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)

<table>
<thead>
<tr>
<th>FREQUENTLY MISSING INFORMATION</th>
<th>/</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any history of allergy (including drugs, food, etc.)?</td>
<td></td>
</tr>
<tr>
<td>Any underlying illnesses?</td>
<td></td>
</tr>
<tr>
<td>The <strong>specific indication</strong> of the suspected drug (e.g.: <em>pneumonia due to S. Pneumoniae</em> - not ‘infection’ or ‘antibiotic’)</td>
<td></td>
</tr>
<tr>
<td>If the ADR reappeared after reintroducing drug (<strong>rechallenge</strong>), please describe the rechallenge fully (dose given, timing, brand used, etc.)</td>
<td></td>
</tr>
<tr>
<td>Was any treatment given for the ADR, or if suspected drug was stopped, what alternative was given and patient’s response? (<strong>Please describe</strong>)</td>
<td></td>
</tr>
<tr>
<td>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</td>
<td></td>
</tr>
<tr>
<td>Description of the specific type and location of skin reaction? (Use the Cutaneous ADR form available on npra.gov.mog.my)</td>
<td></td>
</tr>
<tr>
<td>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).</td>
<td></td>
</tr>
</tbody>
</table>

¹ 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.
# ADR Reporting Form

**Report on Suspected Adverse Drug Reactions**

**National Centre for Adverse Drug Reactions Monitoring**

(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.)

### Patient Information

<table>
<thead>
<tr>
<th>I.C. No. / R/N / Initials</th>
<th>*Age</th>
<th>*Gender (please tick)</th>
<th>*Height (cm)</th>
<th>*Weight (kg)</th>
<th>*Ethnic Group</th>
<th>Please tick (if applicable):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Male</td>
<td>Female</td>
<td></td>
<td></td>
<td>Initial Report</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Follow-up Report</td>
</tr>
</tbody>
</table>

### Adverse Reaction Description

- **Time to onset of reaction:**
  - mins/ hours/ days/ months/ years
- **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
- Recovering
- Not recovered
- Unknown
- Fatal

### Date & Cause of death:

### Drug-Reaction Relationship:

- Certain
- Probable
- Possible
- Unlikely
- Unclassifiable

### Suspected Drug

<table>
<thead>
<tr>
<th>Product / Generic Name</th>
<th>Dose &amp; Frequency Given</th>
<th>MAL and Batch No.</th>
<th>Therapy Dates Start</th>
<th>Therapy Dates Stop</th>
<th>Indication</th>
</tr>
</thead>
</table>

### Concomitant Drug (please state ‘NIL’ if none):

<table>
<thead>
<tr>
<th>Product / Generic Name</th>
<th>Dose &amp; Frequency Given</th>
<th>MAL and Batch No.</th>
<th>Therapy Dates Start</th>
<th>Therapy Dates Stop</th>
<th>Indication</th>
</tr>
</thead>
</table>

### 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:**

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.
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):

<table>
<thead>
<tr>
<th>Suspected Drugs:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allopurinol</td>
</tr>
<tr>
<td>1. Specific indication</td>
</tr>
<tr>
<td>2. Category of prescriber</td>
</tr>
<tr>
<td>3. Renal function of patient</td>
</tr>
<tr>
<td>4. If prescribed for asymptomatic hyperuricaemia:</td>
</tr>
<tr>
<td>- Name, address and tel. no. of primary prescriber</td>
</tr>
<tr>
<td>- Allopurinol is not indicated for the treatment of asymptomatic hyperuricaemia.</td>
</tr>
<tr>
<td>- Approved prescriber category: A/KK</td>
</tr>
</tbody>
</table>

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

**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.

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

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

<table>
<thead>
<tr>
<th>Post Area</th>
<th>Charge (RM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>From To</td>
<td>&lt;500g</td>
</tr>
<tr>
<td>Peninsular Malaysia Peninsular Malaysia</td>
<td>5.30</td>
</tr>
<tr>
<td>Sabah/Sarawak</td>
<td>5.30</td>
</tr>
<tr>
<td>Peninsular Malaysia Sabah/Sarawak</td>
<td>8.50</td>
</tr>
<tr>
<td>Sabah/Sarawak</td>
<td>8.50</td>
</tr>
</tbody>
</table>

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.

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 erythematosus (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.


*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 Bureau (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
FAREWELL PUAN SITI

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

Our diary!

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

‘Puasa dan Ubat’
Talk

May – June