaksi
DRUG SAFETY NEWS

Proton Pump Inhibitors (PPIs): Potential Long-term Safety Issues

Overview

Proton pump inhibitors (PPIs) have long been considered a safe and well-tolerated drug class. However, there are emerging concerns on the safety of PPIs, particularly associated with long-term use. **Overutilization** PPIs is known to occur worldwide, in both in-patient and outpatient settings.

PPIs are widely used for the treatment of gastro-oesophageal reflux disease (GERD), *Helicobacter pylori* eradication, stress ulcer prophylaxis, as well as the prophylaxis of gastrointestinal bleeding in patients on non-steroidal anti-inflammatory drugs (NSAIDS) or dual antiplatelet therapy post-percutaneous coronary intervention.

The NPRA is currently reviewing several potential safety issues which have been linked to PPI use, including the risk of subacute cutaneous lupus erythematous (SCLE), hypomagnesaemia, fractures, dementia, and rhabdomyolysis. It should be noted that some of these issues were described in epidemiological studies, and **no causal link** has been established. The results of this review and any risk minimization action required will be communicated once the review is completed.

Local Scenario

There are 72 products containing PPIs registered in Malaysia currently, namely 58 oral products and 14 injectables. The types of PPIs registered are omeprazole (30 products); pantoprazole (22); lansoprazole (11); esomeprazole (4); rabeprazole (3); and dexlansoprazole (2). Data from the National Medicines Utilization Survey and IMS Health Malaysia Sdn. Bhd. revealed that omeprazole was the most commonly used PPI in Malaysia in 2014 (3.449 DDD/1000 population/day), followed by esomeprazole (1.470 DDD/1000 population/day).

Adverse Drug Reaction Reports

The NPRA Malaysian ADR database contains 468 reports (823 adverse events) suspected to be due to PPIs reported between year 2000- June 2015. Majority of the reports involved ADRs occurring within 2 weeks of starting the PPI. Only 7% (33 reports) stated a time to onset of reaction of more than 2 weeks, with ADRs including itching, maculopapular rash, abdominal discomfort, and Stevens-Johnson syndrome/ toxic epidermal necrolysis (SJS/TEN) overlap.

A search of the WHO International ADR database* revealed reported adverse events involving the potential safety issues under NPRA review, such as SCLE, hypomagnesaemia, osteoporosis fracture, *C. difficile* infection, and dementia. Details of these reports will be further considered as part of the review.

Advice for Healthcare Professionals

Please review each individual patient's need for PPI therapy at every follow-up, use 'on-demand' or 'step-down' therapy, and discontinue any unnecessary PPIs.

Monitor patients for possible long-term ADRs, including photosensitive dermatosis with arthralgia, cognitive impairment, falls or fractures.

Please report all suspected ADRs associated with PPI use to the National ADR Monitoring Centre, including ADRs following long-term use.

Editor's Note: *In this issue of Reaksi, we would like to highlight safety signals which are currently under review by the NPRA. These signals involve potential safety issues which are being investigated further, and do not mean that the NPRA has concluded there is a problem with the product/ drug. These articles aim to increase awareness among healthcare professionals and stimulate ADR reporting, particularly of any reactions related to the safety issues below.*

(Source: National Pharmaceutical Regulatory Agency, Drug Safety News March 2016, No. 28)

*****DISCLAIMER:*** *The information in the WHO ADR database comes from a variety of sources, and the likelihood that the suspected adverse reaction is drug-related is not the same in all cases. This information does not represent the opinion of WHO.*

Our New Chief Pharmacist

NAME: Puan Nur Shazrina bt Ahmad
DATE OF BIRTH: 27 Februari 1981
PLACE OF BIRTH: Pulau Pinang
EDUCATION:
Bachelor of Pharmacy (hons) University Malaya

WORKING EXPERIENCES

2005 – National Pharmaceutical Control Bereau (NPCB)
2005 – Pharmacist in Bahagian Perkhidmatan Farmasi Petaling Jaya
2006 – Pharmacist in Hospital Kuala Lumpur
2006 – Pharmacist in KK Gunung Rapat , PKD Kinta , Perak
2008 – Pharmacist in KK Labis, PKD Segamat , Johor
2011 – Pharmacist in Hospital Segamat, Johor
2016 – Chief Pharmacist Hospital Segamat, Johor

ENROLLMENT AND ACHIEVEMENTS IN CAREER:

2007 – Won 1st place in Perak QA competition
2008 – Participate in National QA Seminar in Kuching
2010-2011 – Ambulatory Committee Member, BPFJ
2012 – Received Excellency Award of Hospital Segamat
2013 – Third place in Johor Creative Innovation Competition
2014 – Participate in Johor Innovation Convention (Flora Group)
2014-2016 – ADAF Auditor and Committee Member, BPFJ
2016 – Third place in Johor Innovation Convention
2016 – Advisor of EKSA, Pharmacy Department, Hospital Segamat
2016 – Advisor of Welfare and Social, Pharmacy Department, Hospital Segamat

Our diary!

FAREWELL PUAN SITI

Last April marked the last day of Pn Siti in Hospital Segamat. She had been transfered to PKD Muar. All the best in new place Pn Siti!

EID CELEBRATIONS

Ramadhan celebration at VIP Hotel

Puan Hida's Open House

CONGRATES DEAR COMRADES!!

Our QA team won the 2nd place in QA competition! Good job! We are so proud of you.

Kenali Ubat Anda

May – June

'Puasa dan Ubat' Talk