MADRAC
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Malaysian Adverse Drug Reactions Newsletter
National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia

Contents

WELCOMING THE NEW MADRAC MEMBERS

The new Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) for 2016-2018 gathered for its first meeting on 1 March 2016. A perfect blend of experienced members and fresh new faces, MADRAC strives to ensure the safety of medicines in Malaysia while improving pharmacovigilance in-line with the times. We hope that with this new committee come new ideas and perspectives, as MADRAC continues to work on "Keeping Medicines Safe for the Nation".

MADRAC Members (2016-2018)

Organisation / Area of Specialty		MADRAC Member	Alternate Member
Ministry of Health (MOH):	Internal Medicine	Dr. G.R. Letchuman Ramanathan	Dr. Noel Thomas Ross
	Rheumatology	Dato' Dr. Gun Suk Chyn	Dr. Azmillah Rosman
	Paediatrics	Dr. Norzila Mohamed Zainudin	Dr. Tan Kah Kee
	Psychiatry	Dr. Ramli Ali	Dr. Uma Visvalingam
	Nephrology	Dr. Sunita Bavanandan	Dr. Suryati Yakob
	Dermatology	Dr. Noor Zalmy Azizan	Dr. Rohna Ridzwan
	Cardiology	Dr. Mohd. Sapawi Mohamed	Dr. Siti Khairani Zainal Abidin
	Oncology	Dr. Voon Pei Jye	Dr. Ibtisam Muhamad Nor
MOH Disease Control Division (expertise in vaccines)		Dr. Rohani Jahis	Dr. Faridah Kusnin
Pharmaceutical Services Division, MOH		Pn. Noraini Mohamad	Pn. Rosliza Lajis
Academicians		Prof. Datin Dr. Zoriah Aziz	Dr. Adliah Mhd. Ali
Malaysian Medical Association (MMA)		Dr. R. Thirunavukarasu	Dr. L. Sivanaesan
Federation of Private Medical Practitioners Associations Malaysia (FPMPAM)		Dr. Steven Chow	Dr. G. Shanmuganathan
Association of Private Hospitals of Malaysia (APHM)		Pn. Eliza Basir	Cik Lee Seng Dee
Malaysian Pharmaceutical Society (MPS)		En. Wan Mohd. Hamidi	En. Lee Min Shen

SAFETY ISSUE OF CURRENT INTEREST

PHARMACOGENOMICS IN DETERMINING DRUG RESPONSE
by Jazlina Liza Dato' Jamaluddin

Different patients may respond in different ways to the same medication[1]. Some may experience good treatment response, poor treatment response, or even adverse drug reactions (ADRs). According to Kalow et al., genetics can account for 20% to 95% of variability in drug disposition and effects[2]. Unlike other non-genetic factors influencing drug response, inherited determinants generally are stable and permanent throughout an individual's lifetime[1].

Pharmacogenomics is the study on how genes affect response to drugs. An overview of pharmacogenomics was previously published in MADRAC Bulletin April 2014, while the association of particular genes with drug hypersensitivity syndrome was addressed in Bulletin December 2014.

In this issue, we feature a recent local pharmacogenomics study which was conducted by one of our NPRA Pharmacovigilance officers, on using genes to determine drug response.

Clinical and genetic predictors of dipeptidyl peptidase-4 inhibitor treatment response in Type 2 diabetes

Jamaluddin, J.L., Huri, H.Z., & Vethakkan, S.R.
Adapted from: Pharmacogenomics [2016, 17(8), 867-881].

Aim: To determine the clinical and genetic predictors of the dipeptidyl peptidase-4 (DPP-4) inhibitor treatment response in type 2 diabetes (T2D) patients.

Methods:

Gene Selection

Three genes were selected for this study for the following reasons:

The genes dipeptidyl peptidase-4 (DPP4), Wolfram syndrome 1 (WFS1), and potassium channel Kir6.2 (KCNJ11) have been hypothesised as having the potential of possible relevance to be associated with the response to DPP-4 inhibitors. This was based on the understanding of the disease pathogenesis and the mechanism of drug action.

Following meal ingestion, the intestinal L cells mediate the release of the incretin hormone glucagon-like peptide-1 (GLP-1) into the gastrointestinal circulation[3]. DPP-4 inhibitors prevent GLP-1 from being inactivated[4] resulting in increased active GLP-1 to bind with its receptor (GLP-1R) on the pancreatic β-cell[5]. This transmits a signal in the PI3K pathway[6] activating cascades of action in producing insulin including the WFS1 gene in the pancreas endoplasmic reticulum, the expression of which plays a significant role in β-cell insulin secretion[7]. Next, following the incretin pathway, the release of insulin into the circulation[8] through the pancreatic β-cell ATP-sensitive potassium channels is mediated by the KCNJ11 gene[9].

Patient Selection

T2D patients treated with DPP-4 inhibitors (sitagliptin, vildagliptin, or linagliptin). A total of 662 patients were recruited.

Genotyping Analysis
DPP4, WFS1 and KCNJ11 (rs2285676) gene polymorphisms were genotyped for 662 T2D patients treated with DPP-4 inhibitors (sitagliptin, vildagliptin, or linagliptin). Genotyping was performed by Applied Biosystems TaqMan SNP genotyping assay. Drug response was measured by using HbA1c levels.

Results: Patients aged below 65 years old [odds ratio (OR) 2.3; 95% confidence interval (CI): 1.180–4.296], with triglyceride levels less than 1.7 mmol/L [Odds Ratio (OR): 2.2; 95% Confidence Interval (CI): 1.031–4.723], DBP less than 90 mmHg [OR: 1.7; 95% CI: 1.009–2.892], and KCNJ11 rs2285676 (genotype CC) [OR: 2.0; 95% CI: 1.025-3.767] were more likely to respond to DPP-4 inhibitor treatment compared with other patients, as measured by HbA1c levels.

Conclusions: Age, triglyceride levels, DBP, and the KCNJ11 (rs2285676) gene are predictors of DPP-4 inhibitor treatment response in T2D patients.

In this current era, we cannot deny the exciting clinical utility of pharmacogenomics in determining the outcome of drug response. In future, provided with more clinical studies, pharmacogenomics databases may provide significant genetic information in selecting the perfect therapy tailored for a patient, as well as predict and reduce ADR incidences in a population.

References:

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REGULATORY MATTERS

AZITHROMYCIN: RISK OF QT PROLONGATION AND DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS)

All products containing azithromycin registered in Malaysia have been directed to update their local package inserts (PIs) with information on the risk of **two serious adverse events**, namely prolongation of the QT interval, and drug reaction with eosinophilia and systemic symptoms (DRESS).

Azithromycin is the first azalide antibiotic, a subclass of the macrolide antibiotics. It has an extended spectrum of activity, including against gram-positive and gram-negative organisms, as well as atypical pathogens.

Background of the Safety Issues

In March 2013, the United States Food and Drug Administration (US FDA) issued a warning on the risk of QT prolongation, *torsades de pointes* and fatal arrhythmia with the use of azithromycin. This was a result of the review of two studies: the first a study published in the New England Journal of Medicine by medical researchers comparing the risk of cardiovascular death between different antibiotics, and the second a clinical QT study by the drug manufacturer[1].

Following this, in April 2014, Health Canada announced that the package inserts of all products containing azithromycin would be updated with information on the risk of DRESS. Health Canada initiated a review on the risk of DRESS associated with azithromycin following one ADR report of DRESS submitted in Canada, and four cases reported in the literature. A search of the WHO International ADR database (VigiBase®) at the time of this review revealed 14 reported cases of DRESS suspected to be related to azithromycin use[2].

Local Scenario

There are currently 34 products containing azithromycin registered in Malaysia, which are available as tablets, capsules, oral suspensions and injectables.

Since year 2000, the NPRA has received **308 ADR reports** with 545 adverse events suspected to be related to azithromycin. Almost 40% of the adverse events involved skin and appendages disorders (211 events, 38.7%), such as maculopapular rash, itching and urticaria. There were also a number of reports on gastrointestinal system disorders (84 events, 15.4%), mainly diarrhoea and vomiting.

With regards to the safety issues concerned, there has been **one case of QT prolongation** reported in Malaysia, involving a 60 year-old lady who took oral azithromycin 500mg daily. This patient had underlying congenital prolonged QT syndrome, and was on concomitant medication which may have contributed to the adverse event, therefore the case was assigned causality C3 (possibly-related to the drug). As yet, **no reports of DRESS** related to azithromycin have been received by the NPRA. The search revealed **six (6) reports** of other serious skin reactions suspected to be related to azithromycin, namely erythema multiforme (EM), Stevens-Johnson syndrome (SJS), and acute generalised exanthematous pustulosis (AGEP). EM and SJS are documented in the innovator product PI.

The package inserts of the innovator products have been updated with warnings and adverse event information on rare reports of QT prolongation and serious cutaneous adverse reactions including DRESS.

Advice to Healthcare Professionals

- Be aware of the potential risk of QT prolongation and DRESS associated with the use of azithromycin.
- **Early diagnosis** and prompt discontinuation of azithromycin are important to achieve the best outcome in patients with DRESS. Distinguishing DRESS from other serious cutaneous drug reactions such as SJS and TEN is important because treatment varies among these conditions. Treatment for DRESS may involve supportive measures including fluid and nutritional support, and/or systemic corticosteroid therapy depending on the severity of the condition.
- **Consider the risk** of *torsades de pointes* and fatal arrhythmia when choosing between azithromycin and other antibacterial drugs, especially for patients who are at higher risk of cardiovascular events.
- **Counselling points:** Patients should be advised to **seek immediate medical attention** if they experience an irregular heartbeat, shortness of breath, dizziness, fainting, rash, fever, sore throat, or eye irritation while taking azithromycin.

We need your help!
Please report any adverse event suspected to be associated with the use of azithromycin, even those which are common or well-known, to the National ADR Monitoring Centre, NPRA.

References:

1. US FDA (2013). Drug Safety Communication: Azithromycin (Zithromax or Zmax) and the risk of potentially fatal heart rhythms. [http://www.fda.gov/Drugs/DrugSafety/ucm341822.htm]
2. Health Canada (2014). Summary Safety Review: Azithromycin - Drug Reaction/Rash with Eosinophilia and Systemic Symptoms (DRESS). [http://www.hc-sc.gc.ca/dhp-mps/medeff/reviews-examens/azithromy-eng.php]

MYCOPHENOLATE (MYCOPHENOLATE MOFETIL AND MYCOPHENOLIC ACID): IMPORTANT NEW INFORMATION ON THE TERATOGENIC RISK

The immunosuppressant medication, mycophenolate (mycophenolate mofetil and mycophenolic acid), is known to have human teratogenic effects. A routine re-evaluation of the benefit-risk balance of medicines containing mycophenolate by the European Medicines Agency (EMA) revealed evidence of an **increased rate** of congenital malformations and spontaneous abortions associated with mycophenolate as compared to other medicines.

Following a review of this new safety information by NPRA, the existing warnings against the use of these medicines in pregnancy have been strengthened with the addition of **new contraindications and advice**. A directive was issued by the Drug Control Authority (DCA) on 25 March 2016 requiring the local package inserts of all products containing mycophenolate to be updated with this new information.

Further Information on Safety Issue

The review of post-marketing ADR reports and literature evidence on the teratogenic risk of mycophenolate revealed the following updated evidence:

(i) **spontaneous abortion** in around 45-49% of pregnancies in women exposed to mycophenolate, compared with reported frequencies of 12-33% in solid organ transplant patients treated with other immunosuppressants.

(ii) **congenital malformations** in 23-27% of the offspring of mothers exposed to mycophenolate during pregnancy, compared with 4-5% in transplant patients treated with other immunosuppressants, and 2-3% in the overall population.

The most frequently reported malformations were:

- Facial malformations such as cleft lip, cleft palate, micrognathia and hypertelorism of the orbits;
- Abnormalities of the ear (e.g. abnormally formed or absent external/ middle ear)
- Abnormalities of the eye (e.g. coloboma, microphthalmos);
- Malformations of the fingers (e.g. polydactyly, syndactyly, brachydactyly);
- Cardiac abnormalities such as atrial and ventricular septal defects;
- Oesophageal malformations (e.g. oesophageal atresia);
- Nervous system malformations (such as spina bifida).

Local Scenario

Products containing mycophenolate have been registered in Malaysia since 1998. Currently, there are nine (9) products registered with the DCA, seven (7) containing mycophenolate mofetil and two (2) containing mycophenolate sodium.

Since year 2000, the NPRA has received 103 ADR reports with 162 adverse events suspected to be related to mycophenolate. The most frequently reported adverse event was diarrhoea, followed by leucopenia, increased hepatic enzymes, abdominal discomfort, and vomiting. As yet, the NPRA has not received any ADR reports on teratogenic effects or reports involving the use of mycophenolate in pregnancy.

A Direct Healthcare Professional Communication (DHPC) related to this issue was approved by the NPRA and distributed in December 2015 to highlight the new safety information to healthcare professionals.

Advice to Healthcare Professionals

- Mycophenolate is contraindicated in pregnancy, breastfeeding, and in women of childbearing potential not using highly effective contraceptive methods.
- Before starting treatment with mycophenolate, women of childbearing potential must have two negative serum or urine pregnancy tests.
- **Counselling points:**
  - Before starting treatment, female and male patients of reproductive potential must be made aware of the increased risk of pregnancy loss and congenital malformations
  - All patients must be counselled regarding pregnancy prevention, and planning.
  - Patients should consult their doctor immediately if they become pregnant.

- **Recommended contraception**:
  - Women of child bearing potential: Use two reliable forms of contraception simultaneously, including one highly-effective method, before starting mycophenolate therapy, during therapy, and for six weeks after discontinuation of therapy.
  - Men (including vasectomised men): Use condoms during treatment and for at least 90 days after cessation of treatment. Female partners of male patients are recommended to use highly effective contraception during treatment and for 90 days after the last dose of mycophenolate.

PROLIA® AND XGEVA® (DENOSUMAB): CLINICALLY SIGNIFICANT CASES OF HYPERCALCAEMIA AFTER CESSATION OF TREATMENT WITH DENOSUMAB IN PAEDIATRIC PATIENTS

Denosumab is a human IgG2 monoclonal antibody that inhibits the activity of osteoclasts, the cells responsible for bone resorption. Currently, there are two (2) products containing denosumab with different strengths and indications registered in Malaysia since 2012, as follow:

(i) Prolia® (60mg) is indicated for the treatment of postmenopausal osteoporosis, male osteoporosis, and bone loss in patients undergoing hormone ablation for cancer;
(ii) Xgeva® (120mg) is indicated for the prevention of skeletal-related events in patients with bone metastases from solid tumours.

Cases of clinically significant hypercalcaemia have been reported weeks to months following discontinuation of denosumab treatment in patients with growing skeletons. These patients presented with nausea and vomiting with or without acute renal failure, and required hospitalisation.

Patients with growing skeletons have received denosumab for indications that have not been approved such as osteogenesis imperfecta, fibrous dysplasia, and juvenile Paget's disease of bone.

Healthcare professionals are advised to monitor patients with growing skeletons at the time of denosumab treatment, for the development of hypercalcaemia following denosumab discontinuation. A Direct Healthcare Professional Communication (DHPC) on this matter has been issued by the product registration holder in agreement with NPRA.

Local ADR Reports

In Malaysia, the NPRA has received five (5) ADR reports since both products were registered in 2012, all involving Prolia® used to treat post-menopausal osteoporosis. The adverse events reported were lower back pain, rash, sore mouth, urticaria, tingling skin and vertigo. All the reports were assigned causality C3 (possibly-related to the drug) by MADRAC.

The prescribing information for Xgeva® has been updated with additional safety information related to hypercalcaemia following treatment discontinuation in patients with growing skeletons. No updates related to this safety issue were required for the Prolia package insert at this time, and the overall benefit-risk profile of denosumab remains favourable for the approved indications.

Advice to Healthcare Professionals

- Denosumab should not be used for indications which are not approved in Malaysia.
- Following discontinuation of denosumab, individuals with growing skeletons at the time of denosumab treatment should be monitored for hypercalcaemia.
- In cases of hypercalcaemia, the patient's renal function should be monitored.
- Please report any ADR suspected to be related to denosumab to the NPRA.

VIEKIRAX® AND EXVIERA®: NOT RECOMMENDED IN PATIENTS WITH MODERATE HEPATIC IMPAIRMENT (CHILD-PUGH B)

The NPRA would like to highlight new safety information related to the hepatic safety of Viekirax® (ombitasvir, paritaprevir, ritonavir) with or without Exviera® (dasabuvir). In Malaysia, Viekirax® and Exviera® are both approved for the treatment of chronic hepatitis C in adults, in combination with other medicinal products.

There have been post-marketing reports of hepatic decompensation and hepatic failure, including cases with severe outcomes such as liver transplantation or death, in patients receiving Viekirax® with Exviera®. Most patients with severe outcomes had evidence of advanced or decompensated cirrhosis prior to starting therapy. Although the specific role of these products is difficult to establish due to the existing advanced liver disease, a potential risk cannot be excluded.

Local Scenario

Viekirax® and Exviera® have been registered in Malaysia since year 2015, and at the time of this publication, the NPRA has not received any ADR reports related to these products.

The product package inserts have been updated with information related to this safety issue, under the Special Warnings and Precautions, Adverse Reactions, Dosing and Administration, and Pharmacokinetic Properties sections.

Advice to Healthcare Professionals

- Viekirax® with or without Exviera® is **not recommended** in patients with **moderate** hepatic impairment (Child-Pugh B) and remains contraindicated in patients with severe hepatic impairment (Child-Pugh C).
- Child-Pugh B patients who are currently on treatment with Viekirax® with or without Exviera® may be continued on treatment after discussing the benefits and risks of continued treatment, with monitoring as stated below.
- Patients who develop evidence of clinically relevant hepatic decompensation should discontinue treatment.
- **Monitoring** of patients with cirrhosis, or Child-Pugh B patients currently on treatment with Viekirax®, with or without Exviera®, who continue the treatment:
  - Monitor for signs and symptoms of hepatic decompensation;
  - Check hepatic laboratory tests including direct bilirubin levels at baseline, during the first 4 weeks of starting treatment, and as clinically indicated.
- **Patient Counselling Points**:
  - Watch for symptoms of liver inflammation, liver failure or hepatic decompensation, including jaundice, upper right abdominal pain, abdominal swelling, nausea, vomiting, or confusion.
  - Consult your doctor or pharmacist without delay if such symptoms occur.
- **Please report** any suspected ADR related to Viekirax® and Exviera® to the NPRA as your information is essential in the safety monitoring of these newly-registered products.

XALKORI® (CRIZOTINIB) – INCLUSION OF A NEW WARNING REGARDING CARDIAC FAILURE

Xalkori® (crizotinib) is a kinase inhibitor, including anaplastic lymphoma kinase (ALK). It is indicated for the treatment of patients with advanced non-small cell lung cancer (NSCLC) with ALK-positive tumours and has been registered in Malaysia since 2012.

A safety review of crizotinib by the European Medicines Agency (EMA) revealed the risk of cardiac failure in patients receiving this medicine. The review was based on clinical trial data as well as post-marketing ADR reports. Cases of cardiac failure, some fatal, were reported in patients receiving crizotinib, including patients with or without pre-existing cardiac disorders.

Among a total of 1,669 patients with ALK-positive NSCLC across clinical studies, 19 patients (1.1%) treated with crizotinib had cardiac failure (any grade). In post-marketing experience, cardiac failure was reported in 40 patients (reporting rate 0.27%) out of more than 14,700 patients estimated to have received crizotinib as of that time.

Local Scenario

Since Xalkori® was first registered in Malaysia in 2012, the NPRA has received 12 ADR reports with 16 adverse events suspected to be related to this product. Among the adverse events reported were pneumonia, urinary tract infection, and hepatotoxicity (a documented reaction for this drug).

The local package insert of Xalkori will be updated with information on the risk of cardiac failure under the 'Warning and Precautions' and 'Adverse Reactions' sections.

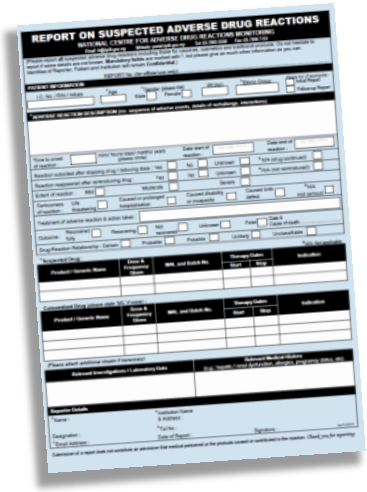
Advice to Healthcare Professionals

- Monitor all patients treated with crizotinib for signs and symptoms of cardiac failure (including dyspnoea, oedema, or rapid weight gain from fluid retention).
- If clinical symptoms of heart failure occur, consider dose reduction, interruption or stopping treatment with crizotinib.
- Please report any ADR suspected to be related to crizotinib to the NPRA.

GUIDE FOR ADR REPORTERS

Calling all pharmacists!

NOW YOU CAN CLAIM CPD POINTS FOR QUALITY ADVERSE DRUG REACTION REPORTS



Beginning January 2016, pharmacists are eligible to claim Continuing Professional Development (CPD) points for the submission of quality ADR reports. The Pharmacy Board Malaysia has agreed to award one (1) CPD point under **category A4** for every ADR report submitted to the NPRA which fulfills the mandatory criteria as stated below. The maximum number of points for ADR reporting is 10 points per person each year [Ref: *KKM-55/BPF/101/001/01 JLD 29 (20)* and *KKM.600-16/1/6(57)*].

Why?

MADRAC suggested awarding CPD points for the submission of ADR reports as a method to increase the quantity and quality of reports, in particular from private sector healthcare professionals.

In 2014, only three (3) ADR reports were received from community pharmacists, making up 0.02% of the total 13,001 reports received. The number of reports received from general practitioners and private hospitals was also low.

The entire process of ADR identification and preparing a quality report involves knowledge of clinical aspects, pharmacology, pharmacokinetics, and more. Most ADR cases also have something to teach us in terms of patient management and monitoring. Thus the decision to encourage quality reporting through awarding CPD points.

Mandatory Criteria

In order to earn a CPD point, the fields shown in **Figure 1** must be completed in the ADR report, stating **'nil' or 'N/A'** if the information cannot be obtained.

Figure 1: Mandatory information fields of ADR report to be completed
✔ Patient Identification (ID) ***e.g. patient NRIC or RN (must be traceable by reporter)***
✔ Patient age
✔ Patient gender
✔ Patient ethnic group
✔ ADR description
✔ Time to onset
✔ Date of reaction
✔ Dechallenge
✔ Rechallenge
✔ Suspected drug name(s)
✔ Reporter name
✔ Reporter email address/ phone no./ postal address ***(must be contactable)***

Verification Process for CPD Points

For government/ semi-government facilities (including university hospitals):

- Verification is carried out by the CPD administrator at the facility itself, as is currently done for other CPD activities.
- ADR reports submitted by pharmacists are to be verified against the checklist in **Figure 1**.
- If all the mandatory fields are completed, the ADR reporter must be informed that he/she is eligible to claim one CPD point.
- The facility must keep a record of the name of reporter and ADR report reference number for all reports which fulfill the minimum criteria. A copy of this record can be used as supporting evidence to claim the CPD points (category A4).
- Maximum number of points for ADR reporting per person = 10 points per year (monitoring should be done at facility-level).

For private sector pharmacists (e.g. community, private hospitals):

- Verification is done by the NPRA Pharmacovigilance (PV) Section.
- ADR reports submitted by private sector pharmacists will be verified against the checklist.
- If all the mandatory fields are completed, the reporter will be sent a reply slip from NPRA stating that they are eligible to claim one CPD point. This slip should be used as supporting evidence to claim the CPD points (category A4).
- The NPRA will keep a record of the name of reporter and ADR report reference number for all reports which fulfill the mandatory criteria.
- CPD Points category: A4 (1 point per report)
- Maximum number of points for ADR reporting: 10 points per year (to be monitored by CPD administrator).

How to report an ADR?

1. Visit npra.moh.gov.my
2. Click on 'ADR Reporting'
3. Go to report as a Healthcare Professional.
4. Print out and submit the form via email, fax or post to NPRA once completed.

Contact details:

The Pharmacovigilance Section,
National Pharmaceutical Regulatory Agency,
Ministry of Health,
Lot 36, Jalan Universiti,
46200 Petaling Jaya, Selangor.

☎ +603 7883 5550 +603 7956 7151

Earn a maximum of 10 points every year for ADR Reporting

Help keep medicines safe for Malaysia while earning CPD Points!

Private sector pharmacist submits completed ADR report to NPRA

NPRA receives and verifies ADR report

NPRA officer sends certification slip to pharmacist via email/post

Pharmacist claims 1 CPD point for each certified report with certification slip as supporting evidence

Maximum of 10 CPD points attainable each year

*To join the **NPRA Safety Information Mailing List,** please send an email with your details (i.e.: full name, designation, workplace address) to fv@npra.gov.my*