

Management of Pharmacovigilance Activities within the National Pharmaceutical Regulatory Agency (NPRA)

Addendum to the Malaysian
Guidelines on Good
Pharmacovigilance Practices (GVP) for
Product Registration Holders (First
Edition August 2021) –
Updated October 2025.

TABLE OF CONTENT

Introduction	1
Scope	1
Legal Basis	1
General Responsibility in Pharmacovigilance	2
Pharmacovigilance System	3
Management of adverse reaction reports	3
Management of registered medicinal product safety document	4
Signal detection	4
Risk Assessment and Risk Minimisation Management	5
Monitoring of Compliance	5
Dissemination of Safety Information	6

1. Introduction

- 1.1 This addendum to the Malaysian Guidelines on Good Pharmacovigilance Practices (GVP) for Product Registration Holders has been developed to facilitate management of pharmacovigilance within the National Pharmaceutical Regulatory Agency (NPRA)
- 1.2 Pharmacovigilance is defined by the World Health Organisation (WHO) as the science and activities related to the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related problems. Essentially, it is about drug safety and the ultimate goal of pharmacovigilance is to accurately determine and optimise the risk-benefit ratio of a drug product throughout its life cycle.
- 1.3 Malaysia set up its national pharmacovigilance system with the establishment of the Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) in 1987. MADRAC acts as an advisory body to the Drug Control Authority (DCA) on local and international drug safety issues. The National Adverse Drug Reaction Monitoring Centre, located within the NPRA serves as the secretariat to MADRAC, and has been a member of the WHO Programme for International Drug Safety Monitoring since 1990.

2. Scope

- 2.1 The NPRA pharmacovigilance system is the system used to fulfil the tasks and responsibilities of the division in relation to pharmacovigilance, and is designed to monitor the safety of registered medicinal products.
- 2.2 This addendum outlines the responsibilities of NPRA to manage risks associated with the use of registered medicinal products including collection of data on the safety of the registered medicinal products analysis and investigation of this data, and adoption of regulatory measures performed by any authority responsible for regulating products in other countries.
- 2.3 These activities will promote the safe and effective use of registered medicinal products in particular through providing timely information about the safety of registered medicinal products to patients, healthcare professionals and the public.
- 2.4 The NPRA pharmacovigilance system also adopts a reliance approach in the conduct of vigilance activities. In addition to the World Health Organization (WHO), NPRA makes reference to other National Regulatory Authorities (NRAs) approved by the Drug Control Authority (DCA), as listed on the NPRA website.

3. Legal Basis

- 3.1 This Addendum should be read in conjunction with Malaysian Guidelines on Good Pharmacovigilance Practices (GVP) for Product Registration Holders,

Part 1: General Information on Pharmacovigilance and any other relevant parts, including the glossary and abbreviations used herein.

3.2 The legal basis of these activities can be found in the Control of Drugs and Cosmetics Regulations 1984, Sale of Drugs Act 1952 (amendment in 2006):

- a) Regulation 28: Reporting adverse reactions - Product Registration Holders or any person who possesses any registered product shall inform immediately the Director of Pharmaceutical Services of any adverse reaction arising from the use of the registered product.
- b) Regulation 29:
 - (1) The Director of Pharmaceutical Services may issue written directives or guidelines to any person or a group of persons as he or she deems necessary for the better carrying out of the provisions of these Regulations and which in particular relate to— (a) product quality, safety and efficacy; (b) labelling; (c) change of particulars of a product; (d) transfer of licences; (e) manufacturing; (f) storage includes requirements as to containers; (g) retailing; (h) promotion
 - (2) Any person who contravenes any directives or guidelines issued by the Director of Pharmaceutical Services under subregulation (1) commits an offence.

4. General Responsibility in Pharmacovigilance

4.1 The NPRA plays a crucial role in ensuring the safety of medicines through pharmacovigilance activities. To achieve these goals, the NPRA undertakes the following: -

- a) Establish, operate and maintain a system for pharmacovigilance which complies with the quality standards.
- b) take all appropriate measures to encourage and facilitate the reporting of suspected adverse reactions;
- c) take all appropriate measures to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports and where necessary, the follow up of suspected adverse reaction reports.
- d) on an ongoing basis, shall evaluate scientifically the information collected under the pharmacovigilance system;
- e) consider options for minimising and preventing risks presented by the registered products;
- f) take appropriate regulatory action, if any.
- g) to ensure the timely exchange of important information on safety concerns relating to the use of a registered product with all stakeholders, including the public.

5. Pharmacovigilance System

- 5.1 A pharmacovigilance system is defined as a system used by an organisation to fulfil its legal tasks and responsibilities in relation to pharmacovigilance. The system is designed to monitor the safety of registered products and detect any change to their risk-benefit balance.
- 5.2 The established system for pharmacovigilance compliance with the quality standards is in place within the NPRA. The system is able to collect, record and assess the information regarding the safety of registered products, including (but not limited to) adverse reaction reports, periodic safety document and risk management plan.
- 5.3 The established pharmacovigilance system within the NPRA consists of: -
- a) Mechanism for healthcare providers, patients and product registration holders (PRH) to report suspected adverse reactions. This involves a standardised reporting form and guidance for reporting.
 - b) Mechanism on managing and maintaining the database to collect, process and record adverse reaction reports including other pharmacovigilance data for the purposes of (but not limited to) trend analysis, signal detection and potential safety issues identification.
 - c) Mechanism on assessment of periodic safety update report dan risk management plans.
 - d) Mechanism on signal management and emerging safety issue assessment.
 - e) Mechanism of risk management including implementation of risk minimisation measures.
 - f) Monitoring compliance towards pharmacovigilance requirement
 - g) Mechanism on safety communication
- 5.4 To ensure the continuation of the pharmacovigilance system, sufficient number of competent and appropriately trained personnel shall be available for the performance of pharmacovigilance activities.
- 5.5 Data protection legislation will be applied to the processing of data in the pharmacovigilance system when necessary.
- 5.6 All data, documents and records related to the pharmacovigilance system may be stored in designated database(s) and files, and retained in accordance with the relevant requirements on data and record management

6. Management of adverse reaction reports

- 6.1 The NPRA is responsible for collecting, managing and analysing information on suspected adverse reactions to registered medicinal products in Malaysia.
- 6.2 In order to full fill these responsibilities, the NPRA task are set out to: -

- a) Screen for reports that are eligible for processing according to the criteria stated in the in-house standard operating procedure.
- b) Record all adverse reactions to registered medicinal products that are submitted by patients or patients' carers, healthcare providers or the product registration holders.
- c) Take appropriate measures to encourage the reporting of suspected adverse reactions from patients or patients' carers, healthcare providers and product registration holders.
- d) Facilitate reporting through various reporting formats.
- e) Take all appropriate measures to obtain accurate and verifiable data including follow up for the scientific evaluation of suspected adverse reaction reports.
- f) Process and assess adverse reaction reports.
- g) Code the original verbatim text, as provided by the reporter, using standardised terminology.
- h) Facilitate the assessment of selected adverse reaction reports by the advisory committee.
- i) Send all the adverse reaction reports that have been processed to the WHO Collaborating Centre for International Drug Monitoring, Uppsala Monitoring Centre (UMC).
- j) Provide feedback to reporters in accordance with the in-house standard operating procedure.
- k) Retain the data and documents relating to the adverse reaction reports.

7. Management of registered medicinal product safety document

7.1 Upon approval of a medicinal products based on the demonstration of its safety and efficacy, it is essential to ensure the continued evaluation of relevant safety, efficacy, and effectiveness information throughout the lifecycle of these registered medicinal product. Such evaluation shall be conducted promptly as new and important findings emerge, and periodically to facilitate a comprehensive assessment of the accumulating data.

7.2 The NPRA is responsible to: -

- a) Assess the product safety document to determine whether there are any new risks, any changes to existing risks, or any modifications to the overall risk–benefit balance of the registered medicinal product.
- b) Ensure the product registration holder submits the product safety document when any concern arises in relation to the product safety.
- c) Direct the product registration holder on the necessary action to be taken based on the outcome of the assessment.

8. Signal detection

8.1 In this guideline “signal” in relation to a registered medicinal product means—

- a) new risks;

- b) risks that have changed; or
- c) changes to the risk-benefit balance.

8.2 The NPRA in relation to each registered medicinal product is responsible to:-

- a) Continuously review the data in the local database in relation to registered medicinal products, as well as information from other sources including (but not limited to) international databases, scientific literature, and product safety update reports, to identify new or changing safety signals.
- b) Conduct signal evaluation and prioritisation when a signal or potential safety issue is detected. The available evidence will be assessed to determine if a causal relationship exists between the medicine and the adverse event. Signals are then prioritised based on the in-house signal prioritisation matrix.

9. Risk Assessment and Risk Minimisation Management:

9.1 The NPRA is responsible to: -

- a) Conducting risk-benefit assessments through a continuous evaluation of the balance between the benefits and risks of registered medicinal product. This assessment informs regulatory decisions regarding risk minimisation measure (but not limited to) such as: -
 - i. safety warnings,
 - ii. updating product information,
 - iii. suspension of registration
 - iv. revocation of registration
 - v. product cancellation
- b) Providing direction to Product Registration Holders on the implementation of risk minimisation measures, when necessary, upon identification of risks.
- c) Taking appropriate regulatory action, when necessary, in cases where the benefit–risk balance of a registered medicinal product is deemed unfavourable or when the Product Registration Holders fails to comply with the required regulatory obligations.

10. Monitoring of Compliance

10.1 As part of NPRA's regulatory oversight to ensure the ongoing safety of medicinal products, Good Pharmacovigilance Practices (GVP) Inspections will be conducted. These inspections aim to ensure that Product Registration Holders (PRHs), or parties engaged by the PRH to perform pharmacovigilance activities, comply with the Malaysian Guidelines on Good Pharmacovigilance Practices (GVP) for PRHs and post-registration safety requirements imposed by NPRA.

11. Dissemination of Safety Information

- 11.1 NPRA utilises various channels to communicate drug safety information to all stakeholders (e.g. healthcare professionals, product registration holders, and the public), including (but not limited to):
- a) Direct Healthcare Professional Communications (DHPCs): interventions to deliver important safety information directly to either individual or a group of healthcare professionals.
 - b) Bulletins: These regular publications provide updates on drug safety issues, new adverse reaction findings, and important regulatory information.
 - c) Safety Alerts: Concise articles on urgent safety concerns issued via website or email blast.
 - d) Press Releases and Public Advisories: Public statements issued to address widespread issues or serious health hazards.
 - e) Consumer Medication Information Leaflets/ *Risalah Maklumat Ubat Pengguna* - RiMUP): These are essential for consumers, providing detailed information on the registered medicinal product use, dosage, side effects, and warnings in clear and understandable language.
 - f) Educational Materials: Awareness campaigns and educational resources to promote the adverse reaction reporting and product safety