National Pharmaceutical Regulatory Agency
Ministry of Health, Malaysia

2019
ANNUAL REPORT
NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING

Ministry of Health, Malaysia

NATIONAL CENTER FOR ADVERSE DRUG REACTIONS MONITORING: ANNUAL REPORT 2019

Published by:
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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 the products registered in Malaysia.

Inside this report

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 (ADR) reports and adverse events following immunisation (AEFI) 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 product, 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 2019, with **22,085 ADR reports** presented for verification of causality.

Ex-officio	Chairman **Datin Dr. Faridah Aryani Md. Yusof** Director of NPRA
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(Alternate members)

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Federation of Private Medical Practitioners' Associations Malaysia (FPMPAM)
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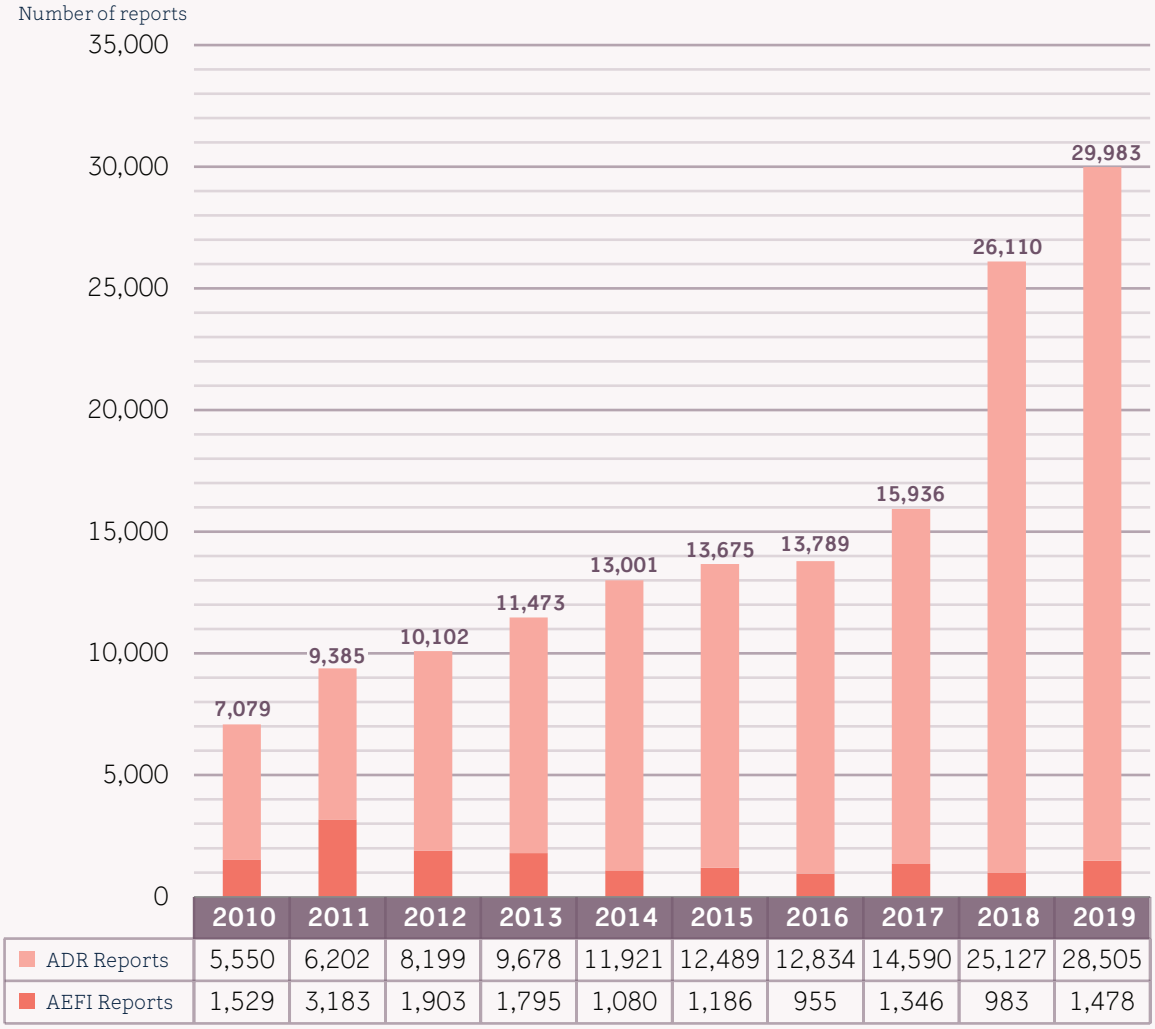
Eliza Basir
Association of Private Hospitals of Malaysia (APHM)
(Zarihasyum Wan Zein)

Harpreet Kaur Darshan Singh
Malaysian Pharmaceutical Society (MPS)
(Charmaine Tan Shwu Fen)

Analysis of ADR/AEFI Reports

The National Centre received **29,983 adverse event reports** in 2019, showing a **12.9%** 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 **27,385 viable new reports** were entered into the Malaysian pharmacovigilance database and sent to the World Health Organisation (WHO) Collaborating Centre for International Drug Monitoring in Uppsala, for inclusion into the VigiBase, the WHO global database of individual case safety reports (ICSRs).

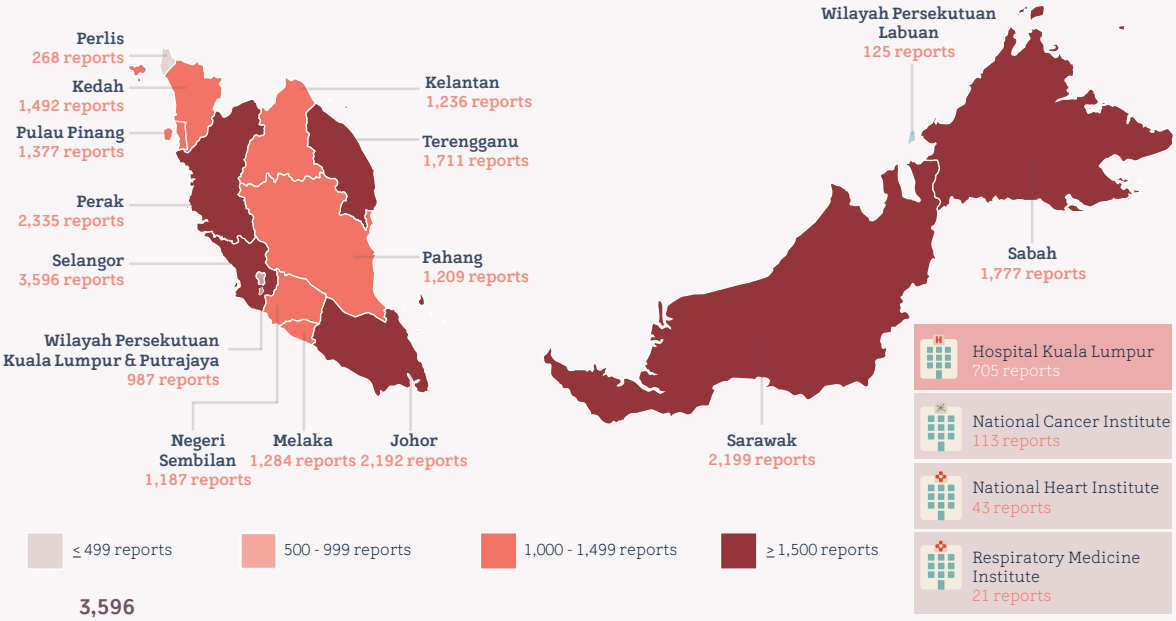
Total Number of ADR and AEFI Reports Received in Malaysia 2010-2019

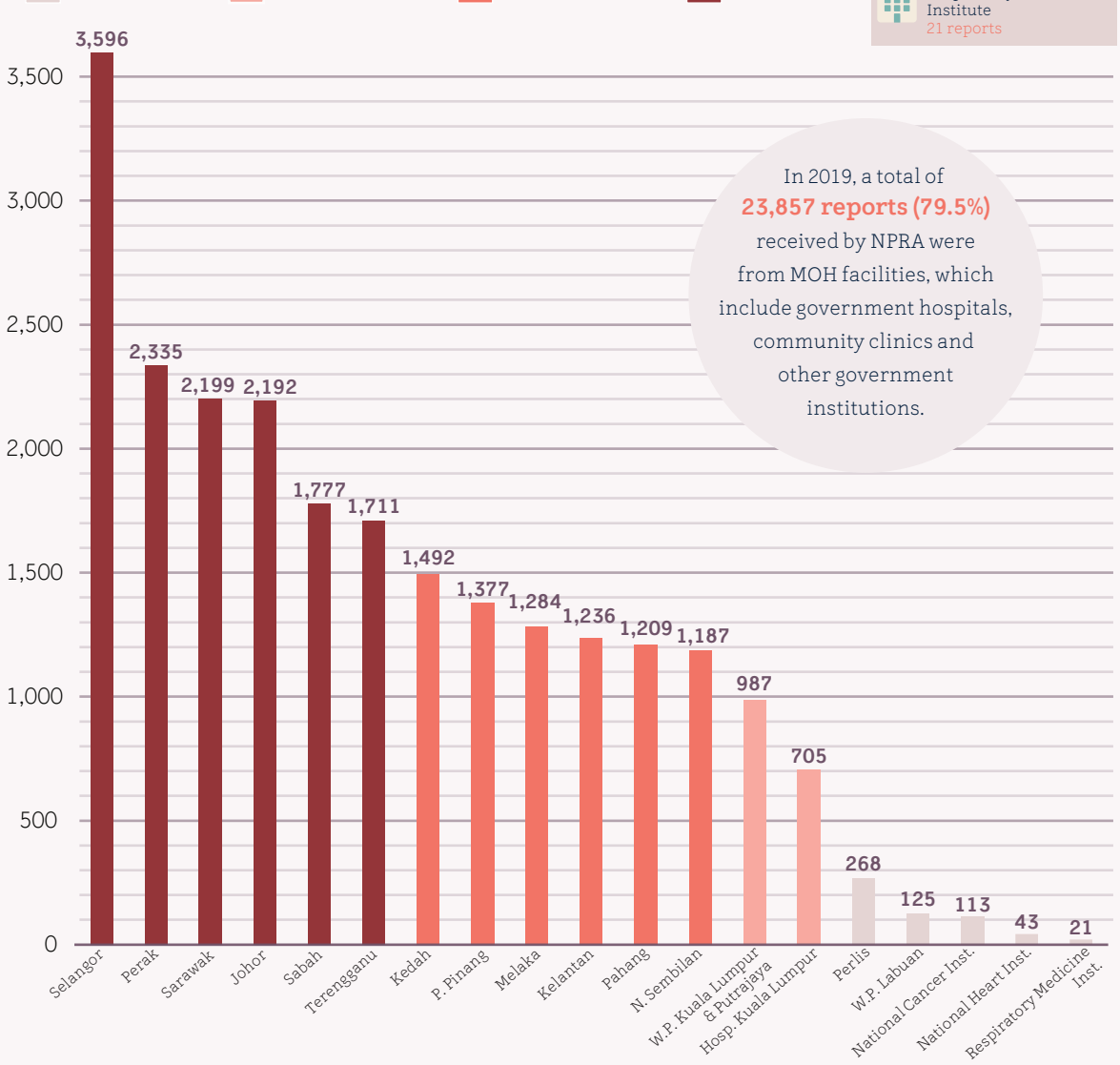


	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
ADR Reports	5,550	6,202	8,199	9,678	11,921	12,489	12,834	14,590	25,127	28,505
AEFI Reports	1,529	3,183	1,903	1,795	1,080	1,186	955	1,346	983	1,478

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.

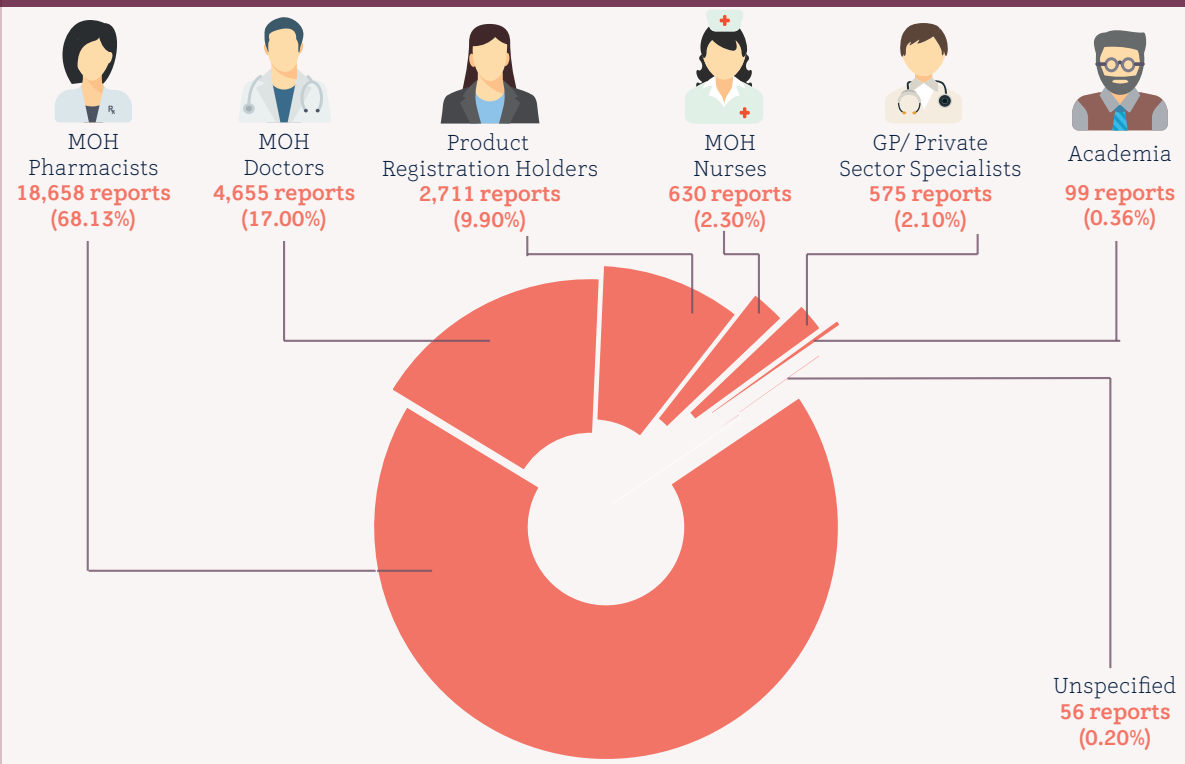
Distribution of ADR / AEFI Reports Received from Ministry of Health (MOH) Facilities, 2019



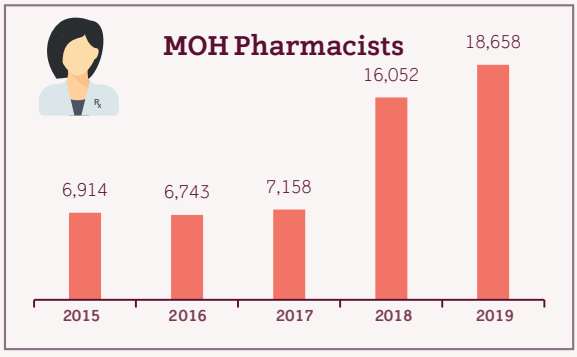


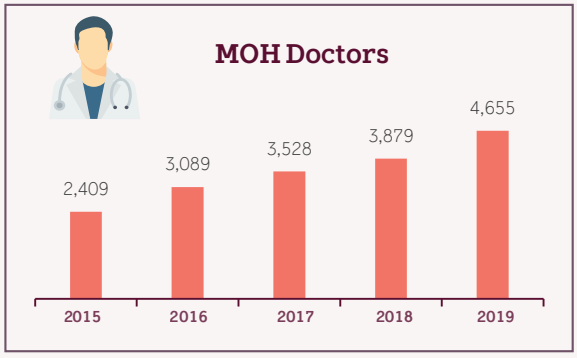
In 2019, a total of **23,857 reports (79.5%)** received by NPRA were from MOH facilities, which include government hospitals, community clinics and other government institutions.

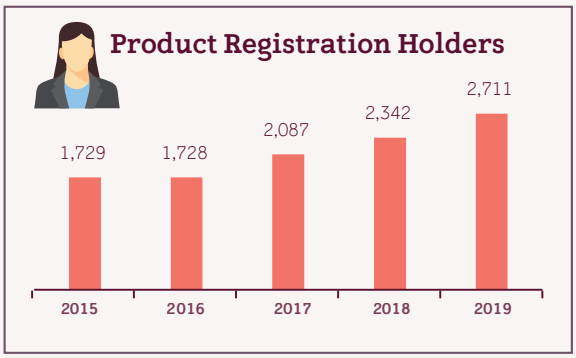
ADR/ AEFI Reports Received by Reporter Category, 2019

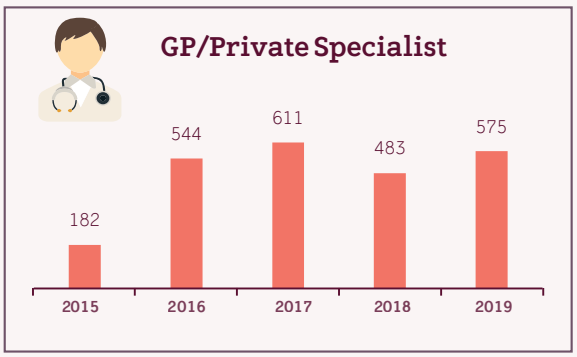


ADR/ AEFI Reports Received by 4 Main Reporter Category 2014-2018









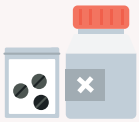
Number of Products Involved in ADR/ AEFI Reports, 2019

26,453
Poisons & prescription items

1,109
Non-poisons

274
Traditional products

65
Food products



231
Unregistered products

ADR/ AEFI Reports Received by Patient's Age Group Category, 2019

27 reports
Neonates less than
1 month old

630 reports
Infants
1 month - 1 year old

2,465 reports
Children
1 - 12 years old

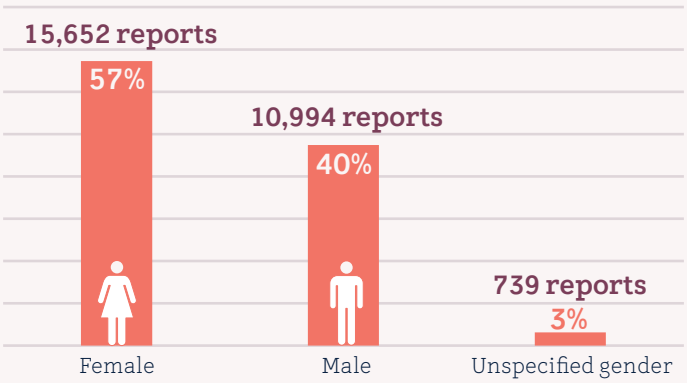
1,232 reports
Adolescents
13 - 18 years old

15,061 reports
Adults
18 - 60 years old

6,572 reports
Elderly more than
60 years old

1,314 reports
Unspecified age

ADR/ AEFI Reports Received by Patient's Gender, 2019



Number of Adverse Drug Reactions Categorised by System Organ Class, 2019

System Organ Class	No. of ADRs
Skin and subcutaneous tissue disorders	13,278
General disorders and administration site conditions	5,720
Respiratory, thoracic and mediastinal disorders	3,700
Gastrointestinal disorders	3,688
Nervous system disorders	3,616
Eye disorders	3,424
Investigations (e.g. platelet count decreased, blood glucose increased)	1,247
Musculoskeletal and connective tissue disorders	747
Cardiac disorders	630
Infections and infestations	550
Vascular disorders	477
Psychiatric disorders	380
Metabolism and nutrition disorders	363
Immune system disorders	308
Renal and urinary disorders	257
Injury, poisoning and procedural complications	214
Blood and lymphatic system disorders	209
Hepatobiliary disorders	156
Ear and labyrinth disorders	145
Reproductive system and breast disorders	123
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	96
Endocrine disorders	53
Pregnancy, puerperium and perinatal conditions	18
Congenital, familial and genetic disorders	5
Surgical and medical procedures	3

2019 Top 10 Most Reported MedDRA System Organ Class

1

Skin and subcutaneous tissue disorders
13,278 ADRs

2

General disorders and administration site conditions
5,720 ADRs

3

Respiratory, thoracic and mediastinal disorders
3,700 ADRs

4

Gastrointestinal disorders
3,688 ADRs

5

Nervous system disorders
3,616 ADRs

6

Eye disorders
3,424 ADRs

7

Investigations
1,247 ADRs

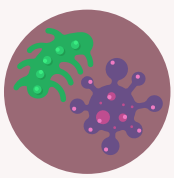
8

Musculoskeletal and connective tissue disorders
747 ADRs

9

Cardiac disorders
630 ADRs

10



Infections and infestations
550 ADRs

Number of Adverse Drug Reactions Categorised by Pharmacological Group, 2019

Pharmacological Group	No. of ADRs
Antiinfectives	6,908
Cardiovascular agents	4,526
Analgesics	4,397
Antidiabetics	1,810
Others	1,773
Vaccines	1,478
Antineoplastics	1,180
Neurogenic agents	1,039
Antihyperlipidaemics	604
Vitamins	516
Antituberculosis	494
Antiulcers	439
Antiemetics	350
Antigouts	335
Antiasthmatics	269
Antivirals	263
Anticoagulants	262
Traditional medicines	248
Health supplements and minerals	231
Immunosuppressive agents	218
Antihistamines	203
Corticosteroids	158
Eye preparations	152
Contrast media	111
Dermatologicals	88
Anaesthetics	81

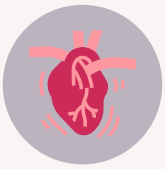
2019 Top 10 Most Reported Pharmacological Group

1

Anti infectives

6,908 ADRs

2



Cardiovascular agents

4,526 ADRs

3

Analgesics

4,397 ADRs

4

Anti diabetics

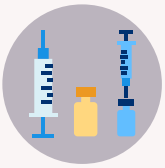
1,810 ADRs

5

Others

1,773 ADRs

6



Vaccines

1,478 ADRs

7

Anti neoplastics

1,180 ADRs

8

Neurogenic agents

1,039 ADRs

9

Anti hyperlipidaemic

604 ADRs

10

Vitamins

516 ADRs

Monitoring Drug Safety Issues

In 2019, a total of **141 drug safety issues** were identified through proactive screening of published information and pharmacovigilance databases. Following review, **17 issues were presented at MADRAC meetings** to determine the appropriate risk minimisation measures (refer to page 15-18). The majority of these issues resulted in updates to the product safety information, such as tightening of indications or additional contraindications. **Regulatory actions** were proposed to the DCA for **13 of these issues** , resulting in DCA directives issued to ensure product inserts and consumer information leaflets of all products containing the affected active ingredients are updated with the required safety information.

6
MADRAC meetings

17
Safety issues presented

13
Safety issues resulted in package insert and consumer medication leaflet updates

6
Direct Healthcare Professional Communication (DHPC) letters

673
Products involved in regulatory action

Besides that, review and approval of safety-related updates to product package inserts were carried out for **185 products (100%)** out of 185 applications received.

MADRAC 167 24 January 2019	DCA Directive	DHPC Letter	Product Information Update	Safety Alert	Further Review
Direct -acting antivirals: Hypoglycaemia					●
Xylometazoline: Increased risk of serious ventricular arrhythmias in patients with long QT syndrome					●
Sodium valproate: Risk of congenital malformation and developmental problem in utero-exposed children					●
Noradrenaline: Stress cardiomyopathy	●		●	●	
Retinoids (oral formulations): Risk of neuropsychiatric disorders	●		●	●	
MADRAC 168 21 March 2019					
Vascular Endothelial Growth Factor Receptor (VEGFR) Tyrosine Kinase Inhibitors (TKI): Risk of artery dissections and artery aneurysms					●
Carbimazole and methimazole (thiamazole): (i) Strenghtening measures on known risk of birth defects and neonatal disorders in case of exposure during pregnancy (ii) Risk of pancreatitits					●
Dulaglutide, exenatide and liraglutide: Diabetic ketoacidosis					●
Tapentadol: Risk of seizures and reports of serotonin syndrome when co-administered with other drugs					●
Fluoroquinolones (excluding topical formulations and eye preparations): Risk of aortic aneurysm and aortic dissection	●		●	●	
Hydrochlorothiazide: Non-melanoma skin cancer (NMSC)	●		●	●	
Montelukast: Obsessive-compulsive symptoms	●		●	●	

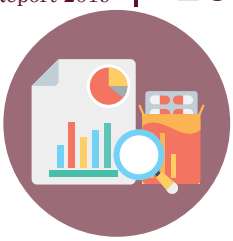
MADRAC 169 16 May 2019	DCA Directive	DHPC Letter	Product Information Update	Safety Alert	Further Review
Posaconazole: Risk of pseudohyperaldosteronism					●
Deferiprone: Risk of neurological disorders in children					●
Tecentriq® (atezolizumab): Risk of immune-related myositis		●		●	
Darzalex® (daratumumab): New identified risk of Hepatitis B reactivation		●		●	
Imovane® (zopiclone): New restriction in indication to "short term" treatment of insomnia and additional warnings on the abuse and dependence related to the duration of treatment		●		●	
Benlysta® (belimumab): Increased risk of serious psychiatric events (depression and/or suicidal ideation or behaviour or self-injury)		●		●	
Sodium valroate: (i) Risk of congenital malformations and developmental problems in infants and children exposed to sodium valproate during pregnancy (ii) Educational materials	●		●	●	
Fluoroquinolones (systemic formulations including oral and injection dosage forms): (i) Restriction of indication and (ii) Warnings on disabling and potentially permanent side effects (tendinitis, tendon rupture, peripheral neuropathy and central nervous system/neuropsychiatric effects)	●		●	●	
Topiramate: Risk of nephrocalcinosis	●		●	●	
Lamotrigine: Risk of Brugada-Type ECG	●		●	●	

MADRAC 170 25 July 2019	DCA Directive	DHPC Letter	Product Information Update	Safety Alert	Further Review
Loperamide overdose: Unmasking of Brugada syndrome					●
Diclofenac (systemic formulations): Risk of anastomotic leakage and Kounis syndrome					●
Clopidogrel: Interaction with boosted antiviral Human Immunodeficiency Virus (HIV) therapy leading to insufficient inhibition of platelet aggregation					●
Actemra® (tocilizumab): New important identified risk of hepatotoxicity		●		●	
Retinoids indicated for treatment of skin diseases (including topical formulations): (i) Strengthening of safety information on teratogenicity (ii) Educational material (oral formulations) (iii) Updates on registration requirement (oral formulations)	●		●	●	
MADRAC 171 26 September 2019					
Propofol: Risk of priapism					●
Temozolomide: Drug reaction with eosinophilia and systemic symptoms (DRESS)					●
Sulfasalazine: Interference with dihydronicotinamide-adenine dinucleotide/ dihydronicotinamide-adenine dinucleotide phosphate (NADH/NADHPH) reaction assays					●
Carbimazole and methimazole (thiamazole): (i) Risk of acute pancreatitis (ii) Risk of congenital malformations	●		●	●	
Loperamide: Unmasking Brugada syndrome associated with overdosage	●		●	●	

MADRAC 172
14 November 2019

	DCA Directive	DHPC Letter	Product Information Update	Safety Alert	Further Review
Cyclin-dependent kinase (CDK 4/6) inhibitor: Risk if severe lung inflammation (interstitial lung disease and pneumonitis)					●
Ondansetron: Birth defects					●
Fingolimod: New contraindication in pregnant women and in women of childbearing potential not using effective contraception					●
Feburic® (febuxostat): Increased risk of cardiovascular death and all-cause mortality		●		●	
Sulfasalazine: Risk of interference with dihydronicotinamide-adenine dinucleotide/dihydronicotinamide-adenine dinucleotide phosphate (NADH/NADHPH) reaction assays	●		●	●	

Safety Monitoring of New Products



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

For the first five years of post-registration, product registration holders are required to submit Periodic Benefit-Risk Evaluation Reports/ Periodic Safety Update Reports (PBRERs/PSURs) on newly registered products, namely New Chemical Entities (NCEs) and biologic products. 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 2019, a total of **98 PBRERs** involving **58 products** were assessed, resulting in implementation of **package insert changes** for **11 products** (11.2%) to ensure that they contain the latest safety information.

Risk Management Plan (RMP)

Product registration holders are required to submit post-registration Risk Management Plans (RMPs) when there is any concern about a risk affecting the benefit-risk balance of a product.

In 2019, a total of **56 post-registration RMPs** were reviewed, which accounted for a total number of **44 registered products**. In addition, **six (6) educational materials** which consisted of information for healthcare professionals and patients were reviewed and approved. These involved **three (3) biologic products** and **three (3) New Chemical Entity (NCE) products**.

Drug Safety Communication

Publications

MADRAC Bulletin

MADRAC Bulletin features articles based on local adverse drug reactions/adverse events following immunisation data of a particular drug, followed by discussion and advice to healthcare professionals. These articles are aimed to capture the interest of healthcare professionals in the clinical setting to help identify adverse drug events, practise caution when prescribing, dispensing or counselling of medicines to patients as well as to encourage ADR/AEFI reporting. MADRAC Bulletin also keeps its readers up to date with new directives issued to communicate recent drug safety issues, changes in drug prescribing information as well as new warnings and precautions.

NPRA has published and distributed three (3) MADRAC Buletin issues in 2019, which are available on the NPRA webiste via MADRAC Bulletin, as follows:

MADRAC Bulletin, Issue 1-2019, Vol. 28

MADRAC Bulletin, Issue 2-2019, Vol. 29

MADRAC Bulletin, Issue 3-2019, Vol. 30

Safety Alerts

Safety Alerts are concise drug-related articles published in the NPRA website which are intended to alert healthcare professionals on new drug safety issues that arise as a result from drug safety reviews by NPRA and other international regulatory agencies. This communication is a form of risk minimisation measure taken to reduce the risk of adverse events of new and existing registered products in Malaysia.

In 2019, NPRA has published 24 safety alerts to highlight drug safety issues. The full list of safety alerts in 2019 is available on the NPRA webiste via Safety Alerts.

Direct Healthcare Professional Communication (DHPC) Letter

Besides the publications above, Direct Health 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. DHPC letters submitted by the product registration holders are reviewed and approved by NPRA before being distributed.

In 2019, a total of **six (6) DHPC letters** were approved by 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 2019, the Pharmacovigilance Section of NPRA has communicated **15 alerts** via ASEAN PMAS, involving **54 active ingredients** for total **693 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, nurse, assistant medical officers, assistant pharmacists, and regulatory affairs professionals.

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 officers in NPRA.

In 2019, a total of **420 RIMUPs** were approved by the Pharmacovigilance Section in NPRA and is available on the NPRA website via Product Search.

Training and Other Pharmacovigilance Activities

In the past years, NPRA has conducted a variety of training sessions for stakeholders in Malaysia, including healthcare professionals from both public and private health institutions, university students, pharmaceutical companies, and regulators. The majority of the training sessions focused on spontaneous reporting and causality assessment; other topics of pharmacovigilance covered included risk assessment, risk management, risk communication, and implementing pharmacovigilance in pharmaceutical companies.

In 2019, a total of **40 training sessions** through seminars, workshops, conferences, on-site visits, awareness campaigns, and media interviews were held and/or attended by NPRA officers as speakers.

These trainings were held in various locations, including Kuala Lumpur, Johor Bahru, Kuantan, Sungai Buloh, Cheras and Kuching throughout the year, which involved an accumulated number of **995 participants**.

Training Sessions on Quality ADR/AEFI Reporting and Causality Assessment

NPRA is making continuous efforts to increase both the quantity and quality of spontaneous reports in Malaysia. The training sessions were conducted throughout the year with the aims to increase awareness on the importance of reporting, to improve the quality of ADR/AEFI reporting, and to train reporters on how to assess causality.

With the new pharmacovigilance system and database being upgraded since 2017 as well as continuing educational programmes for reporters, it is envisioned the National Centre for Adverse Drug Reactions Monitoring will receive a higher volume of high-quality and complete reports in the coming years.

Training Attachment by Officers from the National Drug Authority Uganda on Pharmacovigilance of Herbal Products

On 15th-19th April 2019, NPRA hosted a training attachment attended by officers from the National Drug Authority Uganda to learn about Malaysian experience with regulatory control of traditional medicines including pharmacovigilance of herbal products. Several aspects covering the Malaysian pharmacovigilance system, legislative framework, and adverse event reporting, were shared and discussed.

Radio Interview Session on Consumer Reporting

Pharmacovigilance officers from NPRA were invited to a radio interview session to talk about how medication safety is monitored in Malaysia and to raise public awareness on side effects reporting.

PMDA-ATC Pharmacovigilance Seminar 2019

From 4-7th February 2019, two (2) pharmacovigilance officers were sent to attend a pharmacovigilance seminar organised by Pharmaceuticals and Medical Devices Agency (Japanese national regulatory agency) and Asia Training Center (ATC) for Pharmaceuticals and Medical Devices Regulatory Affairs.

The objective of the seminar was to gain knowledge that PV officers may utilise in order to enhance the pharmacovigilance system in their home countries. Among the topics covered in the seminar were the importance of harmonised regulatory strategies, risk management tools and risk minimisation actions per safety specifications identified by signal detection and benefit-risk analysis, as well as the collection and accumulation of ADR reports and methodology of signal detection using such accumulated data.

5th Asia Pacific Pharmacovigilance Training Course

The Indian Pharmacopoeia Commission (IPC), in collaboration with Uppsala Monitoring Centre (UMC), Sweden, has hosted the 5th "Asia Pacific Pharmacovigilance Training Course" from 4th to 15th March 2019 in Ghaziabad, India. This training course, which was tailored to regional needs and addressed challenges unique to pharmacovigilance, aimed to establish effective, collaborative, and sustainable pharmacovigilance practices for member countries of the WHO Programme for International Drug Monitoring (WHO-PIDM) and individuals involved in the field. With the goal of strengthening future generations' capacity in promoting safe medication use, one pharmacovigilance officer from Malaysia and about 29 participants from other 13 countries — Sweden, Zimbabwe, Malawi, Congo, Swaziland, Bangladesh, Vietnam, etc. — were being acquainted on fundamental knowledge and concept of pharmacovigilance.

Workshops on Country Plan for Vaccine-Preventable Diseases & Implementation Plan for Pneumococcal Vaccine

In 2019, NPRA participated in two (2) national workshops on vaccines organised by the Malaysian MOH's Family Health Development Division. The first workshop on the national plan for vaccine-preventable diseases in February 2019 was aimed at defining targets for the national immunisation programme for children as well as the elimination of the measles virus. The second workshop in October 2019 focused on developing an implementation plan for pneumococcal vaccination, which had been newly introduced to the national immunisation programme.

Expert Witness Training

In April 2019, one pharmacovigilance officer attended the Training on Expert Witness organised by the Medico Legal Section of the Malaysian MOH. The objectives of the course were to train and expose the senior healthcare officers on their roles as an expert witness in court, principles of medical negligence, importance of communication and documentation. The three-day course included lectures by academicians, senior consultant clinicians and legal counsels, as well as a mock trial session.

APEC LSIF RHSC Center of Excellence in Regulatory Sciences Pilot Workshop on Pharmacovigilance

Two (2) pharmacovigilance officers participated in the 2019 APEC LSIF RHSC (Asia Pacific Economic Cooperation, Life Science Innovation Forum, Regulatory Harmonization Steering Committee) Center of Excellence in Regulatory Sciences Pilot Workshop on Pharmacovigilance, which was held 23rd-25th April at Peking University in Beijing, China. The training course was aimed to promote regulatory convergence, capacity, and collaborations among the pharmacovigilance systems of the member economies in the Asia-Pacific region.

Regulatory Training by Swissmedic

One senior pharmacovigilance officer was invited to attend a Regulatory Training course in Switzerland from 29th April to 2nd May 2019, which was jointly organised by Swissmedic and the WHO. The four-day programme included hands-on training and Q&A to help participants from Ethiopia, Kenya, Eritrea, Sudan, South Sudan and Turkey better understand and implement the standard practices to their respective countries. The expert teams gained a better understanding of current capabilities, strengths, and issues of both Swissmedic and visiting national regulatory authorities via the key operational areas addressed in the three modules: "Quality Management Systems" (document management system, QMS within GMP/GCP inspections and laboratory), "Marketing authorisation" (reviewing applications, authorisation processes, case management, preclinical review, clinical review, quality review), and "Market Surveillance" (focusing on pharmacovigilance, overview: market monitoring/illegal activities).

1st TGP Inspirational Leadership Symposium

Since June 2014, the Talent Grooming Programme (TGP) under the Malaysian MOH, has aimed to strengthen leadership capability and develop governance excellence among potential technical healthcare professionals within the Ministry, with the ultimate goal of improving health system performance and population health through effective healthcare leadership. One pharmacovigilance officer had the pleasure of joining the 1st TGP Inspirational Leadership Symposium — "The Building Blocks of Leadership" on 3rd and 4th July 2019, which provided a platform for well-known, established prominent public figures to share their experiences and knowledge gained over their long and illustrious careers.

WHO Global Vaccine Safety Summit

The Global Vaccine Safety Summit, held from 2nd to 3rd December 2019 in conjunction with the 20th anniversary of the WHO's Global Advisory Committee on Vaccine Safety (GACVS), provided an opportunity to reflect on the GACVS's accomplishments and set priorities for the future decade. The Summit was intended for vaccine safety stakeholders from around the world, including current and former members of the GACVS, immunisation programme managers, national regulatory authorities, pharmacovigilance staff (including one officer from NPRA) from all WHO regions, as well as representatives of United Nation agencies, academic institutions, umbrella organisations of pharmaceutical companies, technical partners, industry representatives and funding agencies. The Global Vaccine Safety Blueprint 2.0 strategy for 2021-2030 was also presented at the Summit to key stakeholders for their input prior to publication.

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 2019, a total of **209 ADR reports** (a 45.9% increment from the previous year) received from pharmacists in the private sector were evaluated and approved for CPD points claim.

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