



National Pharmaceutical Regulatory Agency  
Ministry of Health, Malaysia

# 2017

## ANNUAL REPORT

### NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING







Ministry of Health, Malaysia

## **NATIONAL CENTER FOR ADVERSE DRUG REACTIONS MONITORING: ANNUAL REPORT 2017**

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## Our Purpose

# Keeping medicines safe for the nation

This is what inspires and drives us as individuals and as a regulatory agency. This is how we contribute to the society by ensuring the safety of medicines registered in Malaysia.



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### **The National Centre for Adverse Drug Reactions Monitoring**

The National Centre for Adverse Drug Reactions Monitoring serves as a database for all adverse drug reaction reports and adverse events following immunisation reports that are submitted to NPRA.

The national centre plays an important role in managing and analysing information on suspected adverse reactions to medicines or vaccines. Based on the evaluation of a safety concern, NPRA may take regulatory action(s) to improve product safety and protect public health, such as updating product packaging information, restricting the use of the drug, communicating new safety information to the public, or even removing a product from the market.

## The Malaysian Adverse Drug Reactions Advisory Committee (MADRAC)



The Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) was established in 1987 under the Drug Control Authority (DCA) to perform the function of monitoring safety profiles of drugs registered for use in Malaysia.

During MADRAC meetings held once in two months, causality verification is done for all local reports of adverse drug reactions (ADR) as well as adverse events following immunisation (AEFI), and all pertinent drug safety issues are discussed to provide DCA with information and recommendations if required.

A total of **six (6) MADRAC meetings** were held in 2017, with **17,152 adverse drug reaction (ADR) reports** presented for verification of causality.

Ex-officio	<p><u>Chairman</u> <b>Dr. Ramli Zainal</b> Director of NPRA</p>
	<p><u>Secretary</u> <b>Wan Mohaina Wan Mohammad</b> Deputy Director, Centre for Post-Registration of Products and Cosmetic Control, NPRA</p>
	<p><b>YBhg. Datin Dr. Faridah Aryani Md. Yusof</b> Secretary of the Drug Control Authority</p>
Committee Members (Alternate Members)	<p><b>Dr. G.R. Letchuman Ramanathan</b> National Head of Internal Medicine Services, Senior Medical Consultant (Endocrinology), Hospital Raja Permaisuri Bainun, Ipoh.  (YBhg. Datuk Dr. Noel Thomas Ross)</p>
	<p><b>YBhg. Dato' Dr. Gun Suk Chyn</b> Head of Department and Senior Medical Consultant (Rheumatology) Hospital Tuanku Ja'afar  (YBhg. Dato' Dr. Hjh. Azmillah Rosman)</p>
	<p><b>YBhg. Dato' Dr. Noor Zalmy Azizan Mohd. Ali Azizan</b> Senior Consultant Dermatologist Hospital Kuala Lumpur  (Dr. Rohna Ridzwan)</p>

Committee  
Members  
(Alternate  
Members)

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Senior Consultant Paediatrician  
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*(Dr. Tan Kah Kee)*

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**Dr. Ramli Ali**

Senior Consultant Psychiatrist  
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*(Dr. Uma Visvalingam)*

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Hospital Kuala Lumpur

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**Dr. Mohd. Sapawi Mohamed**

Consultant Cardiologist  
Hospital Raja Perempuan Zainab II

*(Dr. Siti Khairani Zainal Abidin)*

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**Dr. Voon Pei Jye**

Medical Oncologist  
Hospital Umum Sarawak

*(Dr. Ibtisam Muhamad Nor)*

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**Dr. Rohani Jahis**

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Disease Control Division  
Ministry of Health

*(Dr. Faridah Kusnin)*

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**YBhg. Professor Datin Dr. Zorlah Aziz**

Head of Pharmacy Department,  
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Universiti Malaya

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Federation of Private Medical Practitioners' Associations Malaysia (FPMPAM)

*(Dr. G. Shanmuganathan)*

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**Eliza Basir**

Association of Private Hospitals of Malaysia (APHM)

*(Lee Seng Dee)*

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**Wan Mohd. Hamidi Wan Sulaiman**

Malaysian Pharmaceutical Society (MPS)

*(Lee Min Shen)*

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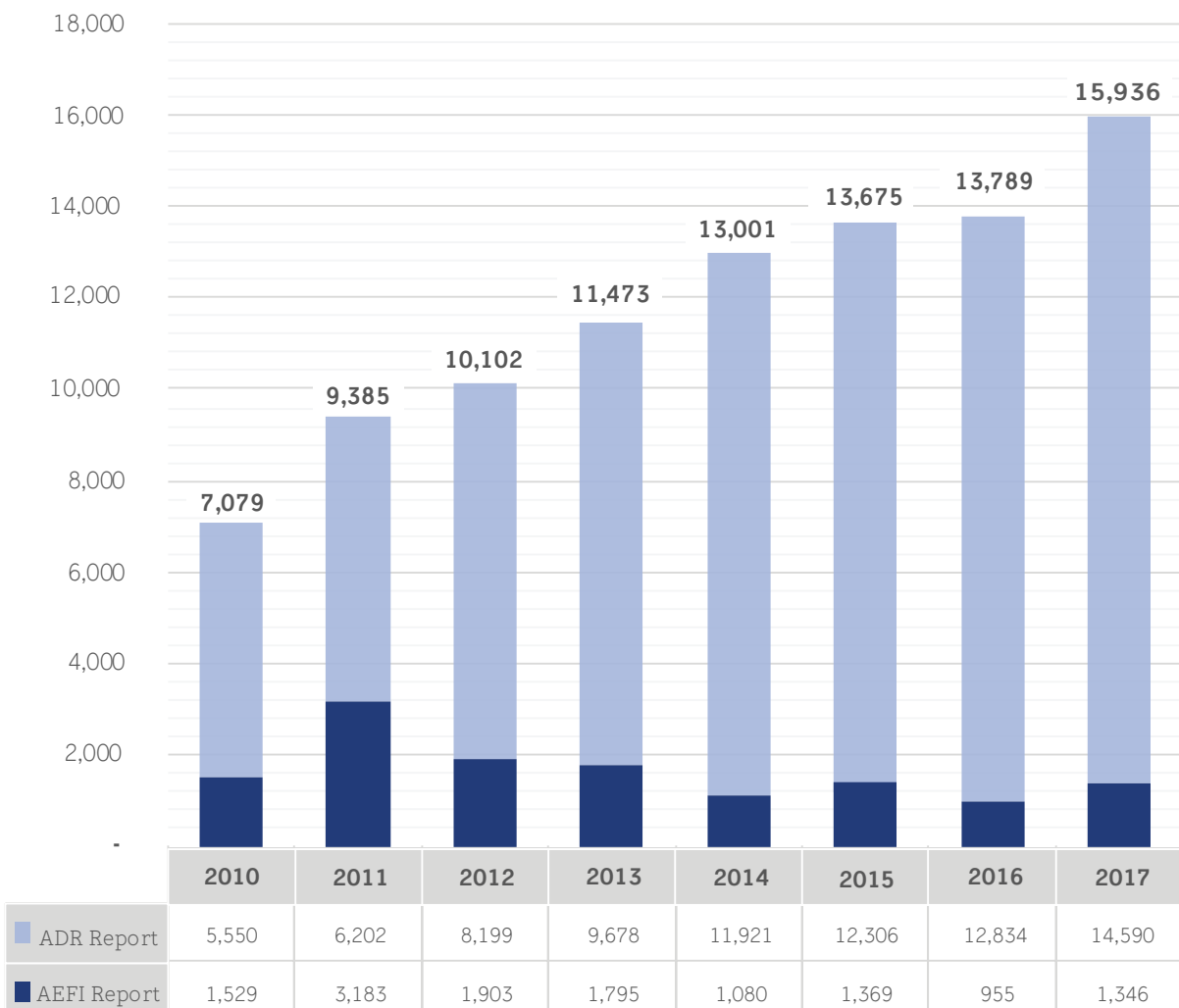
## Analysis of ADR Reports



The National Centre received **15,936 adverse event reports** in 2017, showing a **13.5%** increase from the previous year. Once these reports were processed to exclude any duplicates, follow-up reports to cases sent in earlier, and rejected reports, a total of **14,871 viable new reports** were entered into the Malaysian adverse drug reactions database and sent to the World Health Organisation (WHO) Collaborating Centre for International Drug Monitoring in Uppsala, for inclusion into the WHO database.

### Total Number of ADR and AEFI Reports Received in Malaysia, 2010 - 2017

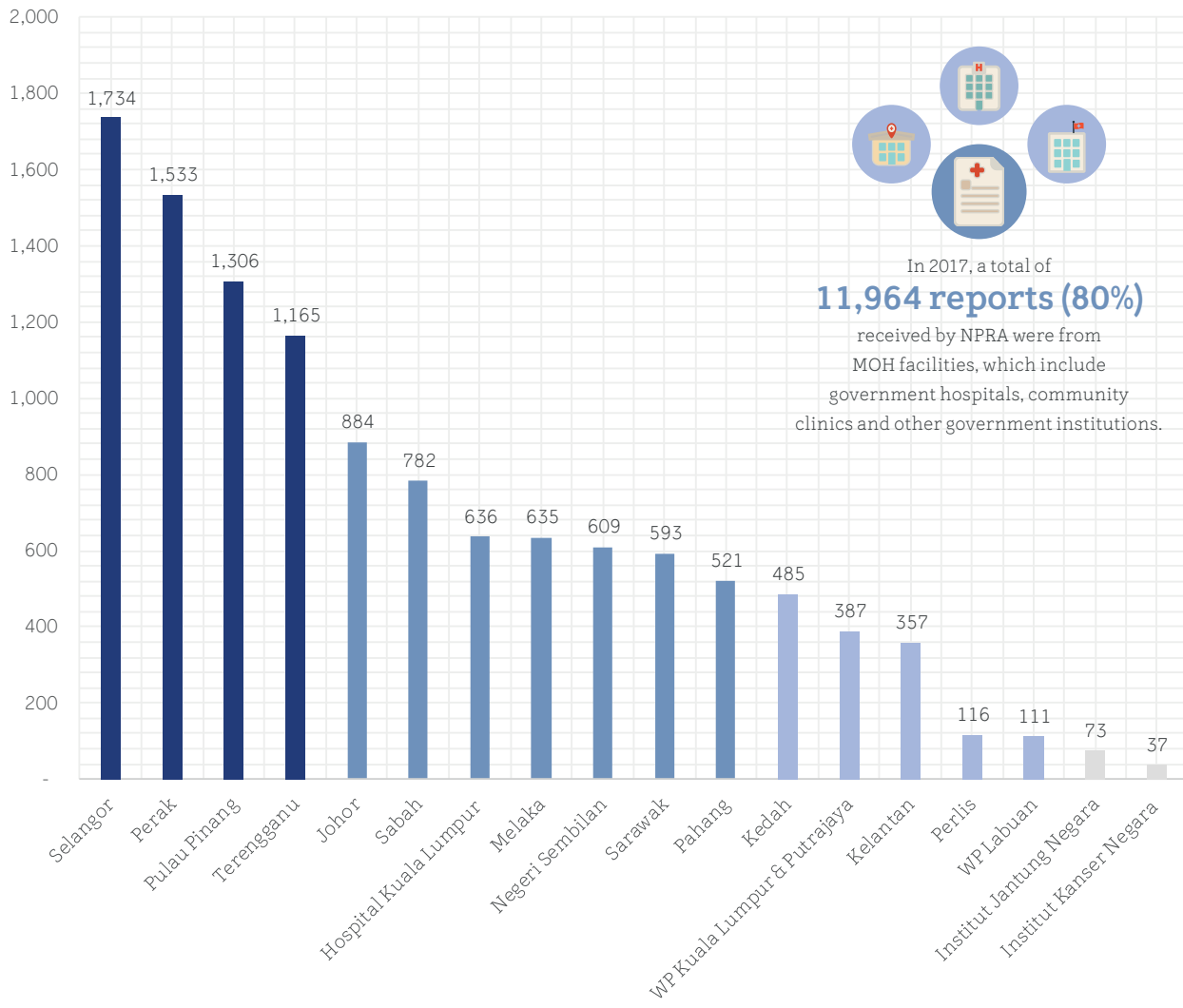
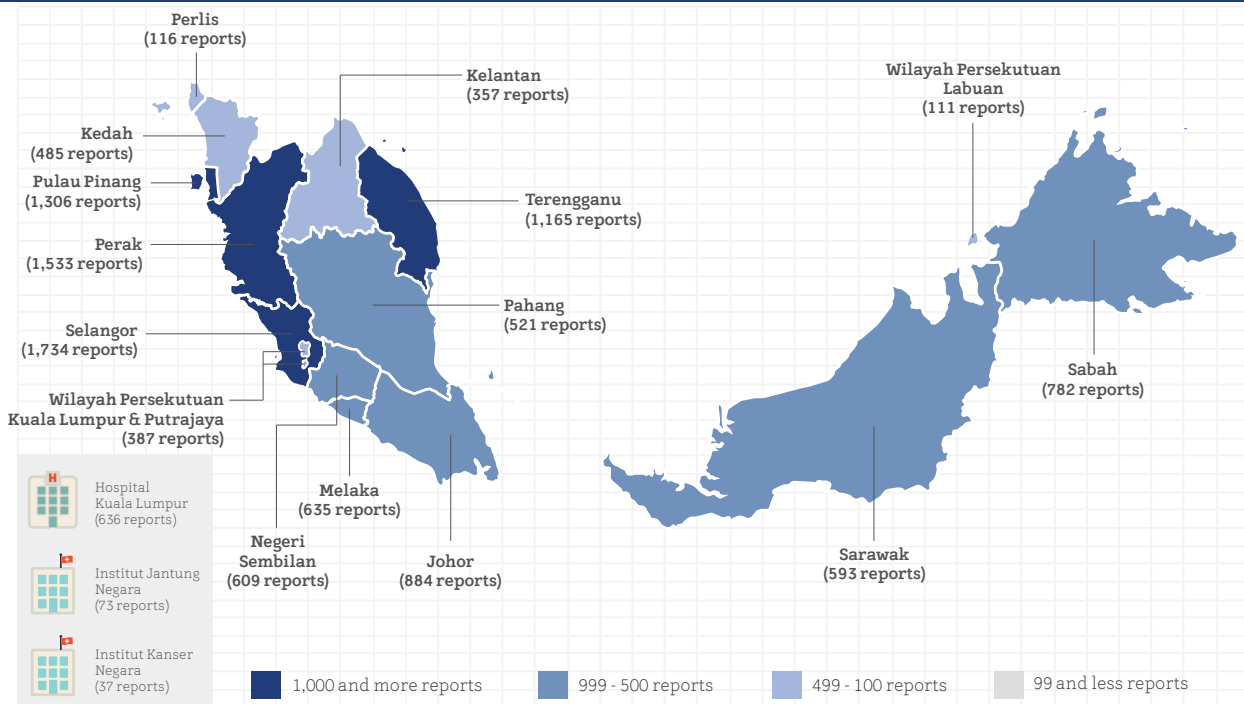
#### No. of Reports



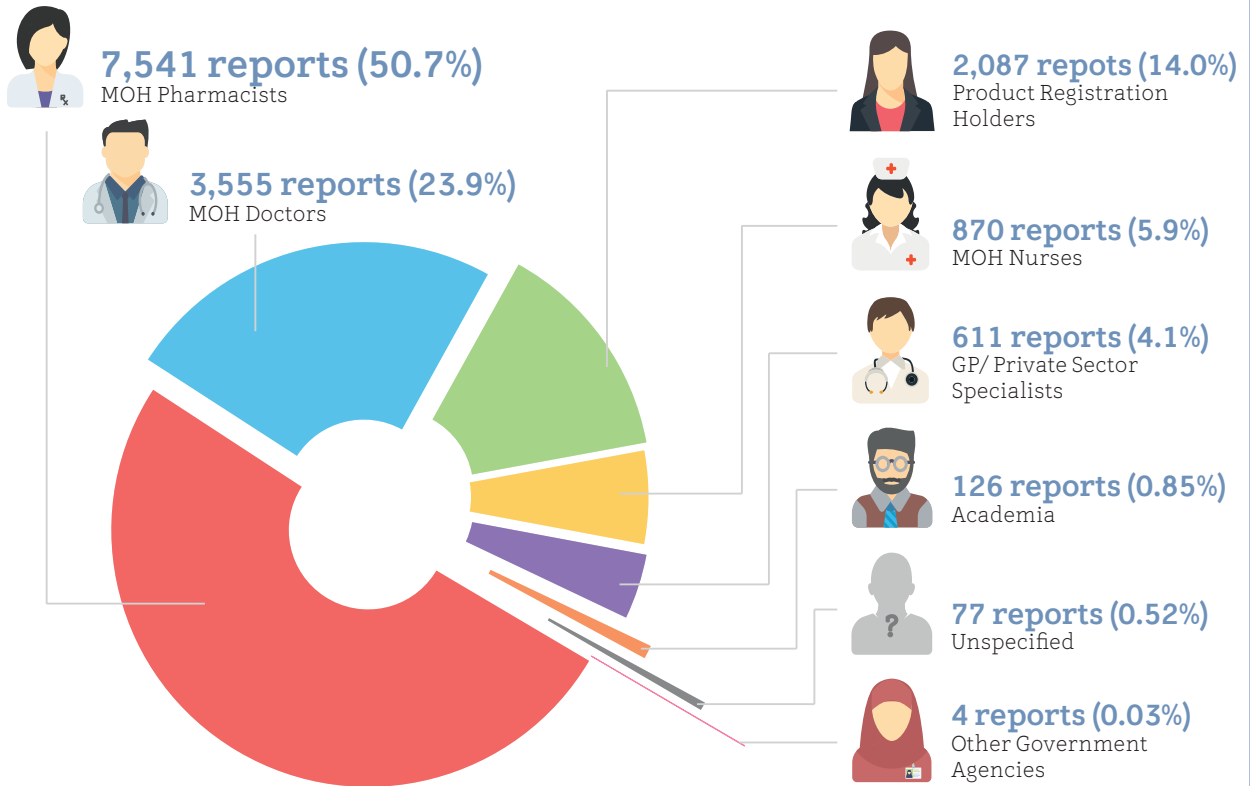
**DISCLAIMER:** The figure above shows the number of reports received by NPRA before the full evaluation is carried out. These adverse events are not necessarily causally related to the product or vaccine.



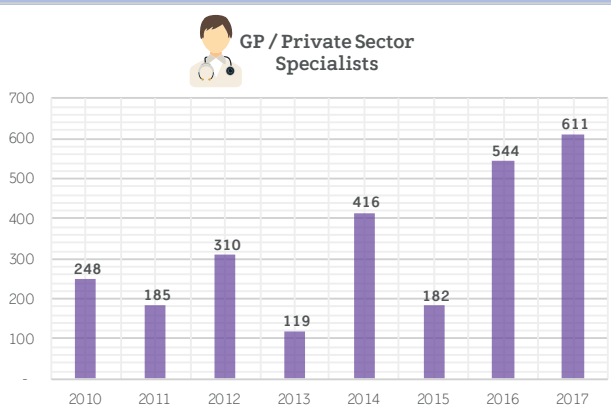
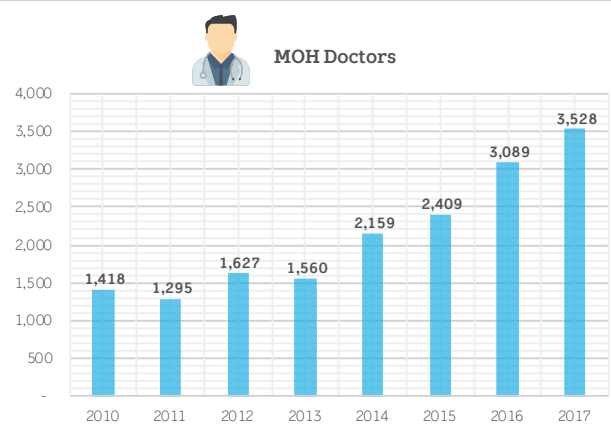
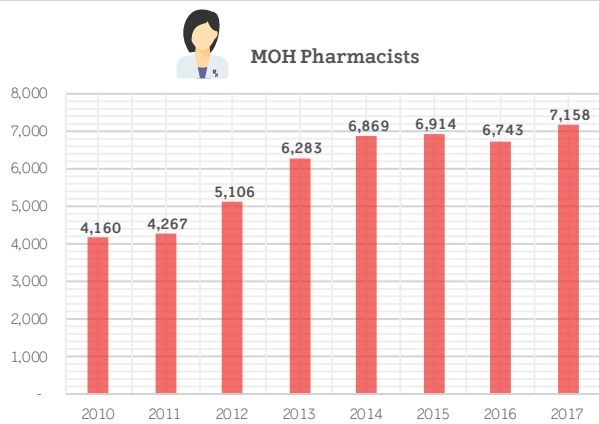
## Distribution of ADR/ AEFI Reports Received from Ministry of Health (MOH) Facilities, 2017



### ADR/ AEFI Reports Received by Reporter Category, 2017



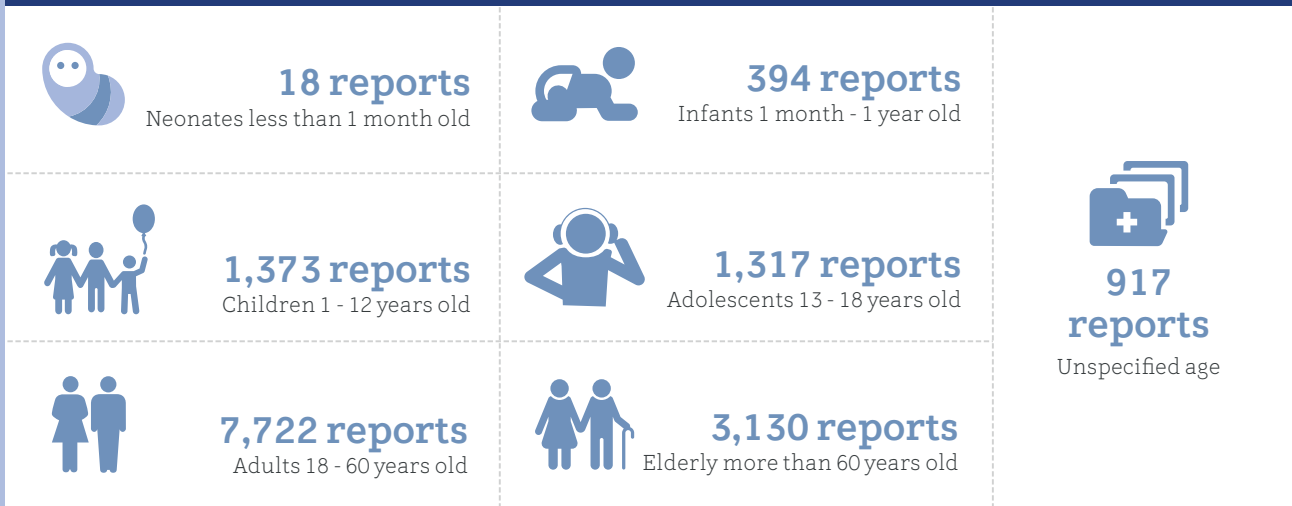
### ADR/ AEFI Reports Received by 4 Main Reporter Category, 2010-2017



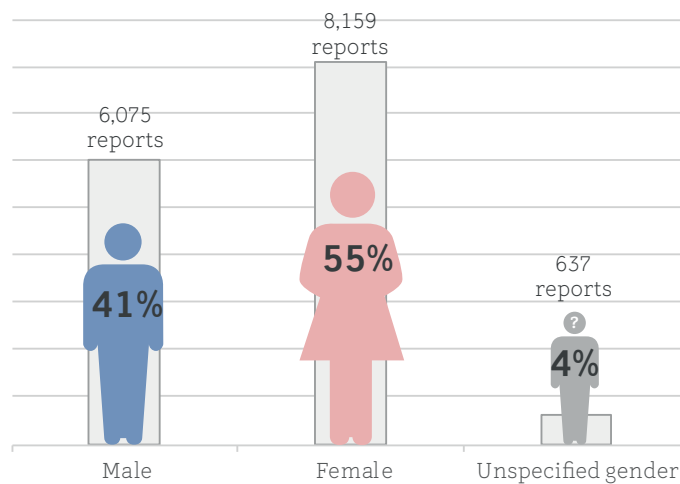
### Number of Products Involved in ADR/ AEFI Reports, 2017



### ADR/ AEFI Reports Received by Patient's Age Group Category, 2017







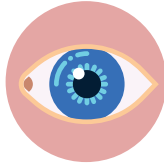
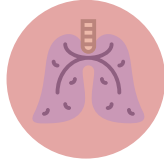




### ADR/ AEFI Reports Received by Patient's Gender, 2017



## Number of Adverse Drug Reactions Categorised by System Organ Class (SOC), 2017

<u>System Organ Class</u>	<u>No. of ADRs</u>
Skin and subcutaneous tissue disorders	8,863
General disorders and administration site conditions	4,665
Gastrointestinal disorders	2,238
Nervous system disorders	2,198
Eye disorders	1,916
Respiratory, thoracic and mediastinal disorders	1,768
Investigations (e.g. platelet count decreased, blood glucose increased)	896
Immune system disorders	654
Musculoskeletal and connective tissue disorders	648
Cardiac disorders	314
Vascular disorders	310
Metabolism and nutrition disorders	283
Psychiatric disorders	241
Infections and infestations	219
Renal and urinary disorders	188
Injury, poisoning and procedural complications	178
Blood and lymphatic system disorders	134
Neoplasms benign, malignant and unspecified	131
Hepatobiliary disorders	123
Reproductive system and breast disorders	78
Ear and labyrinth disorders	66
Endocrine disorders	56
Pregnancy, puerperium and perinatal conditions	7
Surgical and medical procedures	7
Congenital, familiar and genetic disorders	3

## 2017 Top 10 Most Reported MEDdra System Organ Class

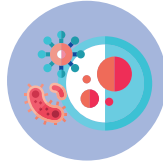
<p><b>1</b></p>  <p>Skin and subcutaneous tissue disorders <b>8,863 ADRs</b></p>		
<p><b>2</b></p>  <p>General disorders and administration site conditions <b>4,665 ADRs</b></p>	<p><b>3</b></p>  <p>Gastrointestinal disorders <b>2,238 ADRs</b></p>	<p><b>4</b></p>  <p>Nervous system disorders <b>2,198 ADRs</b></p>
<p><b>5</b></p>  <p>Eye disorders <b>1,916 ADRs</b></p>	<p><b>6</b></p>  <p>Respiratory, thoracic and mediastinal disorders <b>1,768 ADRs</b></p>	<p><b>7</b></p>  <p>Investigations <b>869 ADRs</b></p>
	<p><b>8</b></p>  <p>Immune system disorders <b>654 ADRs</b></p>	<p><b>9</b></p>  <p>Musculoskeletal and connective tissue disorders <b>648 ADRs</b></p>
		<p><b>10</b></p>  <p>Cardiac disorders <b>314 ADRs</b></p>

## Number of Adverse Drug Reactions Categorised by Pharmacological Group, 2017

<b><u>Pharmacological Group</u></b>	<b><u>No. of ADRs</u></b>
Antiinfective	3,830
Analgesic	2,258
Cardiovascular	2,067
Vaccine	1,371
Antineoplastic	1,061
Others	896
Antidiabetic	615
Antiepileptic	471
Antituberculosis	388
Traditional medicine	385
Antihyperlipidemic	323
Antipsychotic	251
Antiulcer	230
Antiemetic	217
Anticoagulant	206
Antiasthmatic	183
Antigout	157
Antiviral	144
Antihistamine	126
Eye preparations	124
Vitamins	118
Immunosuppressive agent	101
Hormone	93
Contrast media	88
Antidepressant	67
Anesthetic	63
Corticosteroid	55
Dermatological	33
Health supplement	32
Minerals	31
Antispasmodic	24
Antirheumatic	17
Antivenom	6
Antiobesity	2

# 2017 Top 10 most reported Pharmacological Group

1



Anti  
infective

3,830  
ADRs

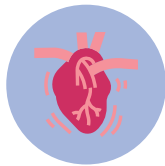
2



Analgesic

2,258  
ADRs

3



Cardiovascular

2,067  
ADRs

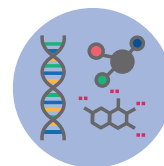
4



Vaccine

1,371  
ADRs

5



Anti  
neoplastic

1,061  
ADRs

6



Others

896  
ADRs

7



Anti  
diabetic

615  
ADRs

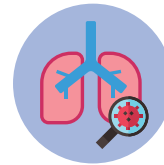
8



Anti  
epileptic

471  
ADRs

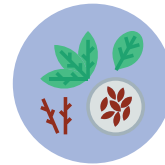
9



Anti  
tuberculosis

388  
ADRs

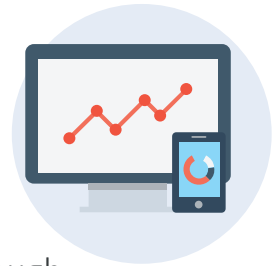
10



Traditional  
medicine

385  
ADRs

## Monitoring Drug Safety Issues



In 2017, a total of **113 drug safety issues** were identified through environmental screening. Following review, **39 issues were presented at MADRAC meetings** to determine the appropriate risk minimisation measures [refer to page 17-19]. The majority of these issues resulted in updates to the package insert safety information, such a tightening of indications or additional contraindications. **Regulatory actions for 32 of these issues** were proposed to the DCA, resulting in DCA directives issued to ensure package inserts of all generic products containing the affected active ingredients are updated with the required safety information.

Besides that, review and approval of safety-related updates to product package inserts were carried out for **363 products (90.5%)** out of 401 applications received.



**6**

MADRAC meetings



**39**

Safety issues presented



**32**

Safety issues resulted in package insert updates



**9**

Direct Healthcare Professional Communication (DHPC) letters



**1,650**

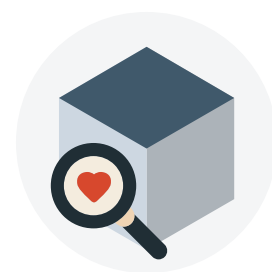
Products involved in regulatory action



<b>MADRAC 155</b> 16 February 2017	DCA Directive	DHPC letter	Product information update	Publish article	Further review
<b>Proton-pump inhibitors:</b> Risk of fundic gland polyps (benign)					•
<b>Pomalyst® (pomalidomide):</b> Reactivation of hepatitis B virus		•	•	•	
<b>Chlorhexidine:</b> Risk of hypersensitivity reactions	•		•	•	
<b>MADRAC 156</b> 20 April 2017					
<b>Gadolinium-based contrast agents:</b> Evidence of gadolinium deposits in the brain after MRI body scans					•
<b>Hyoscine butylbromide (injections):</b> Risk of serious adverse reactions in patients with underlying cardiac disease				•	•
<b>Proton-pump inhibitors:</b> Potential long-term safety issues					•
<b>Inhaled corticosteroids:</b> Increased risk of pneumonia in COPD patients	•		•	•	
<b>Miconazole and warfarin:</b> Risk of bleeding due to drug-drug interaction	•		•	•	
<b>Loperamide:</b> Risk of serious cardiac events following loperamide use above recommended dose and misuse	•		•	•	
<b>Escapelle®, Postinor®-2, Madonna® (levonorgestrel):</b> New advice for users of hepatic-enzyme inducers and contraceptive efficacy	•	• •	•	•	
<b>MADRAC 157</b> 15 June 2017					
<b>Revlimid® (lenalidomide):</b> Cases of viral reactivation		•	•	•	
<b>Zelboraf® (vemurafenib):</b> Risk of Dupuytren's contracture and plantar fascial fibromatosis		•	•	•	
<b>Domide® (thalidomide):</b> Cases of viral reactivation, and pulmonary hypertension		•	•	•	
<b>Keytruda® (pembrolizumab):</b> Fatal case of Steven-Johnson syndrome and fatal case of toxic epidermal necrolysis		•	•	•	
<b>Tramadol:</b> Restricted use in children, and warning of use in pregnancy and lactation	•		•	•	
<b>Proton-pump inhibitors:</b> Risk of adverse events due to long-term use	•		•	•	

	DCA Directive	DHPC letter	Product information update	Publish article	Further review
<b>Proton-pump inhibitors:</b> Risk of elevated circulating levels of chromogranin A (CgA)	●		●		
<b>Etoricoxib:</b> New dosing for rheumatoid arthritis and ankylosing spondylitis	●		●	●	
<b>MADRAC 158</b> 17 August 2017					
<b>Hyoscine (injection):</b> Risk of serious adverse events in patients with heart and cardiovascular disease	●		●	●	
<b>Aripiprazole:</b> Risk of gambling disorders and impulse-control problems	●		●	●	
<b>Testosterone:</b> Adverse events following misuse and drug dependence	●		●		
<b>Metronidazole (excluding topical products):</b> Risk of hepatotoxicity in patients with Cockayne syndrome	●		●	●	
<b>Metformin:</b> New dosage adjustments in renal patients	●		●	●	
<b>Opioid products:</b> Risk of serotonin syndrome when used in combination with serotonergic drugs; Risk of adrenal insufficiency and androgen deficiency in long-term use	●		●		
<b>Opioid and benzodiazepine products:</b> Risk of serious adverse events involving the central nervous system due to drug-drug interaction	●		●		
<b>Fluconazole:</b> Risk of spontaneous abortion; Safety information on multiple congenital abnormalities and use in lactation	●		●	●	
<b>MADRAC 159</b> 9 November 2017					
<b>Gadolinium contrast agents:</b> Evidence of gadolinium deposits in the brain after MRI body scans					●
<b>Modified-release paracetamol:</b> Overdose complexity					●
<b>Ribomustin® (bendamustine):</b> Increased mortality in non-approved combination treatments		●	●		
<b>Azithromycin and erythromycin (excluding topical and ophthalmic products):</b> Risk of Infantile Hypertrophic Pyloric Stenosis (IHPS)	●		●		
<b>Cobicistat and corticosteroids (excluding external use products):</b> Drug-drug interaction leading to risk of corticosteroidal systemic adverse reactions	●		●		

	DCA Directive	DHPC letter	Product information update	Publish article	Further review
<b>Statins:</b> Immune-mediated necrotising myopathy (IMNM)	●		●		
<b>Levetiracetam:</b> Acute kidney injury, rhabdomyolysis/ increased blood creatinine phosphokinase and encephalopathy	●		●		
<b>MADRAC 160</b> 16 January 2018					
<b>Doxycycline:</b> Jarisch-Herxheimer reaction					●
<b>Desloratadine and loratadine:</b> Risk of weight increase in children					●
<b>Camellia sinensis</b> (contained in green tea): Potential risk of hepatotoxicity					●
<b>Xofigo® (radium-223 dichloride):</b> Increased incidence of deaths and fractures in random clinical trials when used in combination with abiraterone acetate and prednisolone/prednisone		●	●		
<b>Minocycline:</b> Drug reaction with eosinophilia and systemic symptoms (DRESS)	●		●		
<b>Propofol and sodium valproate:</b> Risk of increased propofol exposure due to drug-drug interaction when propofol is used together with sodium valproate	●		●		
<b>Amoxicillin (single and combination products):</b> Subcutaneous adverse reactions (SCAR); Drug reaction with eosinophilia and systemic symptoms (DRESS)	●		●		
<b>Gabapentin:</b> Respiratory depression	●		●		
<b>Fluoroquinolones:</b> Persistence of serious side effects mainly affecting muscles, joints, and the nervous system					●



## Safety Monitoring of New Products

### Periodic Benefit-Risk Evaluation Reports (PBRER)/ Periodic Safety Update Reports (PSUR)

Newly registered products, namely New Chemical Entities (NCEs) and biologic products are required to submit Periodic Benefit-Risk Evaluation Reports/ Periodic Safety Update Reports (PBRERs/ PSURs) for the first five years post-registration. PBRERs/ PSURs contain information on the product safety profile in countries where it is registered, and any changes or new findings related to product safety.

In 2017, a total of **123 PBRERs/ PSURs** involving **199 products** were assessed, resulting in implementation of **package insert changes for 23 products (18.7%)** to ensure that they contain the latest safety information.

### Risk Management Plan (RMP)

Risk management plans (RMPs) are also submitted by product registration holders to NPRA when there is any concern about a risk affecting the benefit-risk balance of a product.

The NPRA received **RMPs for 32 registered products** in 2017, of which **four (4) were reviewed**. In addition, NPRA reviewed and approved **eight (8) educational materials** which consisted of information for healthcare professionals and patients. These involved **six (6) biologic products** and **two (2) New Chemical Entity (NCE) products**.



## Drug Safety Communication

### Publications

In 2017, the NPRA published and distributed **three (3) issues of the MADRAC Bulletin** and **six (6) issues of Reaksi drug safety newsletter** to highlight drug safety issues to local healthcare professionals and international regulatory agencies.

## MADRAC *Newsletter*

MADRAC Bulletin is a publication derived from the activities of the Malaysian Adverse Drug Reaction Advisory Committee (MADRAC). Besides the compilation of emerging safety news and regulatory actions on medicinal products as a result of the committee's meetings, it features recent pharmacovigilance activities, including new publications and updates on adverse drug reaction reporting.

[MADRAC Bulletin, Issue 1-2017, Vol. 22](#)

[MADRAC Bulletin, Issue 2-2017, Vol. 23](#)

[MADRAC Bulletin, Issue 3-2017, Vol. 24](#)



Reaksi Drug Safety Newsletter\* is one of NPRA's publications on drug safety. Its aim is to communicate urgent safety information in light of emerging drug safety issues, as well as provide warnings to healthcare professionals on newly identified adverse drug events.

[Reaksi Drug Safety News, January 2017, Vol. 33](#)

[Reaksi Drug Safety News, March 2017, Vol. 34](#)

[Reaksi Drug Safety News, Issue 3-2017, Vol. 35](#)

[Reaksi Drug Safety News, Issue 4-2017, Vol. 36](#)

[Reaksi Drug Safety News, Issue 5-2017, Vol. 37](#)

[Reaksi Drug Safety News, Issue 6-2017, Vol. 38](#)

\*Note: From 2018 onwards, there are no new publications of Reaksi Newsletter. For latest safety issues regarding medicine-use, please refer to Safety Alerts for Healthcare Professionals at [www.npra.gov.my](http://www.npra.gov.my)

## Direct Healthcare Professional Communication Letters

Besides the publications above, Direct Healthcare Professional Communication (DHPC) letters, or previously known as “Dear Doctor” letters, are used to communicate recent safety information to healthcare professionals, including important changes in prescribing information, new contraindications, newfound risks and safety issues. Submitted by the product registration holders, DHPC letters are reviewed and approved by NPRA before being distributed.

In 2017, a total of **nine (9) DHPC letters** were approved by the NPRA.

## ASEAN Post-Marketing Alert System

Developed by the Association of Southeast Asian Nations (ASEAN), the Post-Marketing Alert System (PMAS) functions as a product safety communication sharing system among ASEAN countries for medicinal products, traditional health products and other products. When a safety concern arises, a safety alert will be communicated by the PMAS coordinator of the respective country to ensure the information is distributed to all other ASEAN countries.

The PMAS exchanges information on:

- Products for which registration has been terminated, suspended, or withdrawn due to safety aspects;
- Products recalled from the market due to quality defects with serious public health implications;
- Products found to be adulterated and associated with serious public health implications;
- Significant label changes involving safety;
- New restrictions on usage, contraindication or prescribing information;
- Exchange of Direct Healthcare Professional Communication (DHPC) letters, media releases related to drug safety, and adverse drug reactions.

In 2017, the Pharmacovigilance Section of NPRA has communicated **31 alerts via the ASEAN PMAS**, involving **69 active ingredients** for a total of **1,110 products**.

### Electronic Mailing List

**The NPRA Safety Information Mailing List**, an electronic mailing list, was established in 2014 for healthcare professionals in an effort to ensure wider and faster spread of information. This mailing list is managed by the Pharmacovigilance Section and currently consists of **more than 2,000 individuals**, including doctors, dentists, pharmacists, nurses, assistant medical officers and assistant pharmacists.

### Consumer Medication Information Leaflets

Consumer Medication Information Leaflets, otherwise known as **Risalah Maklumat Ubat untuk Pengguna (RiMUP)** are a source of information for consumers, containing advice on how to use the medicines as well as important warnings. RiMUPs are prepared in Bahasa Malaysia and English by product registration holders, and they are reviewed and approved by the Pharmacovigilance Section in NPRA. Approved RiMUPs are uploaded on to the NPRA website, and are free for both consumers and healthcare professionals to download.

As of the end of 2017, there were RiMUPs for **1,100 products** available on the NPRA website.

### Mass Media

NPRA was also invited to participate in a talk show by **Media Prima** to increase awareness on the safe use of vaccines and clarify common misconceptions on AEFIs.



## Training and Other Pharmacovigilance Activities



### Pharmacovigilance Inspection Training

In May 2017, two NPRA officers were sent for an attachment programme at the **United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA)**. The objective of this training was to gain exposure on the processes involved in the preparation, opening, execution and closing of a pharmacovigilance inspection at a local pharmaceutical company. Facilitated by a team of MHRA PV inspectors, the NPRA officers have acquired new insight and first-hand experience to help establish NPRA's pharmacovigilance inspectorate in Malaysia.





## Vaccine Training Workshops

In 2017, NPRA participated in two international training workshops on vaccines. Both workshops were sponsored by the **World Health Organisation (WHO)** and were held in **Manila, Philippines**.



## Global Vaccine Safety Initiative (GVSI)



Global Vaccine Safety Initiative (GVSI) is a strategic document on vaccine safety that was developed by the World Health Organisation (WHO) and a group of partners to set up a framework aimed at enhancing global vaccine pharmacovigilance and other safety activities. This document defines indicators that aim to ensure all countries to meet a certain benchmark to achieve vaccine safety. GVSI is held annually as an important platform for GVSI member states and partners to interact, exchange information as well as to create opportunities for partnership-building and planning.

On 11-12 October 2017, Malaysia was honored to hold the sixth meeting of GVSI. In co-operation with the Association of Southeast Asian Nations (ASEAN) Pharmaceutical Product Working Group, the Ministry of Health of Malaysia hosted the meeting here in Kuala Lumpur. Among the attending parties were immunisation program managers, national regulatory authorities' pharmacovigilance officers from 24 countries, representatives from UN agencies, academic institutions, umbrella organisation of pharmaceutical companies, industry representatives, technical partners and funding agencies.

Joining in the participation, NPRA shared a session to talk about developing pharmacovigilance inspection capacities in Malaysia as well as other pharmacovigilance activities.



## Training Sessions on ADR Report Analysis and Causality Assessment

Further measures are being taken to increase the quality of ADR reports in Malaysia.

With the new pharmacovigilance system and database, as well as continuous training for reporters, it is hoped that more complete reports will be received.

Over the past five years, NPRA has conducted training sessions all across Malaysia on ADR report analysis and causality assessment. In 2017, training was held in **Pahang**, involving **40 pharmacists**.

Besides the causality assessment training mentioned above, there were **24 training programmes** conducted or presentations delivered, which involved **more than 1,300 participants**. These sessions aimed to increase awareness on the importance of reporting, improve the quality of ADR/AEFI reporting, and training reporters to assess causality.

## CPD Points for ADR Reporting by pharmacists

As part of efforts to increase the quantity and quality of ADR reports in particular from private sector healthcare professionals, 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 (maximum of 10 points per year) under category A4 for every ADR report submitted to the NPRA which fulfills certain mandatory criteria [Ref: KKM-55/BPF/101/001/01 JLD 29 (20) and KKM.600-16/1/6(57)].

In 2017, a total of **52 ADR reports** were evaluated and approved for CPD points claim.

## Annie & Mac's Adventures: Pharmacovigilance Comic Book

In collaboration with the Uppsala Monitoring Centre (UMC), which is the World Health Organisation (WHO) Collaborating Centre for International Drug Monitoring, NPRA has participated in a pilot survey to introduce a comic book entitled “**Annie & Mac's Adventures**” to Malaysian children.

Annie & Mac's Adventures is about a brave young girl, Annie, and her loyal partner Mac, a humming bird. They fight hand-in-hand against criminal mastermind Count Erfeit, whose agenda is to earn profit from selling counterfeit medicines to the public. This comic is aimed at children aged 9-13 years and contains a storyline as well as exciting activity pages for young minds. The goal of the comic book is to create awareness about medicines safety among children, to increase medicines safety knowledge in this target audience, and to empower children to share this knowledge with other children as well as adults in their community.

UMC initiated a pilot phase of the comic's first issue in various countries, including Malaysia. NPRA conducted this pilot survey involving a group of primary school children in Kuala Lumpur. The response received by these children were positive as the comic book was found to be easy to understand, exciting and interactive. The children hoped to see more of Annie & Mac's adventures. Feedback and new ideas were relayed to UMC to further develop the comic.

## Research Collaboration

The National Centre carried out collaboration with local universities for research projects, particularly involving Masters and PhD students.

