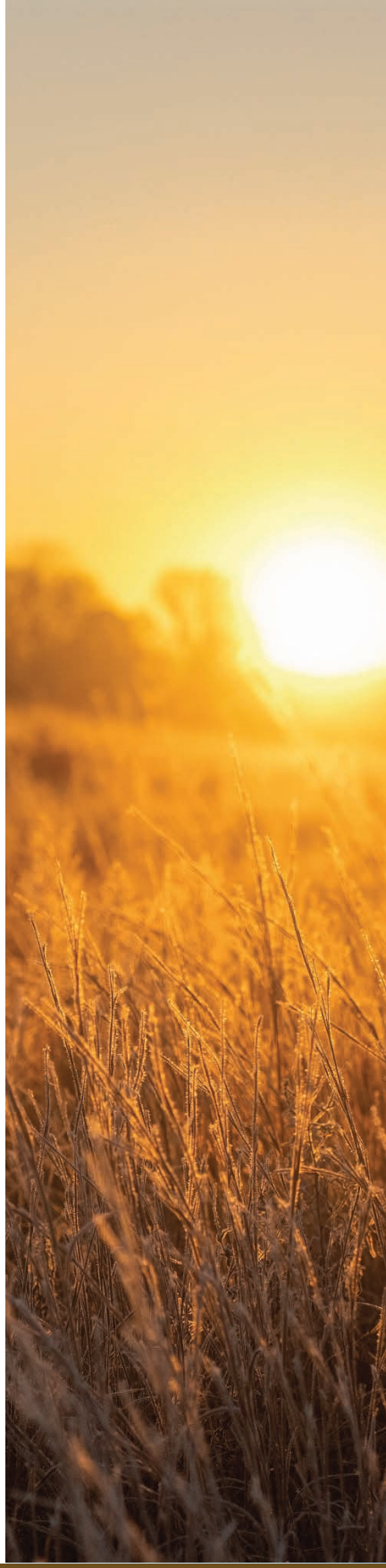
KEMENTERIAN KESIHATAN MALAYSIA
BAHAGIAN REGULATORI FARMASI NEGARA



2024
ANNUAL REPORT
NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING

National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health Malaysia

KEMENTERIAN KESIHATAN MALAYSIA
BAHAGIAN REGULATORI FARMASI NEGARA

NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING: ANNUAL REPORT 2024

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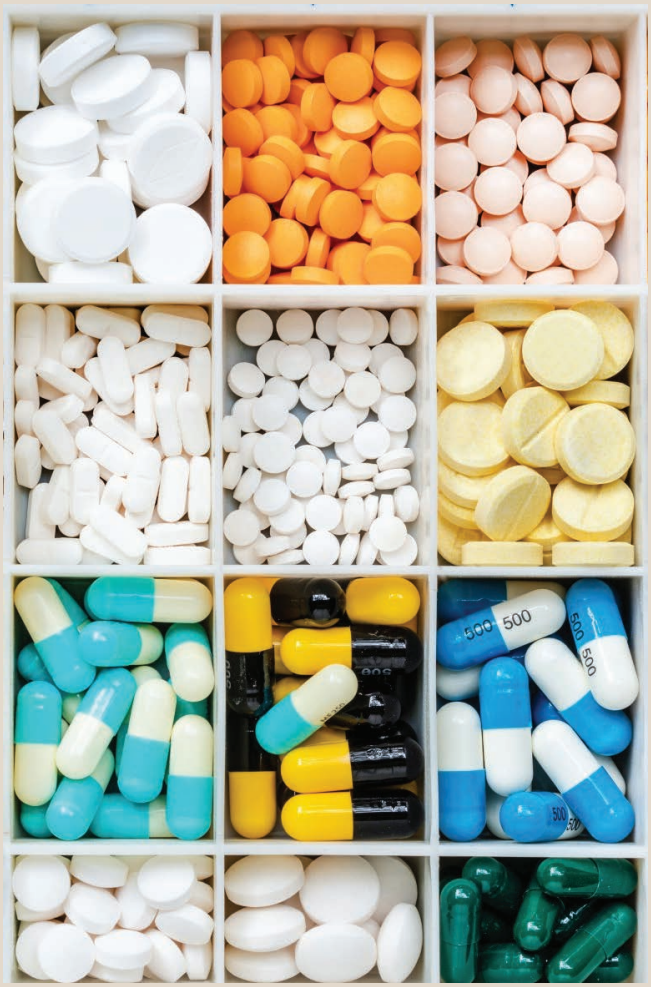
Our Purpose

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

p.30
Pharmacovigilance Inspection

p.33
Pharmacovigilance Capacity Building, Collaborations, Research, and Initiatives

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 is housed within the Pharmacovigilance Section, Centre of Compliance & Quality Control, 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 healthcare professionals and 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 medicinal products 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 2024.

Table 1: Members of MADRAC Session 2024

Ex-officio	Chairperson **YBrs. Pn. Rosilawati Ahmad** Director of NPRA
	Secretary of the MADRAC **YBrs. Dr. Noraida Mohamad Zainoor** Deputy Director, Centre of Compliance & Quality Control
	Secretary of the Drug Control Authority **YBrs. Dr. Azuana Ramli** Deputy Director, Centre of Product & Cosmetic Evaluation
Commitee Members *(Alternate members)*	**YBrs. Dr. Gunavathy Muthusamy** Head of Department and Consultant Internal Medicine and Endocrinologist , Hospital Shah Alam *(YBrs. Dr. Marzilawati Abdul Rahman)*
	YBrs. Dr. Liza Mohd. Isa National Head of Rheumatology Services and Medical Consultant (Rheumatology), Hospital Putrajaya *(YBrs. Dr. Habibah Mohd Yusoof)*
	YBrs. Dr. Azura Mohd. Affandi National Head of Dermatology Services and Consultant Dermatologist, Hospital Kuala Lumpur *(YBrs. Dr. Moonyza Akmal Ahmad Kamil)*

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

YBrs. Dr. Mazni Mat Junus
Head of Department and Consultant Psychiatrist
Hospital Selayang
(YBrs. Dr. Chin Loi Fei)

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

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

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

YBrs. Dr. Mohd Hanif Zailani
Vaccine Preventable Diseases and Food & Water Borne Diseases Sector
Disease Control Division
Ministry of Health
(YBrs. Dr. Jamiatul Aida Md. Sani)

YBrs. Prof. Madya Dr. Adyani Md Redzuan
Faculty of Pharmacy
National University of Malaysia
(YBrs. Dr. Norkasihan Ibrahim)

YBrs. Dr. Nur Sufiza Ahmad
Deputy Director
Formulary Management Branch
Pharmacy Practice & Development Division
(YBrs. Dr. Aliza binti Alias)

YBrs. Dr. Sivanaesan Letchumanan
Malaysian Medical Association (MMA)
(YBrs. Dr. Balachandran Krishnan)

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

Pn. Ho Wan Dien, Jemima
Malaysian Pharmaceutical Society (MPS)
(YBrs. Dr. Syireen Alwi)

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

Highlights: The Evolution of Medicine Risk Communication

Overview

The National Pharmaceutical Regulatory Agency (NPRA) stands as the guardian of pharmaceutical standards in Malaysia. Its primary aim is to ensure that every medicinal product registered in Malaysia meets the stringent criteria for quality, safety, and efficacy. In the aspect of safety, the NPRA Pharmacovigilance (PV) Section takes centre stage. Our mission is to continuously monitor the benefit-risk profile of registered products to ensure they remain safe for use under real-world conditions and throughout the product lifecycle.

The Cycle of Pharmacovigilance activities

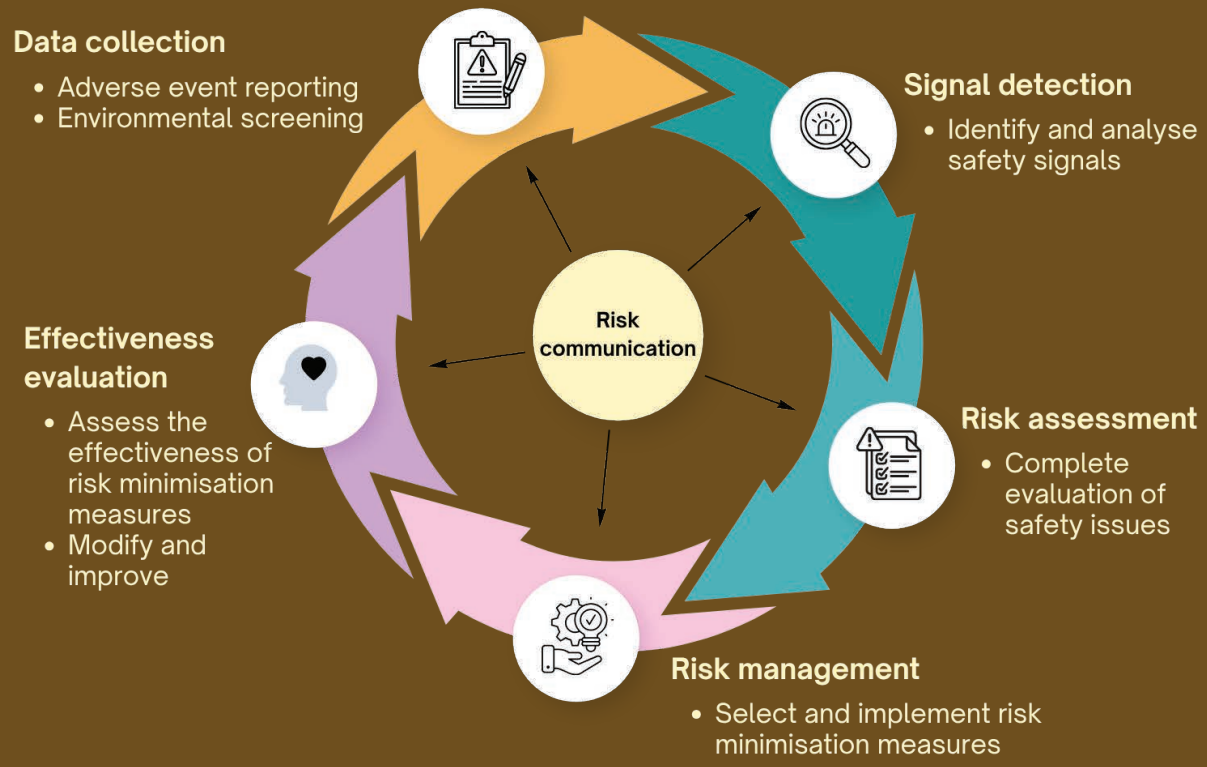


Figure 1. Cycle of pharmacovigilance activities.

The PV Section operates through various activities that form a continuous loop of safety oversight, as illustrated in Figure 1. The PV Cycle begins with **adverse event monitoring**. NPRA maintains the central repository for all Adverse Drug Reaction (ADR) and Adverse Event Following Immunisation (AEFI) reports in Malaysia. Through reports submitted by healthcare professionals (HCPs), Product Registration Holders (PRHs) and the public, we gather vital data on suspected adverse events. This data is used by our experts to identify "**signals**"—new or known adverse events that may be caused by a medicine and require further investigation. Following signal detection, the PV team conducts an in-depth **risk assessment**, weighing the benefits of a medicine against its potential risks to determine if **risk minimisation measures**, including regulatory actions, are required. All risk minimisation actions need to be effectively communicated to the stakeholders. Whether through label updates, safety alerts, or the MADRAC Bulletin, the PV Section strives to ensure that the right information reaches the right people at the right time.

Historical Background

Risk communication forms a core pillar of pharmacovigilance — it ensures that information on the safe use of medicines reaches relevant stakeholders, supports informed decision-making, and ultimately protects public health.

In Malaysia, risk communication has been conducted by the NPRA for over three decades. Over this time, NPRA's risk communication has evolved in scope, format and reach. Historically, communication was largely top-down and targeted to healthcare providers.

Risk Communication Methods used by NPRA

	MADRAC Bulletin	Safety Alert	DHPC	Educational Materials	Directive related to safety issue	Consumer medication information leaflet (RiMUP)
Author	NPRA	NPRA	Product registration holder, reviewed by NPRA	Product registration holder, reviewed by NPRA	NPRA	Product registration holder, reviewed by NPRA
Target Audience	Healthcare professionals	Healthcare professionals	Healthcare professionals	Healthcare professionals or patients	Product registration holders	Consumers
Dissemination Method	• Email to healthcare professionals in NPRA mailing list, administrative heads of healthcare facilities, professional associations • NPRA website	• Email to healthcare professionals in NPRA mailing list, administrative heads of healthcare facilities, professional associations • NPRA website	By product registration holder directly to healthcare professionals who use the product mentioned in DHPC	• By product registration holder or MOH directly to healthcare professionals • By healthcare professionals to patients	NPRA website	NPRA website
Content	• Local ADR case reports • MADRAC activities • Latest pharmacovigilance activities	• Latest or emerging safety issues • Summary of DHPCs	Important changes to medicinal product information.	Additional information to minimize risk of using the product, in addition to package insert information.	Regulatory action to be implemented by product registration holder (e.g., package insert updates)	Product information in layman terms
Frequency of publication	Initially published every four months	As required, depending on known risk of the product				Compulsory for all self-administered products

Research on Risk Communcation in Malaysia

While risk communication has been a longstanding activity in Malaysia, systematic research evaluating its effectiveness has been more recent — largely starting in the last decade. NPRA has conducted two studies related to risk communication in recent years, as detailed below:

2021 Cross-Sectional Study

Panickar et al, 2022

Nationwide survey among doctors and pharmacists evaluating awareness and preferences regarding four risk communication methods:

MADRAC Bulletin	Safety Alerts
DHPCs	Educational Materials

Key Findings:

- Awareness varied widely across communication types, with educational materials being the most recognised.
- Preferences for communication channels differed between professions, with pharmacists more likely to value product package inserts and patient leaflets and doctors favouring clinical guideline updates.

Delphi Study

Panickar et al, 2024

Conducted among local and international experts and recipients of regulatory risk communication to establish priority strategies.

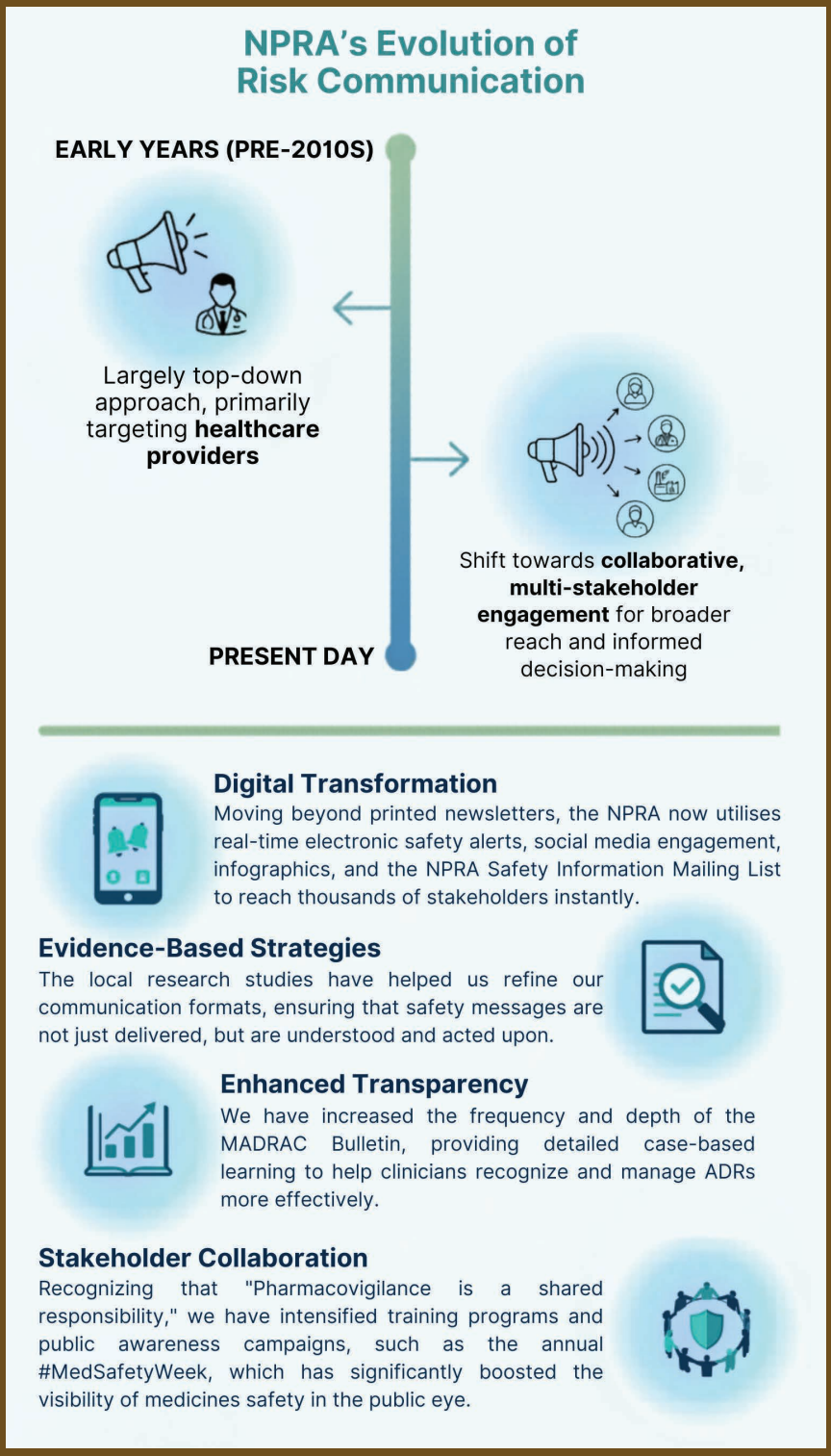
Key Outcomes:

21 priority strategies identified to improve format/content of risk messages, increase technology use, and expand stakeholder collaboration.

Stakeholder engagement is essential — involving communicators, practitioners, and recipients in developing communication approaches.

Recent Growth of Risk Communication in Malaysia

Over the past decade, efforts to reach other stakeholders, such as patients and the broader public, have grown incrementally.



Conclusion

Over the past three decades, risk communication — as part of Malaysia's pharmacovigilance framework — has transitioned from traditional safety notices to a more strategic, evidence-based and stakeholder-inclusive practice. Continued investment in research, coupled with innovative dissemination channels and collaborative outreach, will be essential to ensure that risk communication remains responsive to the evolving needs of healthcare professionals, patients, and the public.

As we look toward the future, the NPRA Pharmacovigilance Section remains committed to bridging the gap between scientific data, clinical practice, and safety outcomes. By fostering an environment of open communication and continuous learning, we ensure that the growth of risk communication continues to serve its ultimate purpose: enhancing patient safety across the nation.

References:

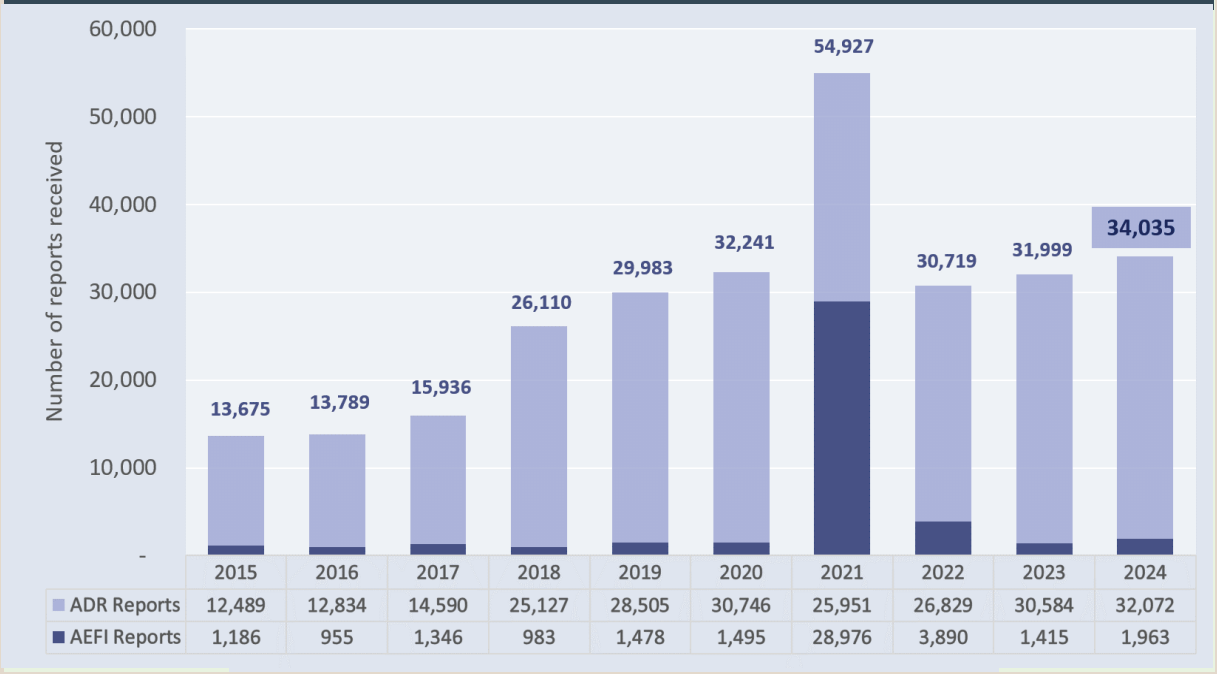
1. Panickar R, Aziz Z, Kamarulzaman A (2022). Enhancing medication risk communication in developing countries: a cross-sectional survey among doctors and pharmacists in Malaysia. BMC Public Health 22:1293. https://doi.org/10.1186/s12889-022-13703-x
2. Panickar R, Aziz Z, Teo CH, & Kamarulzaman A (2024). Strategies to enhance risk communication about medicines in Malaysia: a Delphi study among multinational experts. BMC Health Services Research, 24(1), 1019. https://doi.org/10.1186/s12913-024-11476-0

Analysis of ADR/AEFI Reports

In 2024, the National Centre received **34,035 reports** of adverse events (ADR/AEFI), noting a slight increase of 6.4% compared to 31,999 reports in 2023. After filtering out duplicates, follow-up reports, split reports and those that do not meet the processing criteria, a total of **32,427 reports** were recorded in the Malaysian Pharmacovigilance Database (QUEST). Subsequent to causality assessments conducted during MADRAC meetings, in 2024, 29,021 viable new reports* (excluding unregistered/food products) were submitted 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). The collected data are being continuously monitored for not only changing patterns and trends in any adverse event but also for new safety signals that warrant further evaluation and confirmation.

**This includes reports received by the NPRA in the previous year and does not encompass all reports received in the current year. Due to the meticulous assessment and processing required, followed by causality assessment by MADRAC at quarterly intervals, reports received in a year may be submitted to VigiBase in the following year.*

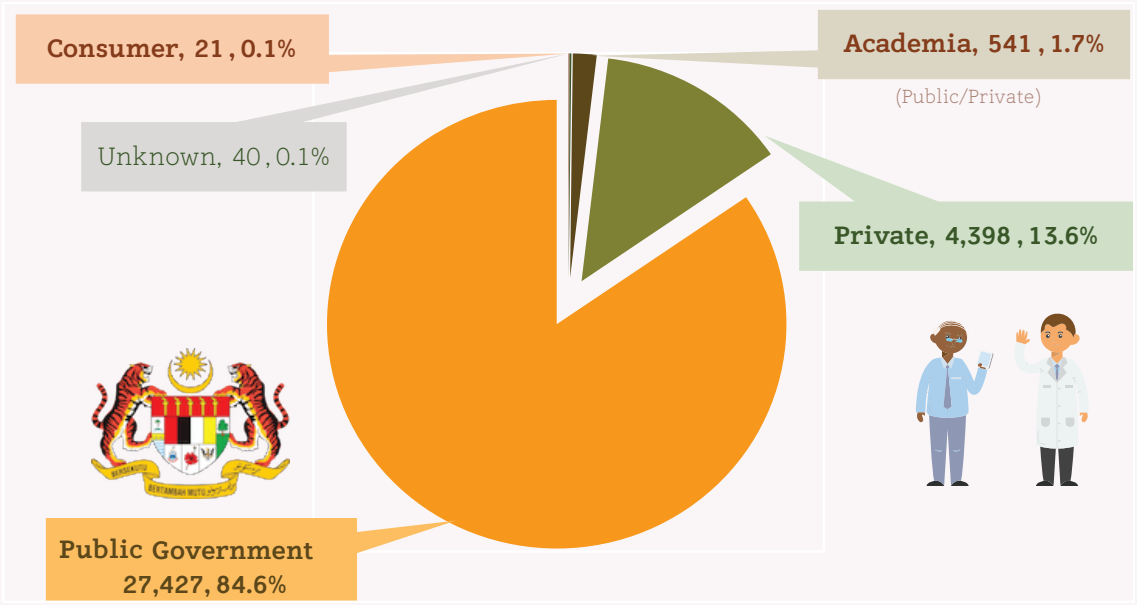
Total Number of ADR and AEFI Reports Received in Malaysia 2015-2024



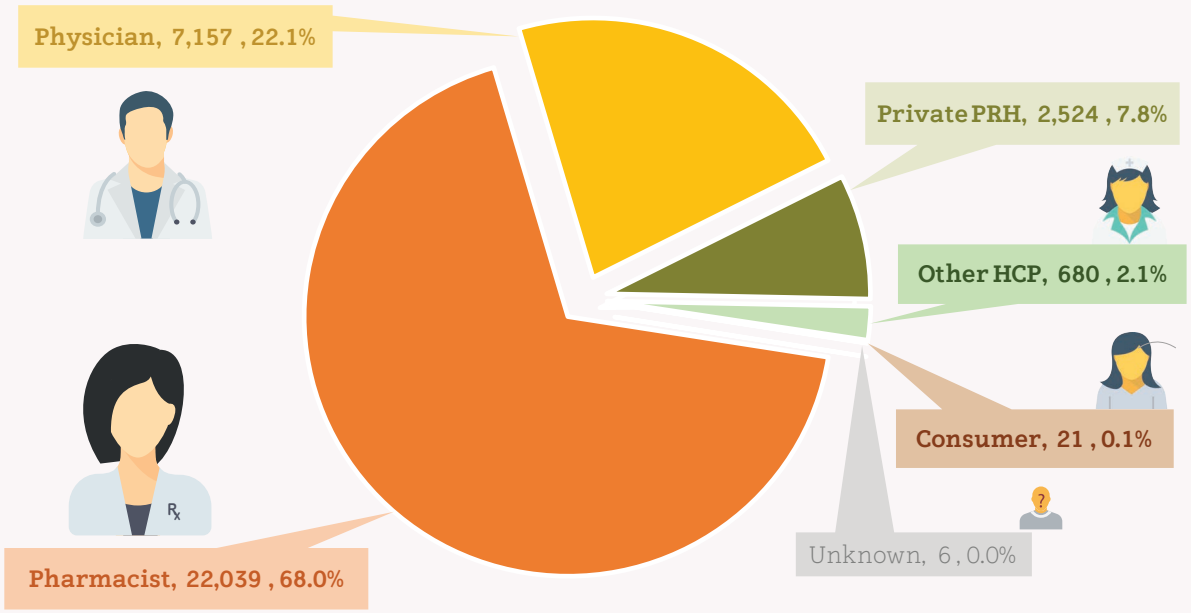
	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
ADR Reports	12,489	12,834	14,590	25,127	28,505	30,746	25,951	26,829	30,584	32,072
AEFI Reports	1,186	955	1,346	983	1,478	1,495	28,976	3,890	1,415	1,963

Note: The apparent surge in 2021 was attributable to the massive influx of AEFI reports following the mass vaccination roll-out under the National Immunisation Program for COVID-19 (PICK) in Malaysia since 24th February 2021.

Distribution of ADR/AEFI Reports Recorded by Sector, 2024*



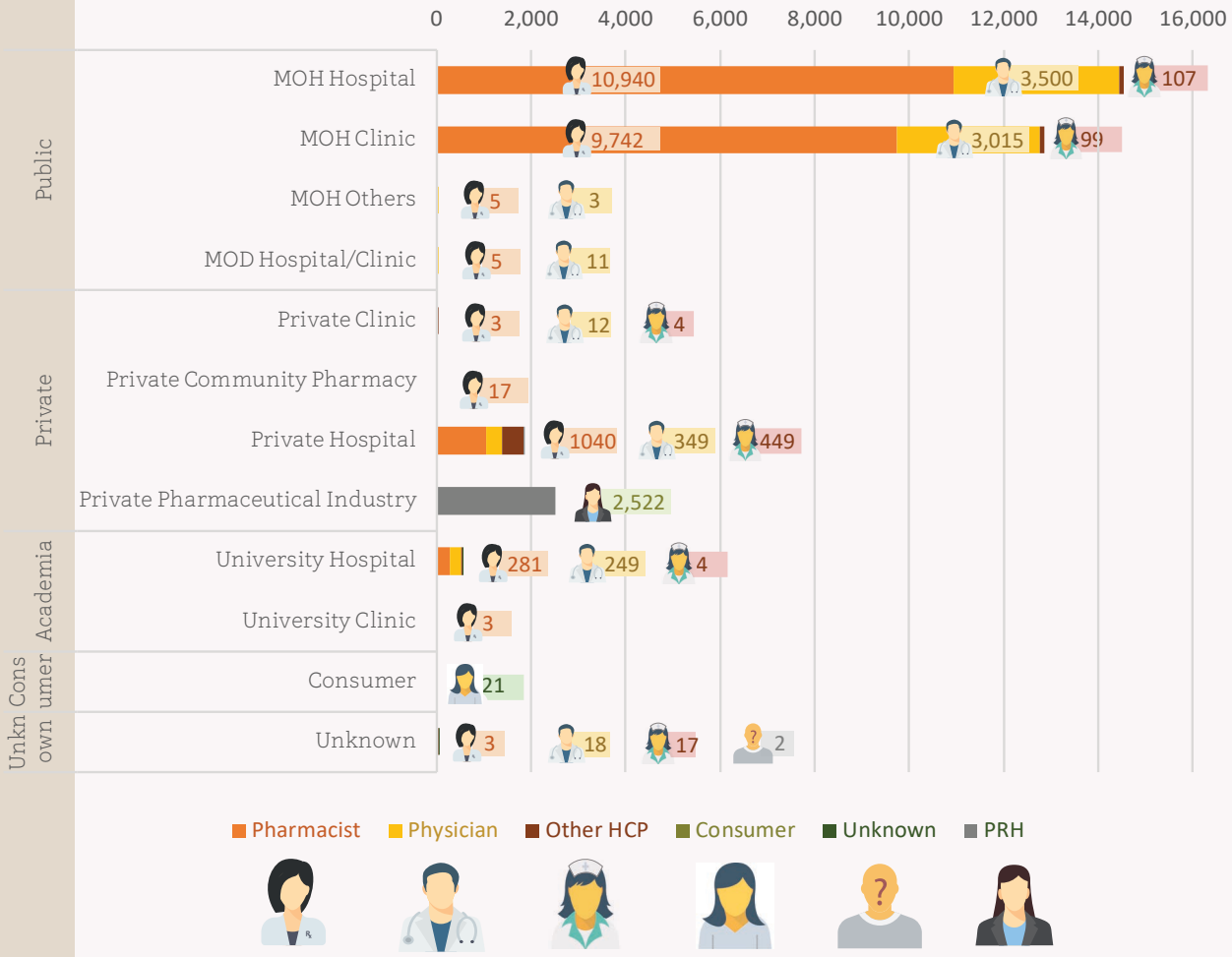
Distribution of ADR/AEFI Reports Recorded By Reporter Qualification, 2024*



HCP: Healthcare professionals; PRH: Product registration holders

*Based on total 32,427 processed ADR/AEFI reports

Distribution of ADR/AEFI Reports Recorded by Institution Type/Reporter Qualification, 2024*

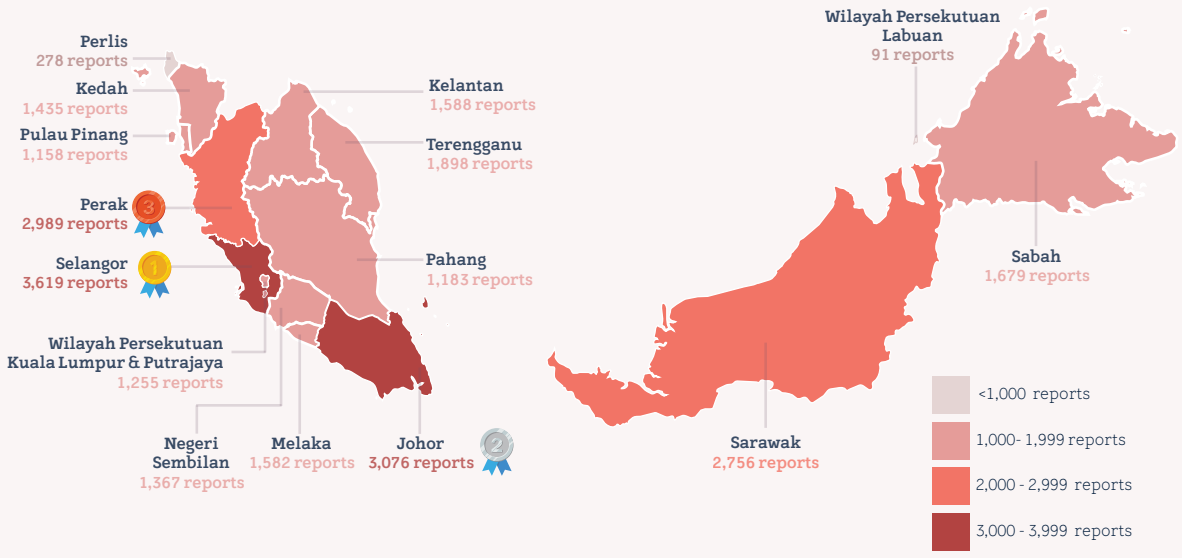


	Public / Government					Private			Academia				
	MOH Hospital	MOH Clinic	MOH Others	MOD Hospital/ Clinic	Pharmaceutical Industry	Hospital	Clinic	Community Pharmacy	University Hospital	University Clinic	Consumer	Unknown	Total
Pharmacist	10,940	9,742	5	5	-	1,040	3	17	281	3	-	3	22,039
Physician	3,500	3,015	3	11	-	349	12	-	249	-	-	18	7,157
Other HCP	107	99	-	-	-	449	4	-	4	-	-	17	680
Consumer	-	-	-	-	-	-	-	-	-	-	21	-	21
Unknown	-	-	-	-	-	-	-	-	4	-	-	2	6
PRH	-	-	-	-	2,522	2	-	-	-	-	-	-	2,524
Total	14,547	12,856	8	16	2,522	1,840	19	17	538	3	21	40	32,427

HCP: Healthcare professionals; KPWKM: Ministry of Women, Family and Community Development; MOD: Ministry of Defence; MOH: Ministry of Health; PRH: Product registration holders

*Based on total 32,427 processed ADR/AEFI reports

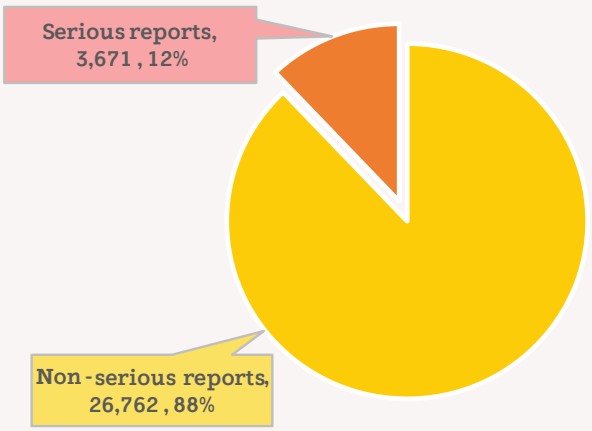
Distribution of ADR/AEFI Reports Recorded from Ministry of Health (MOH) Facilities, 2024*



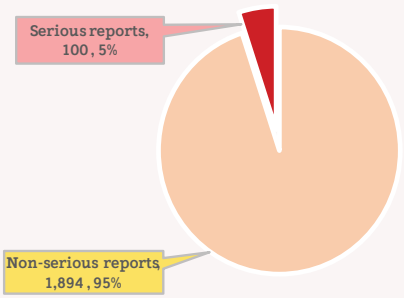
Hospital Kuala Lumpur 693 reports	Respiratory Medicine Institute (IPR) 126 reports
National Heart Institute (IJN) 264 reports	National Cancer Institute (IKN) 51 reports

Distribution of ADR/AEFI Reports Recorded by Case Seriousness, 2024*

ADR Reports



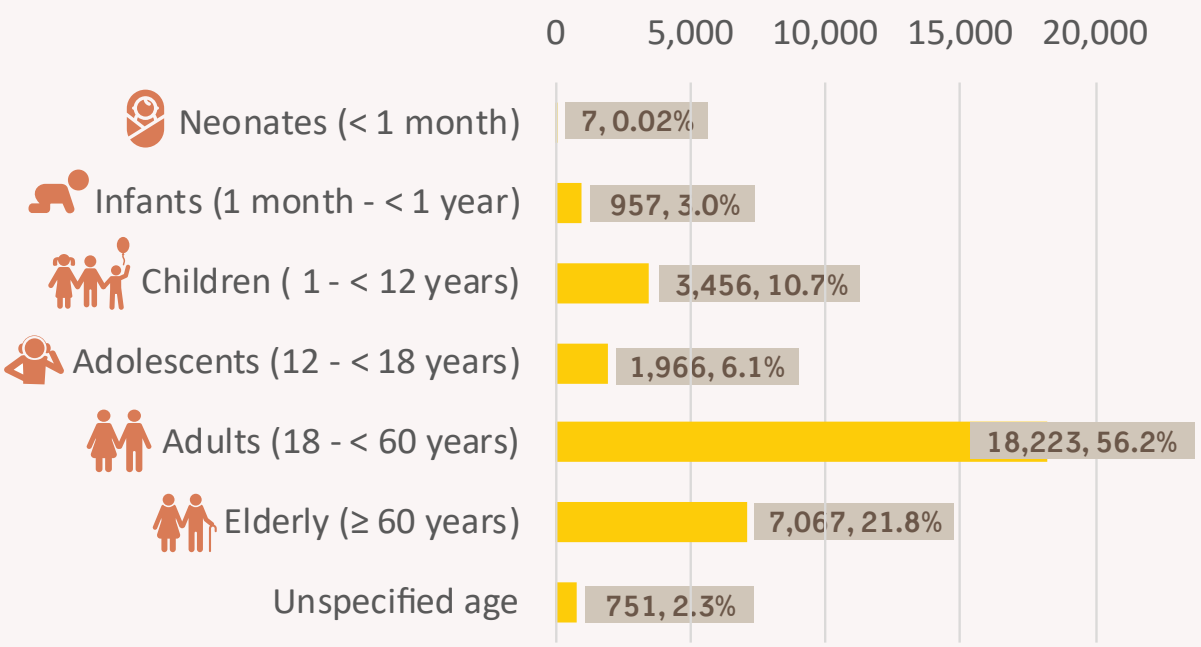
AEFI Reports



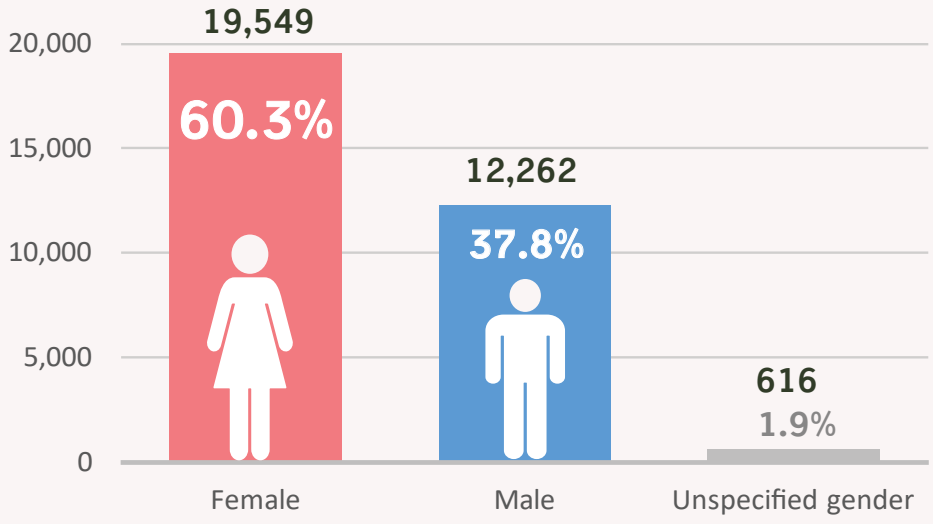
Serious cases include those that require hospitalisation, prolonged existing hospitalisation, are life-threatening, cause persistent or significant disability/incapacity, a congenital anomaly/birth defect, or suspected to cause death

*Based on total 32,427 processed ADR/AEFI reports

Distribution of ADR/AEFI Reports Recorded by Patient's Age Group, 2024*



Distribution of ADR/AEFI Reports Recorded by Patient's Gender, 2024*



*Based on total 32,427 processed ADR/AEFI reports

Number of Products Involved in ADR/AEFI Reports, 2024#

32,447 (93.7%)
Poisons & prescription items

2,001 (5.8%)
Non-poisons

52 (0.2%)
Natural products

122 (0.4%)
Unregistered/Food products

Top 10 Most Reported Route of Administration of the Products Involved, 2024#

Route of Administration	Number (%)
Oral	21,958 (63.4%)
Intravenous (not otherwise specified)	5,545 (16.0%)
Intramuscular	2,408 (7.0%)
Intravenous drip	953 (2.8%)
Subcutaneous	806 (2.3%)
Intravenous bolus	491 (1.4%)
Inhalation	100 (0.3%)
Ophthalmic	99 (0.3%)
Topical	98 (0.3%)
Intraperitoneal	78 (0.2%)
Unknown	1,675 (4.8%)

#Based on total 34,622 products involved in 32,427 processed ADR/AEFI reports
Note: A report may involve one or more medicinal products

Top 10 Most Reported Pharmacological Group of the Products Involved, 2024#

1

Anti infectives

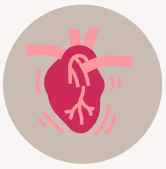
9,491 (27.4%)

2

Analgesics

5,110 (14.8%)

3



Cardiovascular

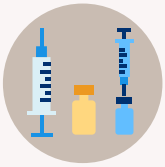
5,016 (14.5%)

4

Others

2,165 (6.3%)

5



Vaccines

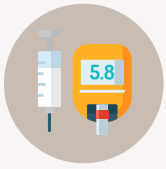
2,017 (5.8%)

6

Anti neoplastic

1,782 (5.1%)

7



Anti diabetics

1,512 (4.4%)

8

Anti hyperlipidaemic

1,116 (3.2%)

9

Anti tuberculosis

579 (1.7%)

10

Vitamin

567 (1.6%)

#Based on total 34,622 products involved in 32,427 processed ADR/AEFI reports
Note: A report may involve one or more medicinal products

Top 10 Most Reported MedDRA System Organ Class of the Adverse Drug Reactions (ADR) Recorded, 2024+

1

Skin and subcutaneous tissue disorders
19,969 (37.8%)

2

General disorders and administration site conditions
6,988 (13.2%)

3

Gastrointestinal disorders
5,654 (10.7%)

4

Eye disorders
5,035 (9.8%)

5

Respiratory, thoracic and mediastinal disorders
4,612 (8.7%)

6

Nervous system disorders
4,014 (7.6%)

7

Investigations
1,428 (2.7%)

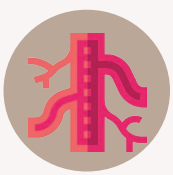
8

Musculoskeletal and connective tissue disorders
843 (1.6%)

9

Cardiac disorders
654 (1.2%)

10



Vascular disorder
554 (1.0%)

+Based on total 52,785 adverse events involved in 30,432 processed ADR reports.
Note: A report may involve one or more adverse events.

Top 10 Most Reported MedDRA System Organ Class of the Adverse Events Following Immunisation (AEFI) Recorded, 2024^

1

General disorders and administration site conditions
2,344 (54.9%)

2

Skin and subcutaneous tissue disorders
667 (15.6%)

3

Nervous system disorders
344 (8.1%)

4

Gastrointestinal disorders
234 (5.5%)

5

Psychiatric disorders
234 (5.5%)

6

Musculoskeletal and connective tissue disorders
168 (3.9%)

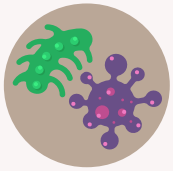
7

Respiratory, thoracic and mediastinal disorders
101 (2.4%)

8

Eye disorders
37 (0.9%)

9



Infections and infestations
36 (0.8%)

10

Metabolism and nutrition disorders
33 (0.8%)

^Based on total 4,266 adverse events involved in 1,994 processed AEFI reports.
Note: A report may involve one or more adverse events.

Safety Signal Detection and Risk Management

Detecting Local Safety Signals

*A **safety signal**, as defined by WHO-UMC, is information suggesting a possible link between a medicine and a new or known side effect, usually based on multiple reports. It does not confirm a causal relationship, but rather serves as a hypothesis that warrants further investigation.*

The process of detecting local safety signals consists of four main steps: signal triage, signal validation and prioritisation, signal assessment, as well as signal review and endorsement. In 2024, the MADRAC endorsed a total of **12 signals**, resulting in **updates of package inserts / consumer medication information leaflets (RiMUP)** for **3 signals** and **risk communication** via MADRAC Bulletin and NPRA website for **4 signals**. The remaining **10 signals** were **closed** as no regulatory actions required at the time of review.

6

Signals resulted in risk minimisation measures

3 Updates of package inserts / RiMUPs required

Spironolactone - Acute kidney injury

Atorvastatin - Erectile dysfunction

Dabigatran - Acute kidney injury

3 Risk communication issued

Ribociclib - Blood creatinine increased

Paracetamol - Fixed drug eruption

Amlodipine - Gingival enlargement

6 Signals closed for monitoring

Handling of Safety Issues

In 2024, a total of **283 drug safety issues** were proactively identified through the environmental screening of published information on reference agencies' websites. Additionally, **419 notifications of safety issues** were received from the product registration holders (PRHs). Following review, **22 safety issues were presented at 4 MADRAC meetings** to determine appropriate risk minimisation measures (refer to the following pages). The majority of these issues resulted in updates to the product safety information, including the addition of details related to newly identified safety concerns, standardisation of product information across all products registered in Malaysia or strengthening the existing information on the product information. Among the regulatory actions taken, one of the safety issues involved cancellation of the registration of all products containing 17-Hydroxyprogesterone Caproate (17-OHPC) in Malaysia. All stocks of 17-OHPC-containing products are being recalled up to the level of sub-distributors (wholesalers). **Eight recommendations for mandatory regulatory action** were proposed to the DCA, resulting in directives issued to ensure package inserts and consumer medication information leaflets (RiMUPs) of all products containing the affected active ingredients are updated with the crucial safety information.

283
Safety issues identified via environmental screening

419
Safety issues notifications received from PRHs

4
MADRAC meetings

22
Safety issues presented

8
Safety issues required mandatory updates of package inserts/ RiMUPs

1
Direct Healthcare Professional Communication (DHPC) letter reviewed

207
Products involved in regulatory actions

MADRAC 189
14 March 2024

	DCA Directive	Safety Alert	DHPC	Press statement	Product recall
Esomeprazole Risk of Erectile Dysfunction		●			
Levetiracetam and Clobazam Risk of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) Syndrome		●			
Anti-Clusters of Differentiation 20 (CD20) Antibodies (Rituximab, Obinutuzumab, Ofatumumab, Ocrelizumab) Risk of Pyoderma Gangrenosum		●			
Fluoroquinolone Risk of Suicidal Thoughts and Behaviour	●	●			
Dapagliflozin, Empagliflozin, Canagliflozin Interaction with Lithium (Therapeutic Use) Leading to Decreased Serum Lithium Concentration	●	●			
Mefanamic Acid Risk of Generalized Bullous Fixed Drug Eruption (GBFDE)	●	●			
Olmesartan Risk of Autoimmune Hepatitis	●	●			
Hydrochlorothiazide Risk of Acute Respiratory Distress Syndrome (ARDS)	●	●			

MADRAC 190
30 May 2024

Pseudoephedrine Risk of Posterior Reversible Encephalopathy Syndrome (PRES) & Reversible Cerebral Vasoconstriction Syndrome (RCVS)		●			
Progestogens (Cyproterone Acetate, Medroxyprogesterone Acetate, Chlormadinone Acetate) Risk of Meningioma		●			
Fluconazole [Updated] Risk of Spontaneous Abortion During Pregnancy and Congenital Malformations in Children Exposed to Fluconazole in Utero		●			
17-Hydroxyprogesterone Caproate (17-OHPC) Potential Cancer Risk in Offspring Exposed in Utero and Limited Efficacy Data		●			
Azacitidine Risk of Cutaneous Vasculitis	●	●			
Hydroxychloroquine Risk of Acute Febrile Neutrophilic Dermatosis (Sweet's Syndrome)	●	●			

MADRAC 191
29 August 2024

	DCA Directive	Safety Alert	DHPC	Press statement	Product recall
Ethambutol Risk of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) Syndrome		●			
17-Hydroxyprogesterone Caproate (17-OHPC) [Updated] Cancellation of Product Registration and Product Recall		●			●

MADRAC 192
17 December 2024

	DCA Directive	Safety Alert	DHPC	Press statement	Product recall
Azithromycin Risk of cardiovascular death		●			
Glucagon-like Peptide-1 (GLP-1) Receptor Agonists (Dulaglutide, Liraglutide, Lixisenatide, Semaglutide and Tirzepatide) Risk of Aspiration and pneumonia aspiration during general anaesthesia or deep sedation		●			
Hydroxychloroquine Risk of major congenital malformation in children exposed to hydroxychloroquine in utero		●			
PLAQUENIL® (Hydroxychloroquine sulphate) Potential risk of major congenital malformations and new risks of phospholipidosis and aggravation of myasthenia gravis symptoms			●		

Assessment of Drug Safety Documents

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

For the first five years post-registration, product registration holders (PRHs) are required to submit Periodic Benefit-Risk Evaluation Reports/ Periodic Safety Update Reports (PBRERs/PSURs) on newly registered products, namely New Drug Products (NDPs) 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 addition, new COVID-19 vaccines and treatment were also required to submit Monthly Safety Summary Reports (MSSRs) as per their conditional registration requirement.

In 2024, assessment was conducted on **251 PBRERs** and **MSSRs** pertaining to **258 products**, including **145 new drug products** and **113 biologic products**. Thereafter, **16% (41/258) of these products underwent package insert updates** to incorporate the latest safety information.

Risk Management Plan (RMP)

A Risk Management Plan (RMP) is a detailed description of the risk management system for a product. After registration, an updated RMP for New Drug Products (NDPs) and Biologic products is required to be submitted by the product registration holder when there is a significant change in the safety specification.

In 2024, a total of **115 RMPs** were assessed. Additional risk minimization measures mainly in the form of educational materials targeted for healthcare professionals and patients were also reviewed. In 2024, **63 educational materials involving 30 products** were reviewed and approved as additional risk minimisation measures for healthcare professionals and patients.

Drug Safety Communication

Publications

MADRAC Bulletin

Starting in 2024, the MADRAC Bulletin transitioned from a quarterly to a bi-monthly publication. It aims to provide a curated selection of local safety signals and articles discussing individual case safety reports (ICSRs), intended to raise awareness among healthcare professionals. The bulletin also features local pharmacovigilance-related activities and includes summaries of directives based on safety issues advised by the Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) and endorsed by the Drug Control Authority (DCA), along with safety alerts published on the NPRA website.

In 2024, NPRA published and distributed **six issues** of the MADRAC Bulletin, all of which are available on the NPRA website under the MADRAC Bulletin section.

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 2024, NPRA has published **22 safety alerts** to highlight drug safety issues. The full list of safety alerts is available on the NPRA website under the Safety Alerts Section.

Direct Healthcare Professional Communication (DHPC) Letters

In addition to the publications listed above, Direct Healthcare 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 2024, a total of **three DHPC letters** were reviewed and **one** was 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 3,200 individuals**, including doctors, dentists, pharmacists, nurse, assistant medical officers, assistant pharmacists, regulatory affairs professionals, academicians, and journal editors.

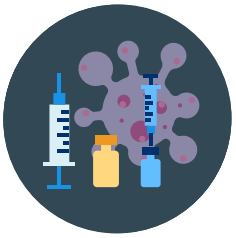
Healthcare professionals are encouraged to join the NPRA Safety Mailing List to receive the latest updates on pharmacovigilance and medicine safety information from the NPRA.

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 Melayu* and English by product registration holders, and are reviewed and approved by the NPRA.

In 2024, a total of **286 RiMUPs** were approved by the Pharmacovigilance Section in NPRA and are available on the NPRA website via Product Search.

Pharmacovigilance Inspection



In line with our commitment to strengthening pharmacovigilance oversight, the National Pharmaceutical Regulatory Agency (NPRA) continued the implementation of the voluntary Good Pharmacovigilance Practice (GVP) inspection program in 2024. This follows the successful initiation of the program in 2023, during which four (4) product registration holders (PRHs) underwent voluntary GVP inspections.

In 2024, five (5) additional PRHs participated in the voluntary inspection program. These inspections were conducted using a hybrid approach, involving both remote and on-site visits. It is important to note that no grading was assigned to the findings from these voluntary inspections. Instead, the focus remained on providing constructive feedback to support industry readiness and compliance. To gather industry perspectives, the PRHs were requested to complete an online survey after the close of each inspection, allowing NPRA to collect valuable feedback on their experience during the voluntary phase.

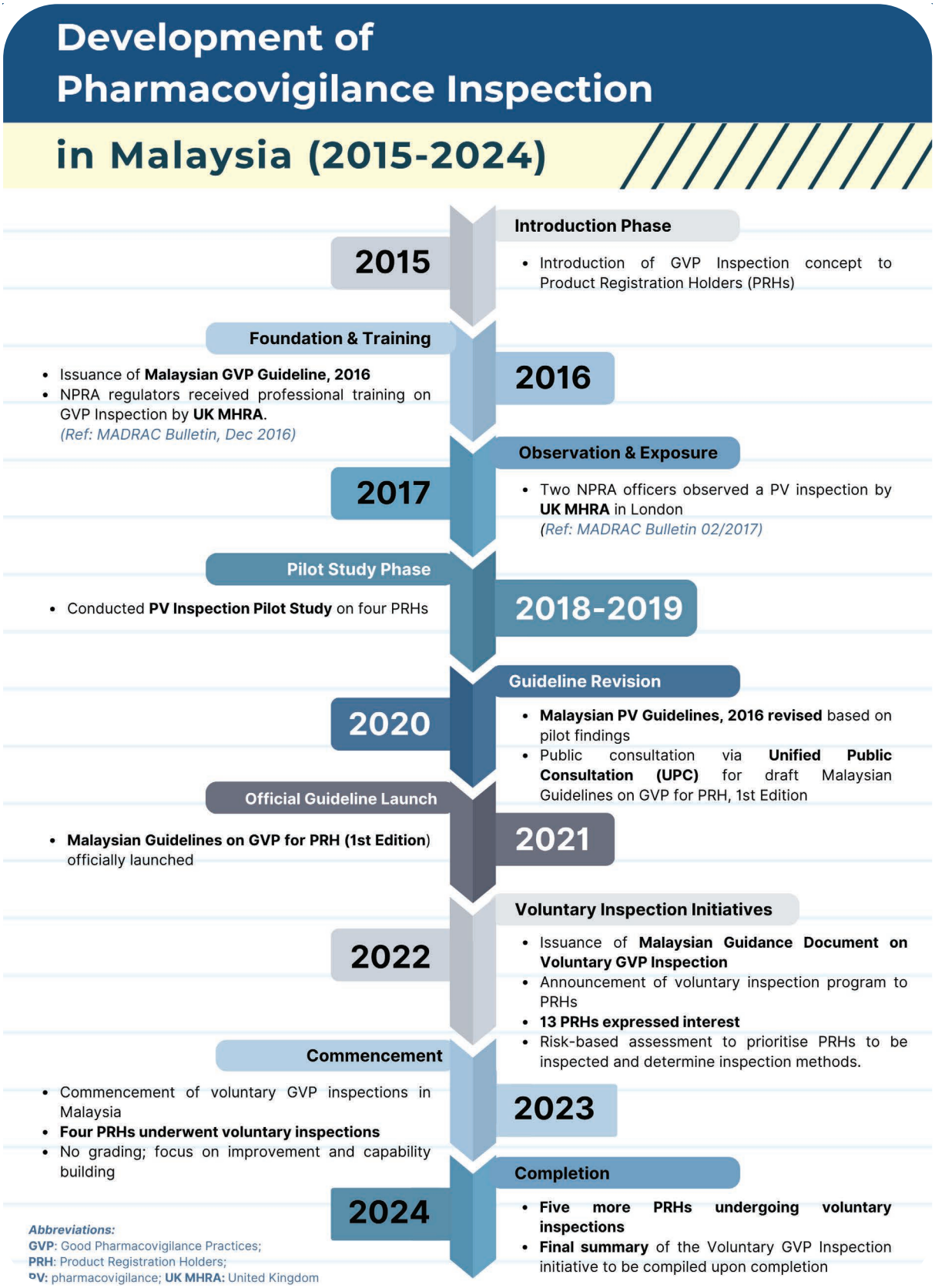
To further engage with stakeholders, NPRA organized a dedicated event in October 2024 titled “Pharmacovigilance in the Pharmaceutical Industry: Latest Updates from NPRA.” A key session, “Good Pharmacovigilance Practices (GVP) Inspection: Where Are We Headed?” was delivered to update PRHs on the direction and future expectations of GVP inspections in Malaysia.

Internally, NPRA officers continued to enhance their technical knowledge and inspection competencies through international collaboration and training. In September 2024, officers participated in the 2024 KIDS-APEC Pharmacovigilance Training hosted by the Korea Institute of Drug Safety & Risk Management (KIDS) – APEC Pharmacovigilance Center of Excellence. This platform allowed for valuable experience-sharing with peer regulators and reinforced NPRA's commitment to inspector accreditation and continuous professional development.

With the completion of the voluntary inspection phase, 2025 will serve as a cooling-off period. No further voluntary inspections are planned during this year. Instead, efforts will focus on consolidating the outcomes of the voluntary phase. A summary of inspection findings will be published on the NPRA website to promote transparency and learning across the industry.

Furthermore, the Malaysian Guidelines on Good Pharmacovigilance Practices for PRHs (1st Edition, August 2021) will be reviewed and updated based on insights and lessons learned from the voluntary inspections. Training for PRHs will also continue in 2025, with the aim of strengthening their understanding of GVP requirements.

Milestones


Development of Pharmacovigilance Inspection in Malaysia (2015-2024)
2015
Introduction Phase
• Introduction of GVP Inspection concept to Product Registration Holders (PRHs)
Foundation & Training
• Issuance of Malaysian GVP Guideline, 2016
• NPRA regulators received professional training on GVP Inspection by UK MHRA.
(Ref: MADRAC Bulletin, Dec 2016)
2016
2017
Observation & Exposure
• Two NPRA officers observed a PV inspection by UK MHRA in London
(Ref: MADRAC Bulletin 02/2017)
Pilot Study Phase
• Conducted PV Inspection Pilot Study on four PRHs
2018-2019
2020
Guideline Revision
• Malaysian PV Guidelines, 2016 revised based on pilot findings
• Public consultation via Unified Public Consultation (UPC) for draft Malaysian Guidelines on GVP for PRH, 1st Edition
Official Guideline Launch
• Malaysian Guidelines on GVP for PRH (1st Edition) officially launched
2021
2022
Voluntary Inspection Initiatives
• Issuance of Malaysian Guidance Document on Voluntary GVP Inspection
• Announcement of voluntary inspection program to PRHs
• 13 PRHs expressed interest
• Risk-based assessment to prioritise PRHs to be inspected and determine inspection methods.
Commencement
• Commencement of voluntary GVP inspections in Malaysia
• Four PRHs underwent voluntary inspections
• No grading; focus on improvement and capability building
2023
2024
Completion
• Five more PRHs undergoing voluntary inspections
• Final summary of the Voluntary GVP Inspection initiative to be compiled upon completion
Abbreviations:
GVP: Good Pharmacovigilance Practices;
PRH: Product Registration Holders;
PV: pharmacovigilance; UK MHRA: United Kingdom

Pharmacovigilance Capacity Building, Collaborations, Research, and Initiatives

Highlights of Training & Local Collaborations

Over the years, the NPRA has consistently provided training or sharing sessions on a wide range of pharmacovigilance topics to various stakeholders. These initiatives have reached healthcare providers in both the public and private sectors, pharmaceutical companies, authorities, and university students.

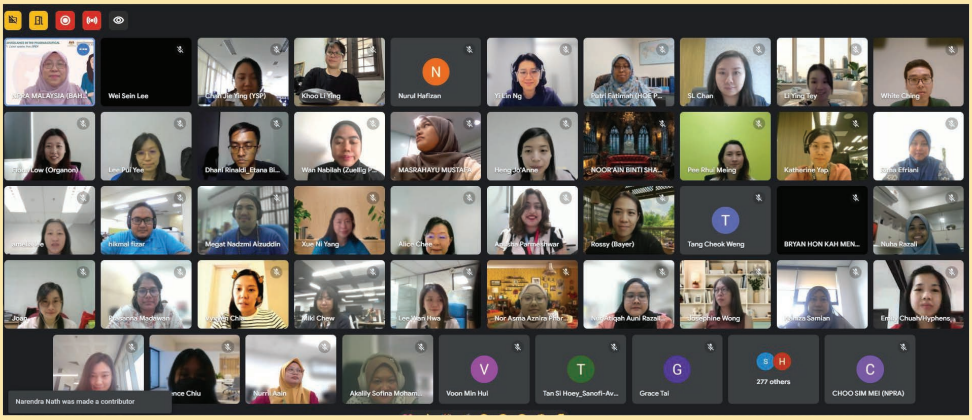
NPRA's National Training Workshops for Local Stakeholders

The Pharmacovigilance Section of NPRA organised two virtual seminars in 2024 as part of its continuous efforts to strengthen pharmacovigilance practices and enhance stakeholders' understanding of regulatory activities related to the safety, quality, and efficacy of pharmaceutical products in Malaysia.

The first seminar titled "Pharmacovigilance Seminar: Monitoring of Registered and Special Approval" was held on 22 April 2024 and attracted more than 350 public-sector healthcare professionals from across the country. The seminar aimed to enhance participants' understanding of post-registration monitoring activities and their role in ensuring the quality, safety, and efficacy of pharmaceutical products in Malaysia. Participants were introduced to the Malaysian pharmacovigilance system and received updates on various regulatory activities, including the monitoring of special approval medicines, handling of product complaints, and the importance of adverse drug reaction (ADR) reporting.

Seminar 1: Pharmacovigilance for Safer Use of Medicines

The second virtual seminar titled "Pharmacovigilance in Pharmaceutical Industry: Latest updates from NPRA" was conducted in October 2024, specifically for the pharmaceutical industry. The seminar aimed to enhance the quality of pharmacovigilance activities undertaken by the industry and covered five key topics related to pharmacovigilance practices.



Seminar 2: Pharmacovigilance in Pharmaceutical Industry: Latest updates from NPRA

Local Engagement and Collaborations

Throughout the year of 2024, NPRA pharmacovigilance officers received gracious invitations from numerous esteemed agencies to share our expertise through talks and presentations on subjects related to medication safety. A total of **20 presentations** were delivered over the course of the year, serving to enlighten and inform the target audiences on critical aspects of pharmacovigilance. Below are selected examples of the engaging talks delivered:

Optimising Post-Implementation Surveillance & AEFI Reporting - National Immunisation Summit (NIS)

On 13 May 2024, an officer from the National Pharmaceutical Regulatory Agency (NPRA) was invited to speak at the first National Immunisation Summit (NIS), held at Zenith Hotel, Putrajaya, in conjunction with Malaysia's National Immunisation Week. The NIS serves as a platform for the Ministry of Health to present the National Immunisation Programme (NIP) achievements and outlook, as well as to discuss the state-of-the-art innovations in the fight against vaccine-preventable diseases.

The officer delivered a presentation titled "Optimising Post-Implementation Surveillance & AEFI Reporting". This session provided comprehensive insights into vaccine safety monitoring and guided participants on preparing high-quality reports. The hybrid event was attended physically by 154 delegates and virtually by 733 delegates.

Foundations to Drug Safety Monitoring, Quality Reporting: Key Pillar of Drug Safety Monitoring, Vaccine Safety & Post-Immunisation Adverse Event Investigation, The Significance of Quality Reporting in Healthcare

On 13th August 2024, the Selangor State Health Department organised a briefing on Strengthening Adverse Drug Reaction (ADR) and Adverse Events Following Immunisation (AEFI) Reporting within the state. Three officers from the Pharmacovigilance Unit were invited as speakers. The event attended by healthcare professionals including doctors, pharmacists, matrons and nurses, aimed to enhance their knowledge and skills in reporting and managing cases of adverse drug reactions and vaccine-related adverse events. It covered topics such as Foundations of Drug Safety Monitoring, Quality Reporting: Key Pillar of Drug Safety Monitoring, Vaccine Safety & Post-Immunisation Adverse Event Investigation and The Significance of Quality Reporting in Healthcare. This initiative underscored the vital role of healthcare professionals in safeguarding public health through timely and quality adverse event reporting.

TV and Radio Appearance

NPRA Radio Interview on Asyik FM [MedSafetyWeek]

On 4 November 2024, in conjunction with MedSafetyWeek 2024, the National Pharmaceutical Regulatory Agency (NPRA) participated in a live radio interview on ASYIKfm Kuala Lumpur to provide insight on the topic theme “Tips to Avoid Medicine Side Effects”. During the session, NPRA highlighted the importance of using medicines correctly to minimise the risk of adverse drug reactions (ADRs), recognising early signs of side effects, and seeking timely medical advice when necessary. Listeners were also encouraged to report suspected side effects to NPRA through the available reporting channels, thereby contributing to the continuous monitoring of medicine safety in Malaysia. The interview served as an important platform to raise public awareness of medicine safety and reinforce the shared responsibility of healthcare professionals, patients, and caregivers in preventing medicine-related harm.

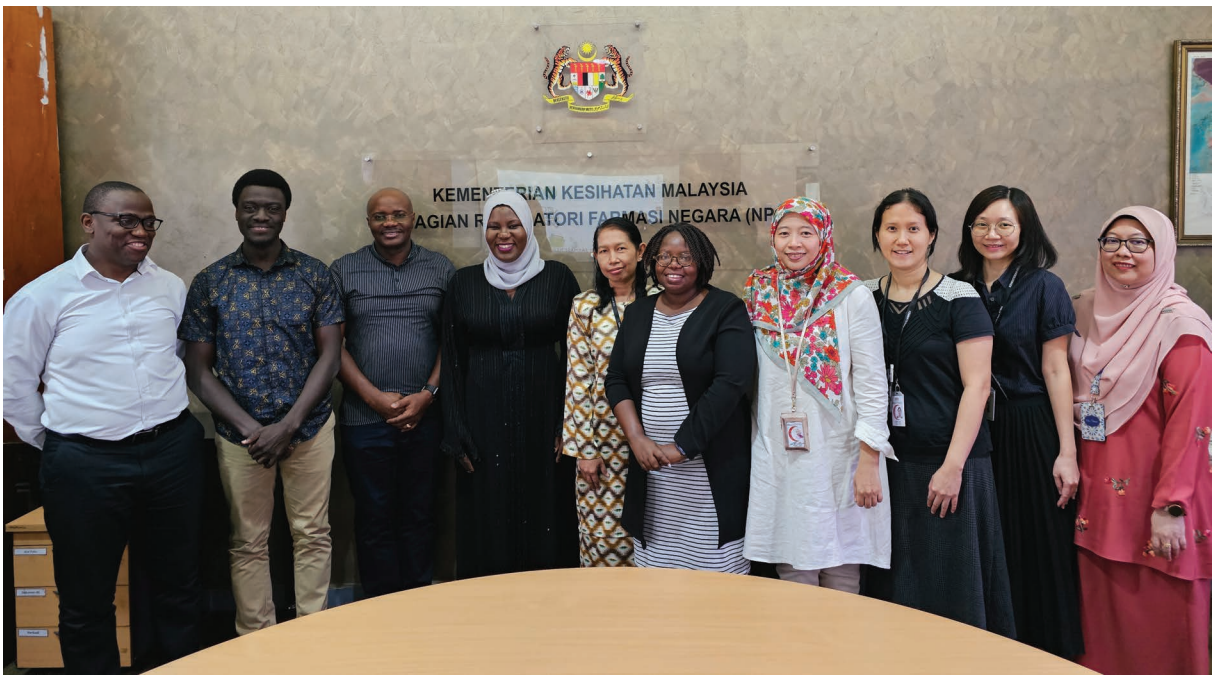
NPRA on Selamat Pagi Malaysia TV1: Tips to Avoid Medicine Side Effects [MedSafetyWeek]

On 14 November 2024, the NPRA was featured on Selamat Pagi Malaysia, a live TV1 talk show broadcast from Wisma Berita Angkasapuri, Kuala Lumpur, to raise public awareness on the safer use of medicines. During the session, the officer explained that adverse drug reactions (ADRs) are unintended effects that may occur even when medicines are used at normal doses, and that individuals may respond differently to the same medicine. Practical advice was shared to reduce the risk of side effects, including following the “Five Rights” of medication use, keeping an updated list of medicines and supplements, reading medicine labels carefully, informing healthcare providers of any allergies, using proper measuring devices for liquid medicines, storing medicines correctly, and avoiding sharing, altering, or using expired medicines.

International Participation & Collaborations

Uganda National Drug Authority Attachment Programme at NPRA

From 6 to 10 May 2024, NPRA hosted five officers from the Uganda National Drug Authority for an attachment programme aimed at enhancing understanding of Malaysia's regulatory framework and practices. Participants were introduced to various aspects of regulatory control, including the QUEST3+ online system, product registration, Good Manufacturing Practice (GMP), laboratory processes, and pharmacovigilance. The Pharmacovigilance Section delivered comprehensive briefings on Malaysia's pharmacovigilance system, covering key activities such as adverse drug reaction (ADR) monitoring, signal detection, risk assessment, risk management, and risk communication. The programme further strengthened international collaboration and facilitated the exchange of knowledge and best practices in pharmaceutical regulation.



KIDS-APEC Pharmacovigilance Center of Excellence (CoE) Training 2024

NPRA participated in the 2024 KIDS-APEC Pharmacovigilance Training held on 5–6 September 2024, where a presentation entitled "PV Inspections – Regulatory Perspectives" was delivered by an officer from the Pharmacovigilance Section. The session provided an overview of Malaysia's implementation of voluntary Good Pharmacovigilance Practice (GVP) Inspections, including the objectives, scope, inspection methodology, and regulatory expectations for Product Registration Holders (PRHs). The presentation highlighted the role of GVP inspections in assessing industry readiness, strengthening pharmacovigilance compliance, and supporting the development of a more robust regulatory framework for pharmacovigilance oversight in Malaysia.

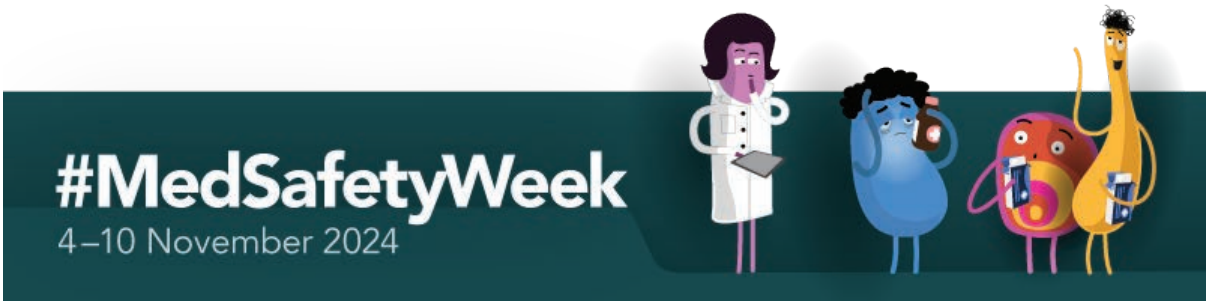
The presentation also outlined the risk-based assessment criteria used in inspection planning, focusing on product-related risks, PRH organisational factors, and pharmacovigilance system performance. Key messages emphasised the importance of maintaining effective pharmacovigilance systems through timely adverse event reporting, comprehensive documentation, continuous staff training, and proactive engagement with regulatory authorities. The session further addressed implementation challenges and future directions for pharmacovigilance inspections, underscoring NPRA's commitment to enhancing pharmacovigilance standards and promoting patient safety through continuous regulatory improvement.

19th International Conference of Drug Regulatory Authorities

The 19th International Conference of Drug Regulatory Authorities (ICDRA) was held from 14 to 18 October 2024 in New Delhi, India. Hosted by the World Health Organization (WHO) and India's Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare, this year's theme is "Smart regulation: Delivering quality assured medical products for all." Under this theme, deliberations covered key global issues such as biosimilars, biologics, clinical trials, Good Clinical Practice (GCP), bioequivalence studies, medical devices and in vitro diagnostics (IVDs), paediatric medicines and maternal health, GMP/GDP inspections, gene and cell therapies, blood and blood products, and pharmacovigilance.

The conference brought together hundreds of regulators from WHO member states, government officials, manufacturers, academics, research institutions, and non-profit organizations to discuss strategies for strengthening regulatory systems, including improving quality assurance, safety monitoring, regional harmonization, and other key regulatory functions. Among the four participants representing Malaysia at the event, two were officers from the NPRA Pharmacovigilance Section, acting as focal points for pharmacovigilance and vaccine safety.

#MedSafetyWeek 2024: Strengthening Medicines Safety Awareness Through Collaboration



#MedSafetyWeek is a global social media campaign spearheaded by the World Health Organization (WHO)-Uppsala Monitoring Centre (UMC) in Sweden, aimed at raising awareness on the safe use of medicines and the importance of reporting suspected side effects. Running from 4 to 10 November 2024, the campaign brought together national medicines regulatory authorities and partner organisations from more than 90 countries worldwide.

Marking Malaysia's fourth consecutive year of participation, NPRA continued to strengthen its outreach efforts through close collaboration with the Pharmacy Practice & Development Division, Ministry of Health Malaysia. A dedicated taskforce comprising officers from both divisions was established to coordinate campaign activities and maximise engagement. Various communication materials, including posters and digital content developed by UMC and NPRA, were disseminated through multiple platforms to promote medicines safety awareness.

The impact of these collaborative efforts was evident, with #MedSafetyWeek campaign materials being widely shared by healthcare facilities and individuals throughout Malaysia, from Johor to Perlis. In addition, the Malaysian Pharmacists Society (MPS) and several pharmaceutical companies supported the initiative by disseminating #MedSafetyWeek posters and key messages, further amplifying the campaign's reach and reinforcing the importance of adverse event reporting in ensuring the safe use of medicines.


MPS-iBulletin 241108

(Broadcast date: 8 November 2024)

JOM SERTAI #MEDSAFETYWEEK 2024 UNTUK KESELAMATAN UBAT DAN VAKSIN YANG LEBIH BAIK

Jom sertai kami untuk menjayakan kempen #MedSafetyWeek!
Minggu Kesedaran Keselamatan Penggubatan (Medication Safety Week) disambut pada tarikh 4-10 November.

Dengan mengambil ubat seperti yang diarahkan dan melaporkan kesan sampingan yang disyaki, anda boleh membantu kami memastikan ubat-ubatan lebih selamat untuk kita semua

Berbincanglah terlebih dahulu dengan anggota kesihatan anda mengenai kesan sampingan sama ada ubat atau vaksin yang dialami sebelum melaporkannya kepada NPRA melalui www.npra.gov.my

Tingkatkan kesedaran anda mengenai pencegahan dan pelaporan kesan sampingan ubat dan juga vaksin.

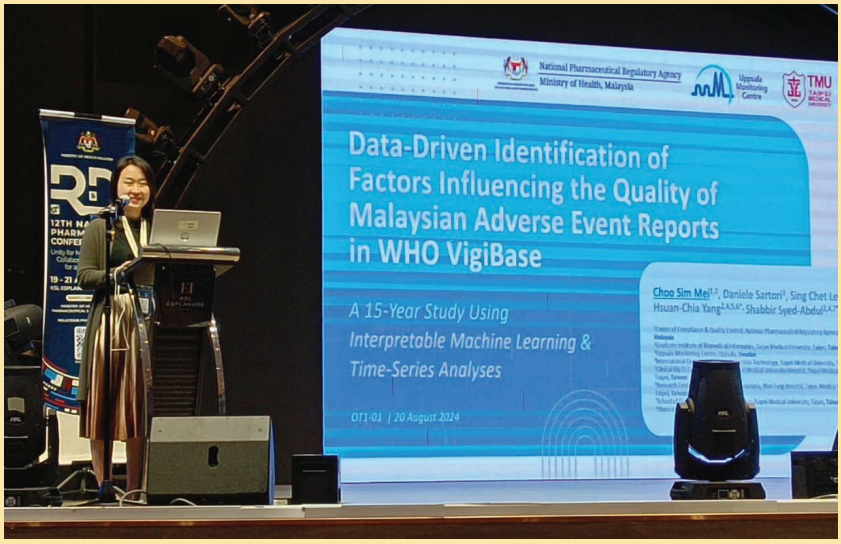
#MedSafetyWeek

Research and Publications

12th National R&D Pharmacy Conference

The 12th National Pharmacy Research and Development (R&D) Conference 2024 was held from 19 to 21 August 2024 at KSL Esplanade Hotel, Klang, with the theme "Unity for Medicines Security: Collaborative Solutions for a Safer Future". This conference brought together researchers, healthcare professionals, policymakers, academics, and industry representatives to showcase research findings and exchange knowledge on advancing pharmaceutical practice, regulation, and medicines security in Malaysia.

As part of the conference, two officers from the Pharmacovigilance Section delivered oral presentations of their research under Track 1: Drug Development & Regulations. Choo Sim Mei kicked-off the presentations with her research entitled “Data-Driven Identification of Factors Influencing the Quality of Malaysian Adverse Event Reports in VigiBase: A 15-Year Study Using Interpretable Machine Learning and Time-Series Analyses”. This study explored the main features affecting the completeness of Malaysian adverse event reports, and identified strategies taken by the Malaysian authorities to enhance adverse event reporting.



A pharmacovigilance officer presenting an oral presentation at the 12th National R&D Pharmacy Conference

Dr Rema Panickar, was awarded 2nd runner-up in Track 1 for her oral presentation entitled "Development of a Strategic Plan to Enhance Medicines Risk Communication in Malaysia". The presentation outlined the development of a five-year strategic plan to strengthen medicines risk communication in Malaysia through a structured, evidence-based approach involving a Delphi study encompassing international and local pharmacovigilance or communication experts. It highlighted NPRA's ongoing commitment to strengthen medicines risk communication as an integral component of the pharmacovigilance system. By promoting the timely dissemination of reliable safety information and encouraging effective stakeholder engagement, these initiatives support informed decision-making, strengthen the safe use of medicines, and contribute to the continuous enhancement of patient safety in Malaysia.

A pharmacovigilance officer was awarded 2nd runner up for her oral presentation at the 12th National R&D Pharmacy Conference

Abstracts for the 12th National Pharmacy R&D Conference 2024 can be assessed in ***Pharmacy Research Reports Volume 7 Supplement Issue August 2024***

Journal Publications

Data-Driven Identification of Factors That Influence the Quality of Adverse Event Reports: 15-Year Interpretable Machine Learning and Time-Series Analyses of VigiBase and QUEST

JMIR Medical Informatics Vol 12; e49643

Strategies to enhance risk communication about medicines in Malaysia: a Delphi study among multinational experts

BMC Health Services Research Vol 24; Article Number: 1019 (2024)

CPD Points for Adverse Event Reporting by pharmacists

As part of efforts to increase the quantity and quality of adverse event (AE) 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 AE reports.

In 2024, a total of **304 reports received** from pharmacists in the private sector were evaluated and **249 reports** were approved for CPD points claim.

--- The End ---

Editorial Team

KEMENTERIAN KESIHATAN MALAYSIA
BAHAGIAN REGULATORI FARMASI NEGARA