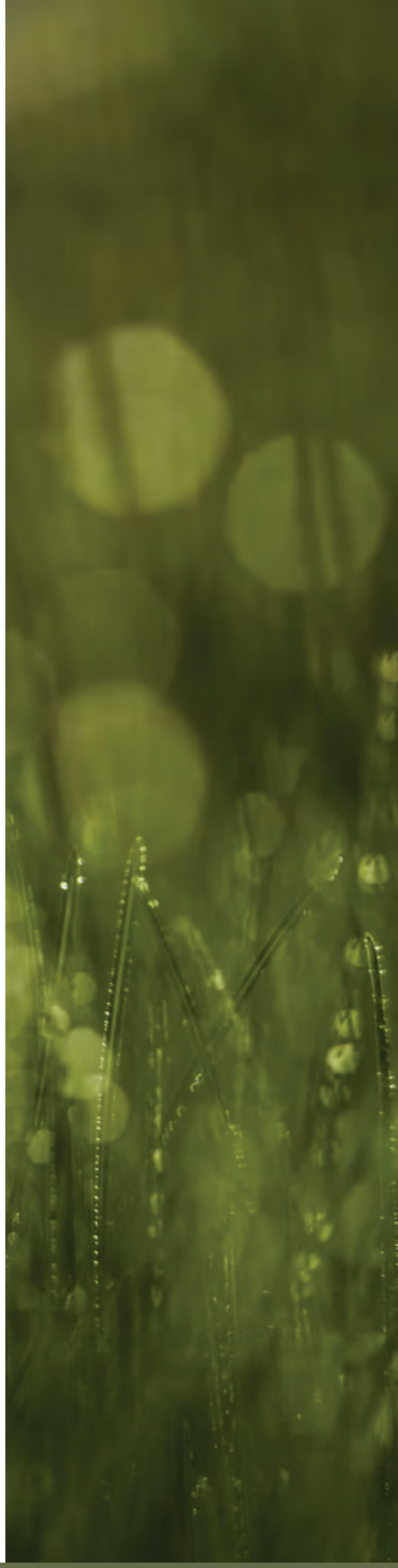
National Pharmaceutical Regulatory Agency
Ministry of Health, Malaysia

2020
ANNUAL REPORT
NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING



Ministry of Health, Malaysia

NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING: ANNUAL REPORT 2020

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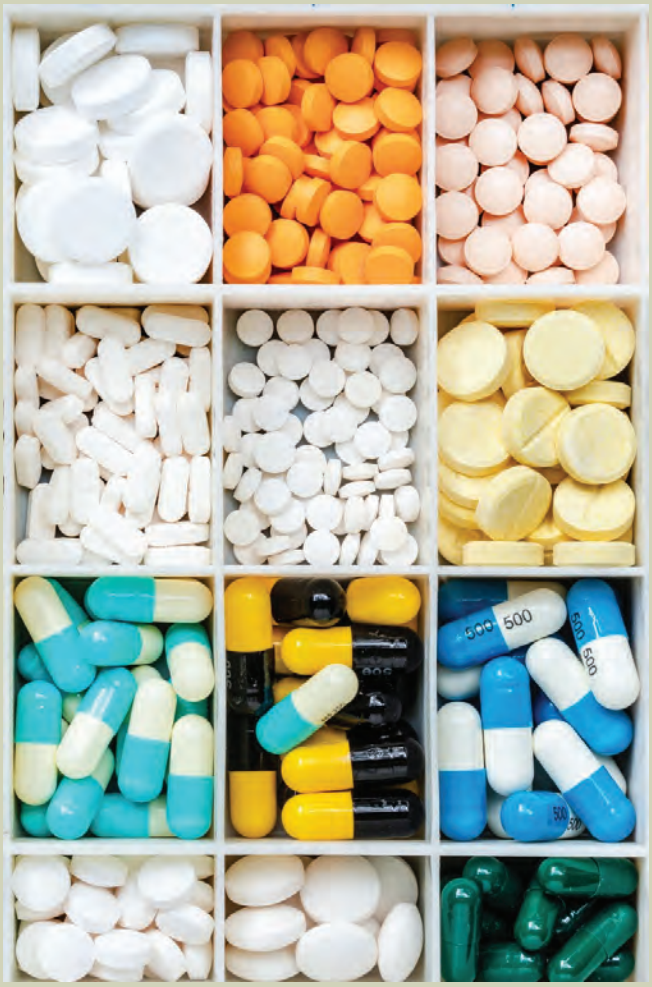
Our Purpose

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 repository for all adverse drug reaction (ADR) reports and adverse events following immunisation (AEFI) reports received by the National Pharmaceutical Regulatory Agency (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.

Appointment of MADRAC members are made every three (3) years, and the Pharmacovigilance Section, Centre of Compliance & Quality Control, NPRA is the Secretariat to the Committee. During MADRAC meetings held once every three months, causality verification is done for all local reports of ADR/AEFI and all pertinent drug safety issues are discussed to provide DCA with information and recommendations if required.

A total of **four (4) MADRAC meetings** were held in 2020.

Table 1: Members of MADRAC Session 2019-2021

Ex-officio	Chairman **YBhg. Datin Dr. Faridah Aryani Md. Yusof / YBrs. Dr. Hasenah Ali** Director of NPRA
	Secretary to MADRAC **YBrs. Dr. Roshayati Mohamad Sani** Deputy Director, Centre for Compliance & Quality Control
	Secretary of the Drug Control Authority **YBrs. Pn. Rosilawati Ahmad** Deputy Director, Centre of Product & Cosmetics Evaluation
Commitee Members *(Alternate members)*	**YBhg. Datuk Dr. Noel Thomas Ross** Senior Medical Consultant Hospital Kuala Lumpur *(Dr. Marzilawati binti Abdul Rahman)*
	Dr. Mollyza Mohd. Zain National Head of Rheumatology and Senior Medical Consultant (Rheumatology), Hospital Selayang *(Dr. Liza Mohd. Isa)*
	Dr. Suganthi Thevarajah National Head of Dermatology and Senior Consultant Dermatologist, Hospital Kuala Lumpur *(Dr. Tang Min Moon)*

Commitee Members

(Alternate members)

Dr. Sunita Bavanandan
Head of Department and Senior Consultant Nephrologist,
Hospital Kuala Lumpur
(Dr. Suryati Yakob)

Dr. Ramli Ali
Senior Consultant Psychiatrist
Hospital Kuala Lumpur
(Dr. Uma Visvalingam)

Dr. Farah Inaz Syed Abdullah
Senior Consultant Paediatrician and Neonatologist,
Hospital Tunku Azizah
(Dr. Lim Poi Giok)

Dr. Mohd. Sapawi Mohamed
Consultant Cardiologist,
Hospital Raja Perempuan Zainab II
(Dr. Siti Khairani Zainal Abidin)

Dr. Voon Pei Jye
Medical Oncologist
Hospital Umum Sarawak
(Dr. Ibtisam Muhamad Nor)

Dr. A'aisah Senin
Head of Vaccine Preventable Diseases and Food & Water Borne Diseases Sector
Disease Control Division
Ministry of Health
(Dr. Jamiatul Aida Md. Sani)

Dr. Adliah Mhd. Ali
Faculty of Pharmacy
Universiti Kebangsaan Malaysia
(Pn. Kamaliah Md. Saman)

Rozita Mohamad
Deputy Director
Pharmaceutical Care Division
Pharmacy Practice & Development Division
(Rosliza Lajis)

Dr. Thirunavukarasu Rajoo
Malaysian Medical Association (MMA)
(Dr. Sivanaesan Letchumanan)

Dr. G. Shanmuganathan
Federation of Private Medical Practitioners' Associations Malaysia (FPMPAM)
(Dr. Pearl Leong Yuet Mae)

Eliza Basir
Association of Private Hospitals of Malaysia (APHM)
(Zarihasyum Wan Zein)

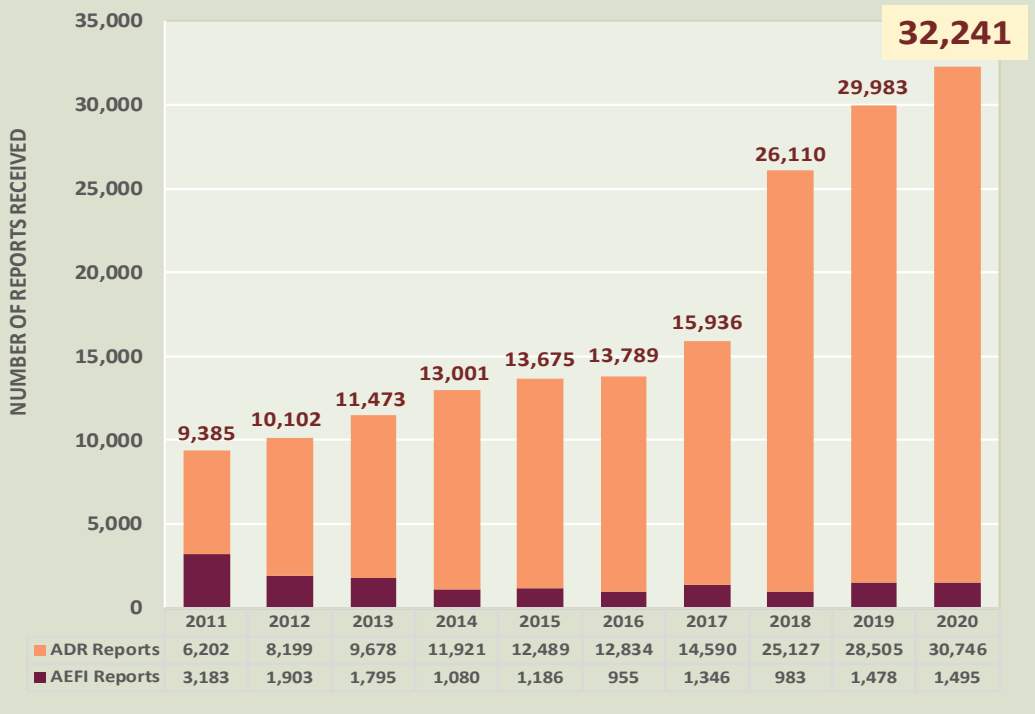
Harpreet Kaur Darshan Singh
Malaysian Pharmaceutical Society (MPS)
(Charmaine Tan Shwu Fen)

Analysis of ADR/AEFI Reports

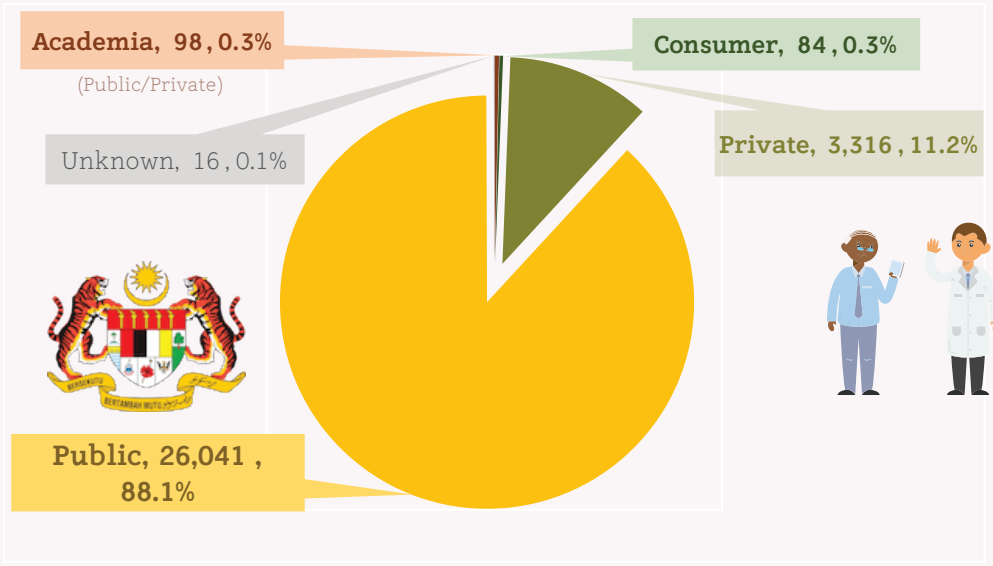
The National Centre received **32,241 adverse event (ADR/AEFI) reports** in 2020, showing a **7.5%** increase from the previous year. Once these reports were processed to exclude any duplicates, follow-up reports to cases sent in earlier, and rejected reports, a total of **29,555 reports** were recorded in the Malaysian pharmacovigilance database (QUEST). Following causality assessment at MADRAC meetings, in 2020, **20,269 viable new reports** (excluding traditional products/food products) were submitted to the World Health Organisation (WHO) Collaborating Centre for International Drug Monitoring in Uppsala, for inclusion into the VigiBase, which is the WHO global database of individual case safety reports (ICSRs).

The collected data will be reviewed and analysed not only for changing patterns and trends of any adverse event but also for new safety signals that can be further evaluated and confirmed.

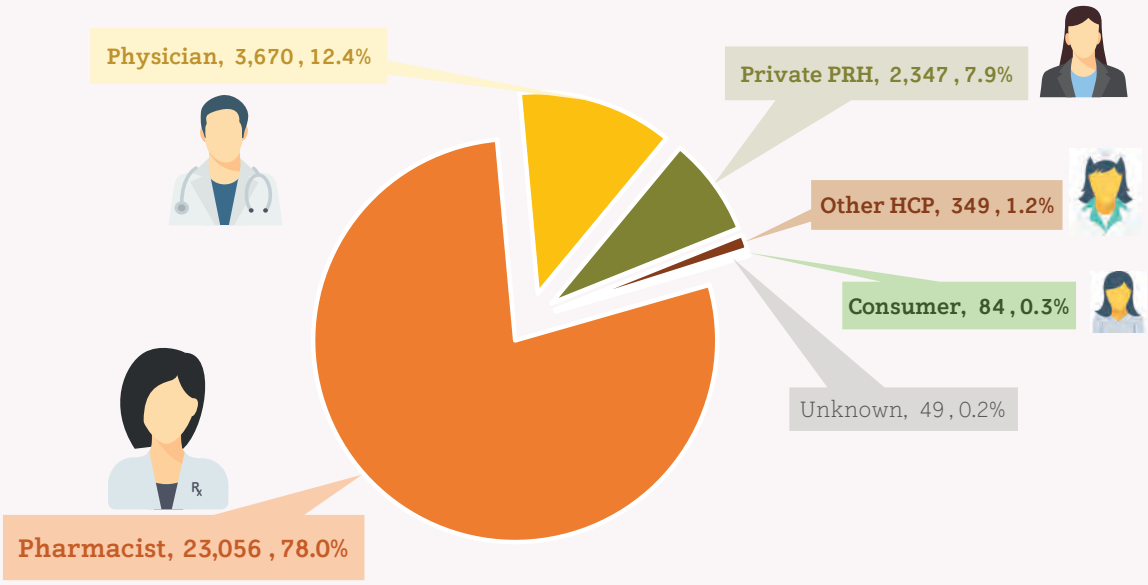
Total Number of ADR and AEFI Reports Received in Malaysia 2011-2020



Distribution of ADR/AEFI Reports Recorded by Sector, 2020*



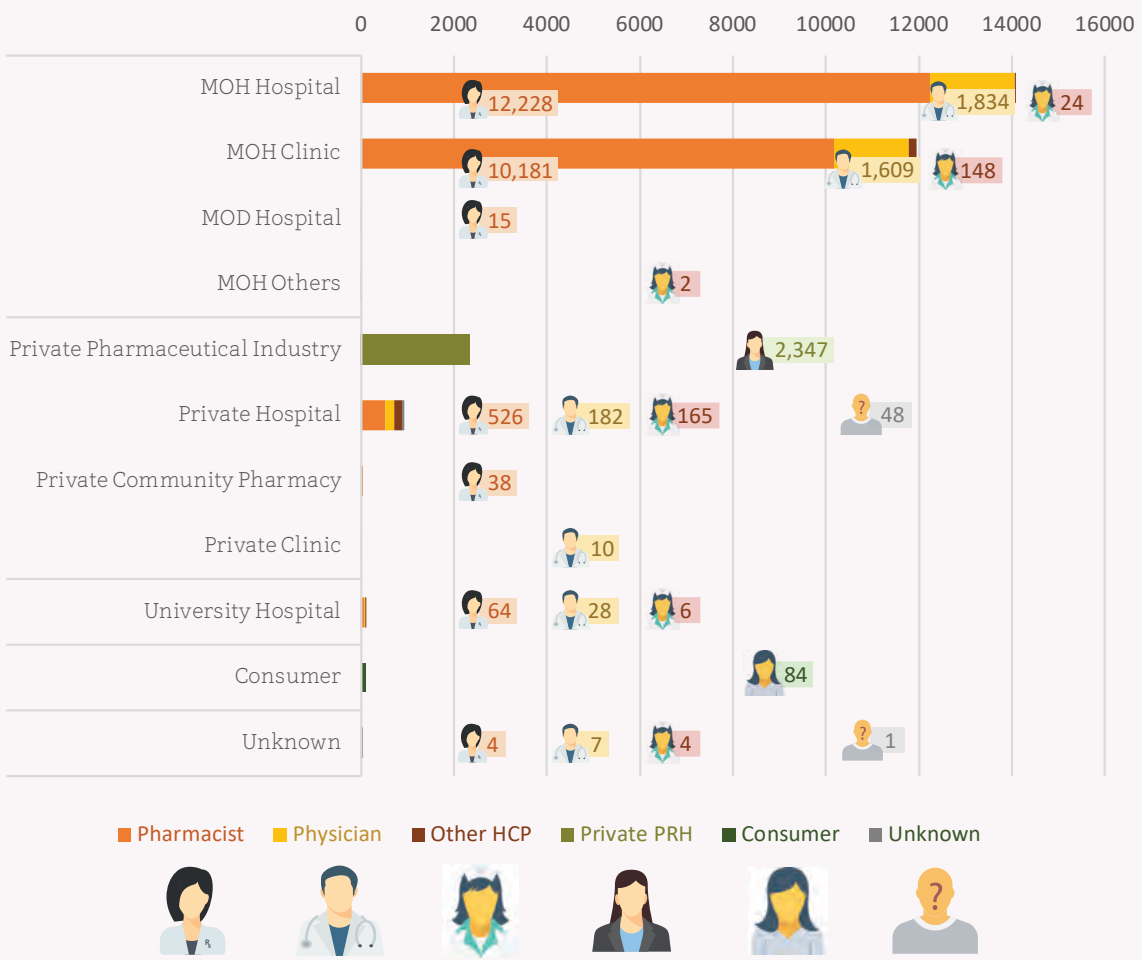
Distribution of ADR/AEFI Reports Recorded By Reporter Qualification, 2020*



HCP: Healthcare professionals; PRH: Product registration holders

*Based on total 29,555 processed ADR/AEFI reports

Distribution of ADR/AEFI Reports Recorded by Institution Type/Reporter Qualification, 2020*

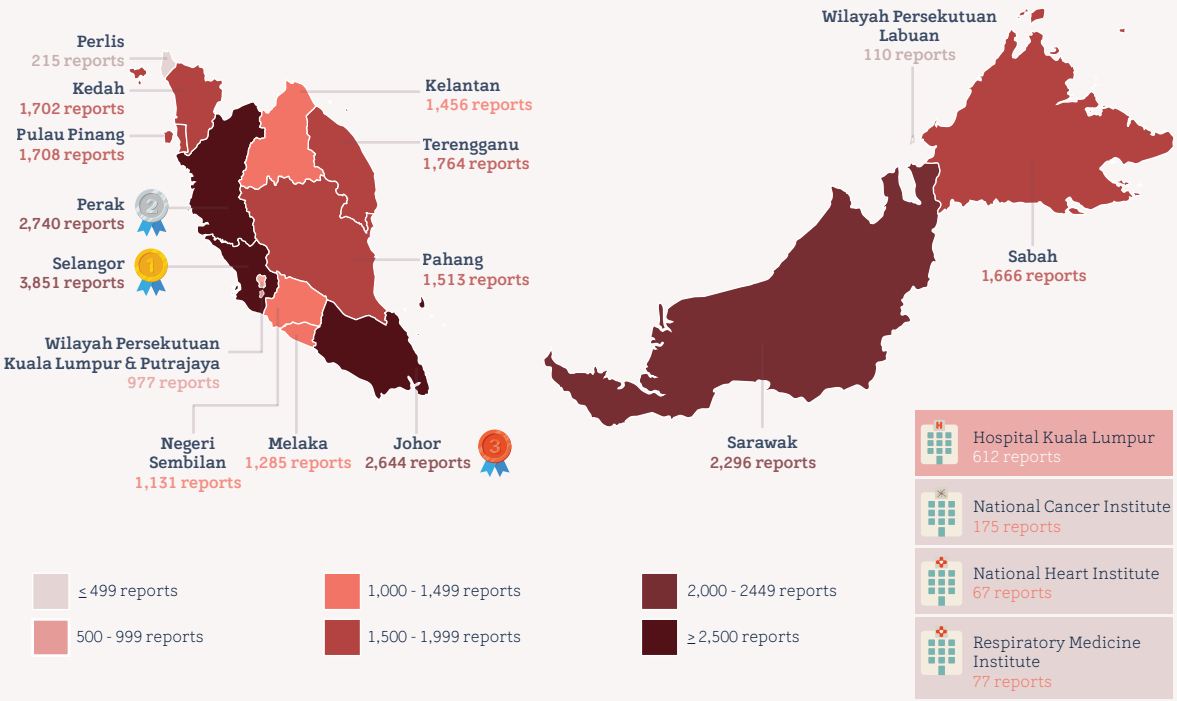


	Government					Private			Academia			
	MOH Hospital	MOH Clinic	MOD Hospital	MOH Others	Pharmaceutical Industry	Hospital	Community Pharmacy	Clinic	University Hospital	Consumer	Unknown	**Total**
Pharmacist	12,228	10,181	15			526	38		64		4	**23,056**
Physician	1,834	1,609				182		10	28		7	**3,670**
Other HCP	24	148		2		165			6		4	**349**
Private PRH					2,347							**2,347**
Consumer										84		**84**
Unknown						48					1	**49**
Total	**14,086**	**11,938**	**15**	**2**	**2,347**	**921**	**38**	**10**	**98**	**84**	**16**	**29,555**

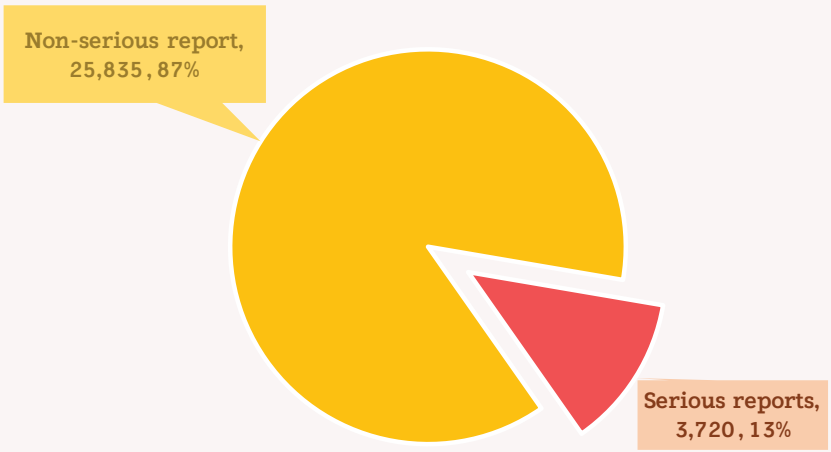
HCP: Healthcare professionals; MOD: Ministry of Defence; MOH: Ministry of Health; PRH: Product registration holders

*Based on total 29,555 processed ADR/AEFI reports

Distribution of ADR/AEFI Reports Recorded from Ministry of Health (MOH) Facilities, 2020*



Distribution of ADR/AEFI Reports Recorded by Case Seriousness, 2020*



Serious cases include those that require hospitalisation, prolonged existing hospitalisation, are life-threatening, cause persistent or significant disability/incapacity, a congenital anomaly/birth defect, or suspected to cause death

*Based on total 29,555 processed ADR/AEFI reports

Distribution of ADR/AEFI Reports Recorded by Patient's Age Group, 2020*

29 reports, 0.1%
Neonates
< 1 month old

1,553 reports, 5.3%
Infants
1 month – < 1 year old

2,630 reports, 8.9%
Children
1 – < 12 years old

1,021 reports, 3.5%
Adolescents
12 – < 18 years old

16,564 reports, 56.0%
Adults
18 – < 60 years old

6,812 reports, 23.0%
Elderly
≥ 60 years old

946 reports
Unspecified age

Distribution of ADR/AEFI Reports Recorded by Patient's Gender, 2020*

16,577 reports

Female

12,201 reports

Male

777 reports
2.6%

Unspecified gender

*Based on total 29,555 processed ADR/AEFI reports

Number of Products Involved in ADR/AEFI Reports, 2020#

53,228 (92.2%)
Poisons & prescription items

3,747 (6.5%)
Non-poisons

173 (0.3%)
Traditional products

60 (0.1%)
Food products

512 (0.9%)
Unregistered products

Top 10 Most Reported Route of Administration of The Products Involved, 2020#

Route of Administration	Number (%)
1  Oral	35,964 (62.3%)
 Intravenous (not otherwise specified)	8,071 (14.0%)
 Intramuscular	6,099 (10.6%)
 Subcutaneous	1,506 (2.6%)
 Intravenous drip	943 (1.6%)
 Intravenous bolus	367 (0.6%)
Intraperitoneal	226 (0.4%)
 Ophthalmic	218 (0.4%)
 Topical	194 (0.3%)
 Inhalation	181 (0.3%)

#Based on total 57,720 drug-ADR/vaccine-AEFI pairs.
Note: A report may involve one or more medicinal products.

Top 10 Most Reported Pharmacological Group of The Products Involved, 2020#

1

Anti infectives

12,374 (21.4%)

2

Cardiovascular agents

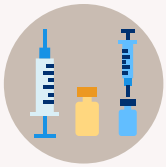
8,618 (14.9%)

3

Analgesics

8,195 (14.2%)

4



Vaccines

6,082 (10.5%)

5

Others

3,656 (6.3%)

6

Anti neoplastics

3,460 (6.0%)

7

Anti diabetics

2,528 (4.4%)

8

Anti hyperlipidaemic

1,326 (2.3%)

9

Anti tuberculosis

1,239 (2.1%)

10

Anti epileptics

972 (1.7%)

#Based on total 57,720 drug-ADR/vaccine-AEFI pairs.
Note: A report may involve one or more medicinal products.

Top 10 Most Reported MedDRA System Organ Class of The Adverse Events Reported, 2020#

1

Skin and subcutaneous tissue disorders
19,030 (33.0%)

2

General disorders and administration site conditions
10,822 (18.7%)

3

Gastrointestinal disorders
5,649 (9.8%)

4

Respiratory, thoracic and mediastinal disorders
4,735 (8.2%)

5

Eye disorders
4,646 (8.0%)

6

Nervous system disorders
4,444 (7.7%)

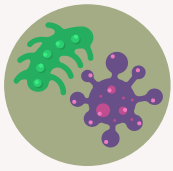
7

Investigations
1,867 (3.2%)

8

Musculoskeletal and connective tissue disorders
900 (1.6%)

9



Infections and infestations
726 (1.3%)

10

Cardiac disorders
710 (1.2%)

#Based on total 57,720 drug-ADR/vaccine-AEFI pairs.
Note: A report may involve one or more adverse events

Monitoring Drug Safety Issues

In 2020, a total of **221 drug safety issues** were proactively identified through the enviromental screening of published information on reference agencies' websites. Additionally, **33 notifications of drug safety issues** were received from the product registration holders (PRH). Following review, **30 safety issues were presented at MADRAC meetings** to determine the appropriate risk minimisation measures (refer to page 15–17). The majority of these issues resulted in updates to the product safety information, such as tightening of indications or additional contraindications. **Thirteen (13) recommendations for mandatory regulatory action** were proposed to the DCA resulting in directives issued to ensure package inserts and consumer medication information leaflets (RiMUP) of all products containing the affected active ingredients are updated with the crucial safety information.

4
MADRAC meetings

30
Safety issues presented

13
Safety issues required mandatory updates of package inserts and consumer medication information leaflets

7
Direct Healthcare Professional Communication (DHPC) letters reviewed

268
Products involved in regulatory action

MADRAC 173 27 February 2020	DCA Directive	DHPC Letter	PI/RiMUP Update	Safety Alert	Further Review	Others
Nivolumab: Reports of cytomegalovirus (CMV) infection/ reactivation				●	●	
Intravenous iron-containing products: Risk of Kounis Syndrome				●	●	
Guselkumab: Risk of anaphylaxis/anaphylactic reaction			●	●		
Carfilzomib (KYPROLIS®): (i) Risk of progressive multifocal leukoencephalopathy (PML) (ii) Risk of hepatitis B virus (HBV) reactivation		●	●	●		
Pirfenidone (ESBRIET®): New important safety updates: Drug-induced liver injury (DILI)		●	●	●		
Proton pump inhibitors (PPIs): Risk of microscopic colitis	●		●	●		
Diclofenac (systemic): (i) Risk of anastomotic leakage (ii) Risk of Kounis Syndrome	●		●	●		
Gabapentin: Risk of dysphagia	●		●	●		
Domperidone Restriction of use in paediatric patients less than 12 years of age	●		●	●		
MADRAC 174 22 April 2020						
Nintedanib: Risk of Ischaemic colitis				●	●	
Rocuronium: Risk of Kounis Syndrome				●	●	
Ulipristal acetate (ESMYA®): Temporary suspension on prescribing, dispensing and treatment during ongoing EMA review of liver injury risk		●		●		Withdrawal of product registration
Celecoxib: PRH requested removal of contraindication in patients with cardiovascular disease						Removal of contraindication rejected

MADRAC 175 15 Julai 2020	DCA Directive	DHPC Letter	Product Information Update	Safety Alert	Further Review
Insulin: Risk of cutaneous amyloidosis				●	●
Ibuprofen & ketoprofen (systemic): Serious exacerbation of infections				●	●
Hydroxychloroquine (PLAQUENIL®): Risk of QT prolongation and drug-drug interactions		●		●	
Topiramate: Risk of uveitis	●		●	●	
Parenteral nutrition containing amino acids and/or lipids: Risk of toxic degradations of ingredients when exposed to light, which may lead to adverse outcomes in paediatric patients less than 2 years of age	●		●	●	
Propofol Risk of priapism	●		●	●	
MADRAC 176 24 November 2020					
Tumour necrosis factor alpha (TNFα) inhibitors: Risk of Kaposi's sarcoma				●	●
Memantine: Risk of bradyarrhythmia				●	●
Ganoderma lucidum (lingzhi/reishi): Risk of renal-related and liver-related adverse reactions				●	●
Fingolimod (GILENYA®): Risk of congenital malformations		●	●	●	
Alemtuzumab (LEMTRADA®): New safety information on myocardial ischaemia, myocardial infarction, haemophagocytic lymphohistiocytosis (HLH), autoimmune hepatitis, acquired haemophilia A, Epstein-Barr virus (EBV) reactivation, haemorrhagic stroke, dissection of the cervicocephalic arteries, pulmonary alveolar haemorrhage and thrombocytopenia		●	●	●	
Ondansetron (ZOFRAN®): Risk of birth defects	●	●	●	●	

	DCA Directive	DHPC Letter	Product Information Update	Safety Alert	Further Review
Mesalazine and sulfasalazine: Risk of nephrolithiasis	●		●	●	
Oseltamivir: Risk of thrombocytopenia	●		●	●	
Abiraterone: Risk of hypoglycaemia due to drug interaction	●		●	●	
Efavirenz (including combination products): Risk of late onset neurotoxicity	●		●	●	
Clozapine: Risk of serious bowel complications caused by constipation	●		●	●	

Safety Monitoring of New Products

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

For the first five (5) 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 provide aggregate information on periodic evaluations of the benefit-risk balance of a product in countries where it is registered, especially on any changes or new findings relating to the safety profile.

In 2020, a total of **295 PBRERs** involving **260 products** were assessed, resulting in implementation of **package insert revisions** for **59 products** (20%) to ensure that the safety profile information is kept up to date.

Risk Management Plan (RMP)

A Risk Management Plan is a detailed description of post-marketing activities indended to proactively identify, prioritise, and implement strategies to mitigate risks associated with a product. An updated RMP post-registration for New Drug Products (NDPs) and biologic products is required to be submitted by product registration holder when there is a significant change in the safety specification.

In 2020, a total of **52 post-registration RMPs** were reviewed, which accounted for a total number of **44 registered products**. In addition, **eleven educational materials** for healthcare professionals and patient use were reviewed and approved.

Drug Safety Communication

Publications

MADRAC Bulletin

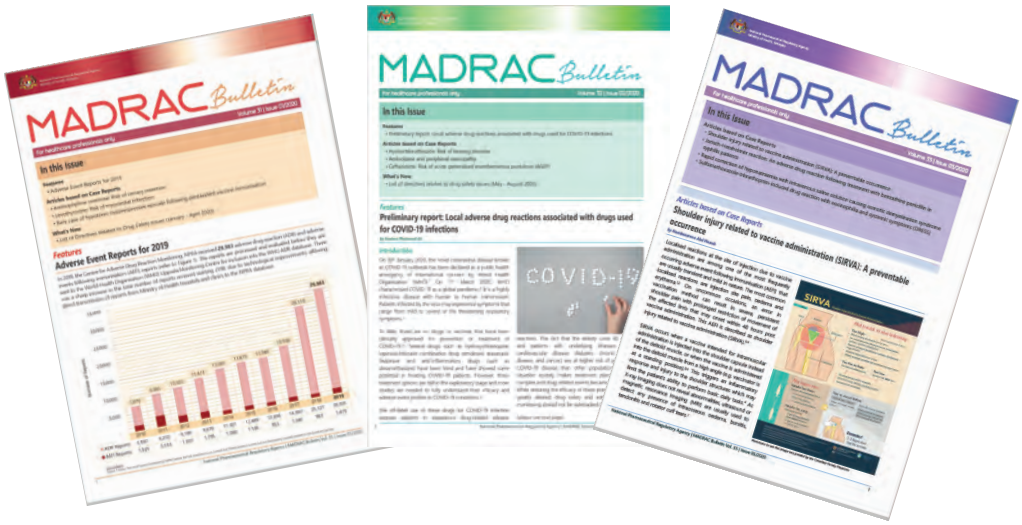
MADRAC Bulletin features articles based on local adverse drug reactions/adverse events following immunisation information of a particular drug, followed by discussion and advice to healthcare professionals. These articles are aimed to capture the interest of healthcare professionals in the clinical setting 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 issued in 2020, which are available on the NPRA website via MADRAC Bulletin, as follows:

MADRAC Bulletin, Issue 1-2020, Vol. 31

MADRAC Bulletin, Issue 2-2020, Vol. 32

MADRAC Bulletin, Issue 3-2020, Vol. 33



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 2020, NPRA has published **24 safety alerts** to highlight drug safety issues. The full list of safety alerts in 2020 is available on the NPRA webiste via Safety Alerts.

Direct Healthcare Professional Communication (DHPC) Letter

In addition to the publications listed above, Direct Health Professional Communication (DHPC) letters, previously known as "Dear Doctor letters", are used to communicate recent safety information to healthcare professionals. Such instances include important new or emerging risks, important changes in prescribing information, new contraindications, suspension or withdrawal of product registrations, and product quality or availability issues that may possess potential detrimental effects on patient care. DHPC letters submitted by the product registration holders are carefully reviewed and approved by NPRA before being distributed.

In 2020, a total of **eight (8) DHPC letters** were reviewed and approved by NPRA.

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, regulatory affairs professionals, and academicians.

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/precautions in more layman and easy-to-understand terms . RiMUPs are prepared in Bahasa Malaysia and English by product registration holders, and to be reviewed and approved by the pharmacy officers in NPRA.

In 2020, a total of **194 RIMUPs** were approved by the Pharmacovigilance Section in NPRA and is available on the NPRA website via Product Search.

Training, International Participation & Collaborations, and Other Pharmacovigilance Activities

Highlights and Trainings Activities

Over the 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 overseas 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 2020, a total of **12 training sessions** were held/attended by NPRA pharmacovigilance officials as speakers in physical seminars and workshops. The number of trainings was profoundly reduced than in previous years, as the COVID-19 pandemic ravaged the globe, including Malaysia, since March 2020.

Vaccine Pharmacovigilance for Immunisation Educators Training & Accreditation Program (ITAP)

In January 2020, NPRA officials was invited as guest speakers at Immunisation Educators Training & Accreditation (ITAP) course for healthcare professionals in Kedah to explain on how NPRA continuously monitors the safety of vaccines through pharmacovigilance activities in Malaysia and ensures that the benefits of vaccines continue to outweigh the risks. The primary goal of ITAP's is to equip Ministry of Health (MOH) personnel, particularly front-liners in Maternal & Child Health Clinics, with the necessary skills and knowledge on how to effectively communicate with vaccine-hesitant or vaccine-refusing parents and to address their concerns.

Signal Detection - VigiLyze: Quantitative Analysis

Monitoring of spontaneous adverse events, which is at the core of pharmacovigilance, is vital to identifying signals or trends that may indicate emerging safety issues in medicines and vaccines. Given the vast amount of incoming reports of adverse events, a case-by-case approach to signal detection may no longer be feasible, and quantitative methods are increasingly utilised. VigiLyze is a signal detection and signal management tool developed by the Uppsala Monitoring Centre (UMC) and provided to national pharmacovigilance centres in all member countries of the World Health Organisation Programme for International Drug Monitoring (WHO PIDM). It supports both quantitative and qualitative assessments, enabling a streamlined signal detection process and greatly increasing the efficiency of the internal process.

An internal training workshop on performing signal detection by using quantitative analysis in VigiLyze had been delivered to all pharmacovigilance officers by the Signal Detection Unit in July 2020. During the workshop, all pharmacovigilance officers gained an overall understanding of the signal management process and learnt how to leverage statistical screening of the national subset in reference to the global dataset recorded in VigiBase (the WHO global database of reported adverse events), including powerful methods for prioritisation of drug or vaccine-event combination.

Biostatistics and Critical Appraisal Workshop

Fundamental understandings and skills of biostatistics and critical appraisal are required for the careful assessment and reliable interpretation of safety evidence derived from clinical research and literature. In September 2020, a two-day Workshop on Biostatistics and Critical Appraisal was held for NPRA personnel, including pharmacovigilance officers.

Experts from the NPRA spent the first day of the workshop introducing the participants to the basic concepts of bio-statistical analysis and demonstrating how it may be applied to the process of evaluating drug safety signals. On the second day, guest speakers from the Malaysian Health Technology Assessment Section (MahTAS), which is under the Medical Programme, Ministry of Health (MOH), were invited to equip the participants with the knowledge and practical skills necessary to conduct systematic search, formulate research questions, organise the literature, and critically appraise the safety evidence from literature.

Enhanced Surveillance on Switching of Pentavalent to Hexavalent Vaccines in the National Immunisation Program for Children

The Ministry of Health (MOH) has replaced the pentavalent combination vaccine against diphtheria, tetanus, polio, pertussis, and Haemophilus influenza B (DTaP-IPV-Hib) with the hexavalent combination vaccine in the Malaysian National Immunisation Program (NIP) for Children in stages commencing in November 2020. The new hexavalent combination vaccine adds protection against hepatitis B to the previous pentavalent combination.

The hexavalent combination vaccine, which has been used in private health facilities in Malaysia since 2013, was shown to be effective and safe, with no serious safety issues reported. While it was considered a new vaccine under the NIP, the MOH committed to monitor the adverse events following immunisation (AEFI) for each child after each injection at MOH health facilities through enhanced surveillance.

In accordance with the MOH effort, NPRA officials had delivered topics on enhanced surveillance and AEFI reporting procedures to MOH healthcare professionals from all over the country at the Seminar on Switching of Pentavalent to Hexavalent Vaccines in the NIP for Children held in Putrajaya in September 2020. Under enhanced surveillance, every recipient of the new hexavalent combination vaccine at MOH health facilities will be given an AEFI reporting form. The parents or caregivers shall report any adverse effect experienced by their child to health staff after each injection by returning the report form, even if the side effects are mild, such as redness at the injection site.

International Participation & Collaborations

PMDA-ATC Pharmacovigilance Seminar 2020

The Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) hosted a four-day pharmacovigilance seminar for worldwide regulators from the 3rd to 6th of February 2020. Two (2) pharmacovigilance officers from NPRA attended the seminar held in Tokyo, Japan.

The objectives of the seminar were to equip regulators with the knowledge and skills they may put in use to enhance the pharmacovigilance system in their respective nations. Among the topics covered in the seminar were recent harmonised regulatory strategies, benefit-risk analysis throughout the life cycle of marketed medicinal products, and appropriate systems for communicating updated information to stakeholders (such as e-labelling). Other topics discussed were collection and accumulation of ADR reports, methodology of signal detection using such accumulated data, case studies on safety specification, and risk minimisation actions under the risk management plan.

WHO Global Benchmarking Tool (GBT) Pre-Assessment Workshop

In 2018, World Health Organisation (WHO) has officially finalised the Global Benchmarking Tool (GBT) Revision VI as the first global standard for objectively assessing regulatory capacity for medicines and vaccines. To ensure that Malaysia's regulatory system is comprehensive, effective, transparent and in line with WHO's highest standards, NPRA has set a goal of achieving the highest level of compliance, i.e. Maturity Level 4 (operating at advanced level of performance and continuous improvement), in the WHO-GBT Tool assessment by year 2024.

On the 12th and 13th of March 2020, NPRA conducted a pre-assessment workshop, and three assessors from WHO were invited to review the self-assessment documents for all nine (9) modules that NPRA had prepared. Representatives from each Centre of NPRA, including officers from Pharmacovigilance Section, participated in the workshop and had a fruitful discussion with the assessors on the requirements and implementation of all GBT indicators. The participants also received hands-on training on how to use the computerised GBT (cGBT) application for the self-assessment exercise. The completed GBT data capturing the self-assessment report is to be submitted to WHO before their next visit to undertake full assessment and official benchmarking.

Swissmedic Regulatory Training, Spring 2020

One pharmacovigilance officer from NPRA participated in the five-day Swissmedic Regulatory Training, that was conducted virtually by the Swiss Agency for Therapeutic Products (Swissmedic) in partnership with the World Health Organisation (WHO) from 15th–19th June 2020.

This regulatory training was structured as a "peer learning" event. During the workshop, participants from national regulatory agencies (NRAs) in Malaysia, Georgia, Turkey, Nepal, Iraq, Africa Nigeria, Rwanda, South Africa, and Central African Republic developed a better understanding and skills for developing and implementing the standard practices specific to their respective nations. This training also provided a practical reference to the current situation and pandemic crisis management by the participating NRAs.

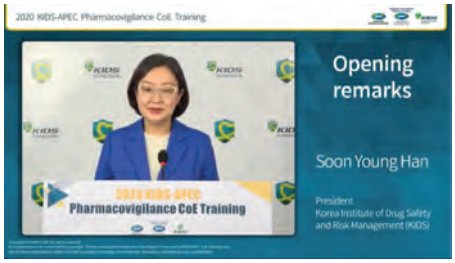
Following the presentations and discussions, different expert teams were able to learn more about the current capacities, strengths and challenges of both Swissmedic and participating NRAs. Among the modules covered included introduction to Swissmedic and World Health Organisation (WHO), quality management systems (within good manufacturing/clinical practice inspections and laboratory), marketing authorisation (reviewing applications, authorisation processes, regulatory management, case management), and market surveillance (focusing on pharmacovigilance).

swissmedic

2020 KIDS-APEC Pharmacovigilance Centre of Excellence Training

The Korea Institute of Drug Safety and Risk Management (KIDS) – Asia-Pacific Economic Cooperation (APEC) Pharmacovigilance Centre of Excellence Training Program was held virtually from 16th–18th September 2020. This training programme included speakers from KIDS, the Korean Ministry of Food and Drug Safety (MFDS), the United States Food & Drug Administration (US FDA), the Uppsala Monitoring Centre (UMC), and the International Society of Pharmacovigilance (ISoP), as well as participants from national regulatory agencies (NRAs) in Malaysia, Azerbaijan, Indonesia, Mexico, New Zealand, the Republic of Korea, Saudi Arabia, Singapore, Taiwan, Thailand, and the Philippines. programme. Four pharmacovigilance officers from the NPRA attended the virtual training programme.

The first day of the workshop featured an overview of the Korean pharmacovigilance system, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines, data science in pharmacovigilance, as well as safety and risk management for biologics. Among the topics covered on the second day included real world evidence-based decision-making in pharmacoepidemiology , effective analysis of electronic medical record data using common data model (CDM), utilising various data sources for signal detection, as well as safety measures on recall and revocation of permission. On the third day, risk management planning and risk minimisation measures were discussed from both regulatory and industry perspectives, followed by a hands-on exercise on implementing risk minimisation measures.



10th Asia Regulatory Conference (ARC) 2020

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the Pharmaceutical Association of Malaysia (PhAMA), with the engagement from the NPRA, hosted the four-day 10th Asia Regulatory Conference (ARC) as a key Asian regulatory platform to exchange opinions and seek recommendations on the regulatory environment in Asia from 3–6 November 2020.

It was a virtual conference with themes centred around building trust & partnership to deliver Universal Health Coverage (UHC) in Asia, stimulating debates on capacity building, and recent advancements in this region focused on regulatory reliance and collaboration. Representatives from national regulatory agencies (NRAs) in Asia, including pharmacovigilance officers from NPRA, international organisations, as well as the pharmaceutical industry, have participated in the conference as speakers, panellists, and attendees.

Research and Publications

In 2020, a research paper entitled "*Allopurinol-induced severe cutaneous adverse drug reactions: Risk minimization measures in Malaysia*" was published by the National Centre in collaboration with research universities and senior consultant physicians in the Pharmacoepidemiology and Drug Safety journal.[1] This paper described the **risk minimization measures (RMMs) implemented in Malaysia for allopurinol-induced severe cutaneous adverse drug reactions (SCARs)** and examined their impact using real-world data on allopurinol usage and ADR reports associated with allopurinol. The research findings showed that RMMs to promote the appropriate use of allopurinol and prescriber education have a positive impact.

[1]Panickar R, Wo WK, Ali NM, Tang MM, Ramanathan GRL, Kamarulzaman A, Aziz Z. Allopurinol-induced severe cutaneous adverse drug reactions: Risk minimization measures in Malaysia. Pharmacoepidemiol Drug Saf. 2020 Oct;29(10):1254-1262. doi: 10.1002/pds.5033. PMID: 33084196.

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 2020, a total of **209 ADR reports** received from pharmacists in the private sector were evaluated and approved for CPD points claim. This is a 45.9% increment from the previous year.

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