



Ministry of Health Malaysia

PHARMACY RESEARCH REPORTS

Volume 9 · Supplement Issue · October 2026

COMPENDIUM OF ABSTRACTS

NATIONAL REGULATORY CONFERENCE 2026

**RegTech: Driving Innovation and
Efficiency in Regulatory**

30 JUNE - 2 JULY 2026



PHARMACY RESEARCH REPORTS

Volume 9 • Supplement Issue • October 2026

The Pharmacy Research Reports is a peer-reviewed journal published by the Pharmaceutical Services Programme, Ministry of Health Malaysia (MOH). This is an International Standard Serial Number (ISSN) registered publication with the National Bibliography Centre, National Library of Malaysia. This document contains compilation of peer-reviewed original scientific research articles of pharmacy related research conducted in the MOH or by MOH pharmacists and pharmacy personnel. All research included in this report were registered with the National Medical Research Register (NMRR) and ethics approvals had been obtained from the Medical Research and Ethics Committee (MREC). The opinions expressed in all articles are the authors' own and do not necessarily reflect the view of the Pharmaceutical Services Programme, Ministry of Health Malaysia.

October 2026

© Pharmaceutical Services Programme, Ministry of Health Malaysia



No. Siri Penerbitan KKM
MOH/F/FAR/205.26(RR) - e

No. Pendaftaran Dokumen Program Perkhidmatan Farmasi
D-RR-130

Editorial Address:

Editor in Chief

Pharmacy Research Reports

Pharmacy Policy and Strategic Planning Division

Pharmaceutical Services Programme

Ministry of Health Malaysia

Lot 36, Jalan Prof Diraja Ungku Aziz, 46200 Petaling Jaya, Selangor, Malaysia

Tel : (603) 7841 3200

Email : rndfarmasi@moh.gov.my

Website : <https://www.pharmacy.gov.my> / <https://research.pharmacy.gov.my>

PHARMACY RESEARCH REPORTS

Volume 9 • Supplement Issue • October 2026

EDITORIAL BOARD

Advisor

Mdm. Nur'Ain Shuhaila Shohaimi
&
MOH Pharmacy Research and Development (R&D) Committee

Editor in Chief

Dr. Abdul Haniff Mohd Yahaya

Reviews Editor

Ho See Wan

Secretariat

Siti Nur Su'aidah binti Nasarudin

Jessie Ho Jia Yi

MOH PHARMACY RESEARCH AND DEVELOPMENT (R&D) COMMITTEE 2024-2026

Chairperson

Mdm. Nur 'Ain Shuhaila binti Shohaimi
Director of Pharmacy Policy and Strategic Planning Division

Secretary

Dr. Abdul Haniff Mohd Yahaya
Deputy Director, Pharmacy Policy and Strategic Planning Division

Committee Members

Mr. Manzatul Azrul Azrie Sulaiman
Pharmacy Enforcement Division

Dr. Rema Panickar a/p Sugunan @ Vasanthan
National Pharmaceutical Regulatory Agency

Mr. Ahmad Farhan Paiman
Pharmacy Board Malaysia

Dr. Subramaniam a/l Thanimalai
Hospital Sultanah Bahiyah, Kedah

Mdm. Ong Zee Yun
Hospital Melaka

Mdm. Zaidah Abd Karim
Pahang State Health Department

Dr. Doris a/p Geroge Visuvasam
Hospital Taiping, Perak

Dr. Shamala Balan
Hospital Tengku Ampuan Rahimah Klang, Selangor

Mr. Jerry Liew Ee Siung
Hospital Queen Elizabeth, Sabah

Mr. Tan Zhi Shan Sujata
Hospital Labuan

YBrs. Dr. Rahela Ambaras Khan
Hospital Kuala Lumpur

Dr. Nur Liyana Zainal Bahrin
Pharmacy Practice and Development Division

Ms. Siti Fatimah binti Ayob
Pharmacy Policy and Strategic Planning Division

Mdm. Ong Bee Yean
Hospital Enche' Besar Hajjah Khalsom

Mdm. Noraniza binti Mohamad Zalik
Hospital Pasir Mas, Kelantan

Mdm. Nurul Salwa Saleh
Hospital Tuanku Ampuan Najihah, Negeri Sembilan

Mr. Teoh Chee Jia
Hospital Seberang Jaya, Penang

Mdm. Soo Pei Pei
Perlis State Health Department

Ms. Mazlina Mukhtar
Hospital Sultanah Nur Zahirah, Terengganu

Dr. Samuel Ting Chuo Yew
Sarawak State Health Department

Dr. Navin Kumar Loganadan
Hospital Putrajaya, WP Kuala Lumpur & Putrajaya

Ms. Izzati binti Yussof
National Cancer Institute

Secretariat

Mdm. Chan Pui Lim
Pharmacy Policy and Strategic Planning Division

Mr. Mohd Azli Fakri Abdul Aziz
Pharmacy Policy and Strategic Planning Division

Dr. Hafidza Baharum
Pharmacy Policy and Strategic Planning Division

Mdm. Siti Nur Su'aidah Nasarudin
Pharmacy Policy and Strategic Planning Division

Ms. Ho See Wan
Pharmacy Policy and Strategic Planning Division

Mdm. Nur Fasihah Ashari
Pharmacy Policy and Strategic Planning Division

Dr. Nor Ilham Ainaa Muhsin
Pharmacy Policy and Strategic Planning Division

Ms. Jessie Ho Jia Yi
Pharmacy Policy and Strategic Planning Division

NATIONAL REGULATORY CONFERENCE 2026

ORGANISING COMMITTEE

Chair Person

Mdm. Wan Noraimi binti Wan Ibrahim
Director of National Pharmaceutical Regulatory Division (NPRA)

Deputy Chair Person

Dr. Noraida binti Mohamad Zainoor
National Pharmaceutical Regulatory Division (NPRA)

Mdm. Rosliza binti Lajis
National Pharmaceutical Regulatory Division (NPRA)

Mdm. Saleha binti Abd Rahman @ Ngah
National Pharmaceutical Regulatory Division (NPRA)

COORDINATION & FINANCE COMMITTEE

Mdm. Zarina binti Rosli (*Head*)

Mdm. Aiza Adlina binti Abdullah (*Assistant Head*)

Mdm. Maslinda binti Mahat

Dr. Phuar Hsiao Ling

Mdm. Melanie binti Hassim

Mdm. Zeti Hulwani binti Baba

Mdm. Emilia binti Ahmad

Mdm. Atika binti Che Omar

SOCIAL & PROTOCOL COMMITTEE

Mdm. Irdawaty binti Mohd Salleh (*Head*)

Mdm. Nurhirza binti Shaiful Yamin (*Assistant Head*)

Mdm. Siti Fatimah binti Idris

Mdm. Nadia binti Mohd Izham

Ms. Siti Nor Rahizah binti Razak

Mr. Helmi Hafiz bin Hashim

Mdm. Nurul Izzah Hany binti Ismail

Mdm. Ameirah binti Abd Karim

Mr. Mohd Rezuwan bin Ahmad

Mdm. Nur Atiqah binti Kamal Rodin

Mdm. Fatin Izzati binti Zainal

Mdm. Woon Yoke Yee

Mr. Muhammad Amirul Naquiuddin bin M. Azmi

Mdm. Noratikah binti Mohd Jam Jam

SECRETARIATE & REGISTRATION COMMITTEE

Ms. Fadhilah binti Hasbullah (*Head*)

Mdm. Azura binti Abdullah (*Assistant Head*)

Ms. Nur Aziah binti Mohd Rasali @ Razali

Mdm. Nafiza binti Mohd. Ismail

Ms. Fauziah binti Mohamed Kasim

Mdm. Nurul Aimi binti Mohd Reduzan

Mdm. Tan Shih Leng

Mr. Gopinatha Ganesh

Mr. Gan Kok Zheng

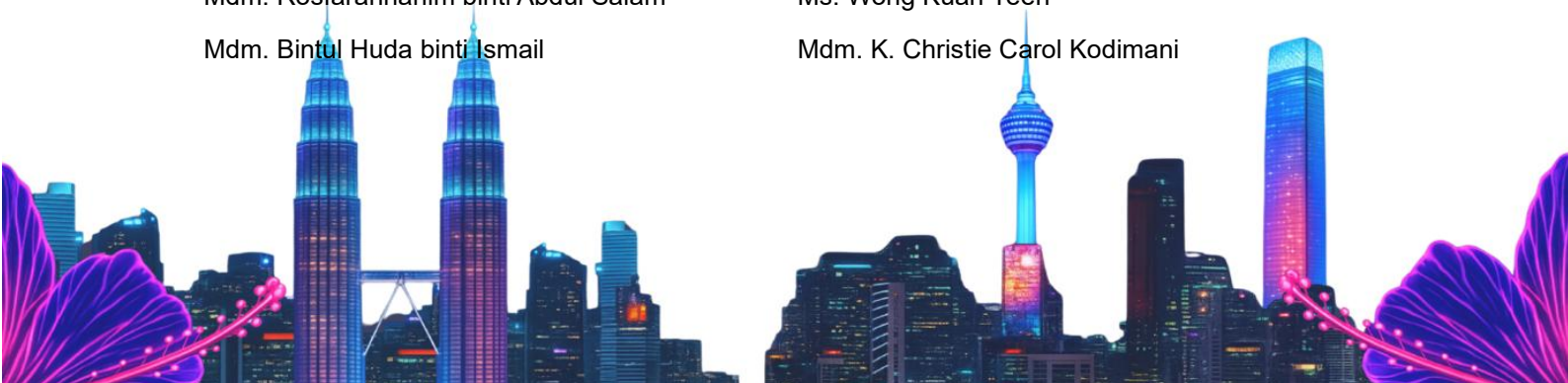
Ms. Sabariah binti Pakeer Oothuman

Mdm. Rosfarahhanim binti Abdul Salam

Ms. Wong Kuan Yeen

Mdm. Bintul Huda binti Ismail

Mdm. K. Christie Carol Kodimani



SCIENTIFIC COMMITTEE

Dr. Seetha a/p Ramasamy (<i>Head</i>)	Dr Noraisyah binti Mohd Sani (<i>Assistant Head</i>)
Mdm. Fazillahnor binti Ab. Rahim	Dr. Ahmad Yusri bin Mohd Yusop
Dr. Wan Najbah binti Nik Nabil	Dr. Lim Bee Yee
Dr. Vidhya Hariraj	Ms. Elizabeth Chong May Foong
Mdm. Ong Swan Wui	Mdm. Lee Wei Xin
Mr. Jeevanandan Narayanan	Mdm. Charlene Tay Szu Lynn
Mdm. Kavitha Sathasivan	Mr. Encik Muhammad Amirul bin Amil

PROGRAM & PUBLICITY COMMITTEE

Mdm. Siti Nasoha binti Aras (<i>Head</i>)	Mr Muhammad Mawardi bin Zakaria (<i>Assistant Head</i>)
Mdm. Azniza binti Zulkeply	Mdm. Nur Amani binti Shaari
Mr. Zulzahidi bin Yussof	Mr. Wayne Wong Guan Wei
Ms. Liew Fei Hoong	Mdm. Nur Zuhaida binti Zainal Baharin
Ms. Jacinda Khoo Mien Harn	Mdm. Sharifah Mastura binti Ahmad Fuad
Ms. Sharifah Arina binti Syed Md Hanafiah	

TECHNICAL & LOGISTIC COMMITTEE

Mr. Ng Wei Han (<i>Head</i>)	Mr Muhammad Shahriz bin Mohamad Adzib (<i>Assistant Head</i>)
Mr. Mohd Shahril bin Mat Nordin	Mdm. Nor Lisa Assakina binti Jamil
Mr. Mohamad Fitri bin Md Zuberi	Mr. Shahiran bin Shuaib
Mr. Mohd Shuhaimi bin Othman	Mr. Yashaiful bin Yayah
Mdm. Siti Jamilah binti Zainuddin	

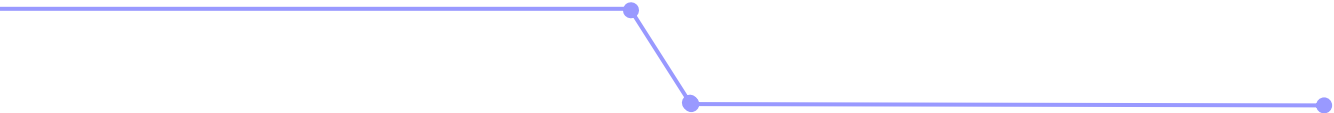
FLOOR MANAGER

Mr. Encik Muhammad Fariq Afifi bin Abdullah	Mr. Lim Wen Jun
Ms. Farah Faridah binti Jamaludin	



NATIONAL REGULATORY CONFERENCE 2026

ABSTRACT REVIEWERS



Dr. Noraisyah Mohd Sani

Dr. Lim Bee Yee

Dr. Wan Najbah Nik Nabil

Mr. Muhammad Amirul bin Amil



NATIONAL REGULATORY CONFERENCE 2026

CONFERENCE BACKGROUND

The National Regulatory Conference (NRC) is jointly organised by the National Pharmaceutical Regulatory Agency (NPRA) and the Malaysian Pharmacists Society (MPS). The conference serves as a premier national platform that brings together regulators, healthcare leaders, policymakers, industry partners, researchers, and academia to exchange knowledge, share experiences, and discuss the latest developments, challenges, and innovations in the regulatory landscape.

The theme for the 2026 conference, **"RegTech: Driving Innovation and Efficiency in Regulatory,"** reflects the increasing role of Regulatory Technology (RegTech) in transforming regulatory systems through digitalisation and emerging technologies. By harnessing innovations such as artificial intelligence (AI), machine learning, big data analytics, blockchain, and cloud computing, RegTech enables regulatory authorities and industry to strengthen regulatory compliance, enhance operational efficiency, improve data-driven decision-making, and foster greater transparency across the regulatory lifecycle.

As the healthcare and regulatory landscape continues to evolve, embracing digital transformation has become essential to meeting growing regulatory demands while ensuring timely access to safe, effective, and quality health products. NRC 2026 provides a collaborative platform for stakeholders to explore emerging technologies, exchange best practices, strengthen strategic partnerships, and discuss innovative regulatory approaches. Through these discussions, the conference aims to support Malaysia's regulatory transformation by promoting innovation, enhancing regulatory efficiency, and fostering a more agile, future-ready regulatory ecosystem that continues to safeguard public health.

CONFERENCE OBJECTIVES

- To share insights on emerging technologies in the regulatory environment.
- To strengthen collaboration and strategic partnerships among stakeholders.
- To drive regulatory efficiency through digitalisation and innovations.



PHARMACY RESEARCH REPORTS

Volume 9 • Supplement Issue • October 2026

CONTENTS

	<i>page</i>
1. Automated Extraction of Adverse Drug Reaction Classification from National Pharmacovigilance Narratives Using Natural Language Processing	1
<i>Sze Gee Lim, Maizatul Akmar Ismail</i>	
2. Microbial Contamination Trends and GMP Compliance in Malaysian Traditional Medicines and Health Supplement (TMHS) Hard-Shell Capsules: A Five-Year Retrospective Analysis	2
<i>Xin Yun Yah, Muhammad Amirul Amil, Jun Hao Koo, Norizzati Adila Salam, Muhammad Mawardi Zakaria</i>	
3. Driving Regulatory Efficiency with LC-HRMS for Nitrosamine Analysis	3
<i>Sara Khalida Jamal Khair, Nur Baizura Bujang, Ahmad Zariq Syafiq Zaire, Muhammad Amirul Shafiq Mohamad Noor, Nur Amani Shaari, Ahmad Yusri Mohd Yusop</i>	
4. A Retrospective Analysis of Functional Training at the National Pharmaceutical Regulatory Agency (NPRA) from 2020 to 2025	4
<i>Jamilatul Wahidah Jamal Rodzi, Sharifah Nor Sazlin Syed Zainuddin</i>	
5. Risk Minimisation Measures for Sodium Valproate: Insights into Malaysian Pharmacists' Knowledge and Practice	5
<i>Rema Panickar, Wan Noor Ardila Wan Abhar, Tuan Mazlelaa Tuan Mahmood, Sabariah Pakeer Oothuman</i>	
6. First-Line Anti-Tuberculosis Drugs in Malaysia: A Descriptive Analysis of the Adult Safety Profile from the National Pharmacovigilance Database	6
<i>Vidhya Hariraj, Farah Faridah Jamaludin, Nur Dayana Nisbar, Norshazareen Abd Manab, Norleen Mohamed Ali</i>	



7. **Cold Chain Management and Knowledge of Person-In-Charge (PIC) for Time- and Temperature-Sensitive Pharmaceutical Products (TTSP) at Licensed A Premises in Klang Valley, Malaysia** 7
Chie Wei Sim, Chun Wei Lim, Nur Azimah Mohd Taman
8. **Ensuring the Safe Glow: In silico ADMET Predictions and HPLC-PDA Method Development and Validation for Triclosan Quantification in Cosmetics** 8
Muhammad Amirul Amil, Malissa Wani Mohammad Amini, Luqmanul Hakim Khudzri, Shahirah Atiqah Osman, Kok Zheng Gan, Nur Baizura Bujang, Ahmad Yusri Mohd Yusop
9. **Stakeholder Acceptance and Regulatory Concerns Regarding the Sale of Drugs (Investigational Products for Clinical Trials) Regulations in Malaysia** 9
Khim Boon Tee, Illayaraja Krishnan, Shin Yee Tan, Wei Xin Lee, Nursafira Khiril Amir, Zakiah Bakar Ali, Nur Atiqah Kamal Rodin, Syazwani Sirdar Ali, Rosliza Lajis, Azuana Ramli, Zaril Harza Zakaria
10. **Enhancing Regulatory Efficiency in Evaluating the Need for Bioequivalence Study Inspections: A 5-Year Retrospective Review of Process Improvements** 10
Nabila Mohd Shaffie, Sharifah Mastura Ahmad Fuad, Mohd Azwadi Kamarudin, Maisarah Mohd Jaafar, Khairulanwar Burhanuddin



Abstract 1

Automated Extraction of Adverse Drug Reaction Classification from National Pharmacovigilance Narratives Using Natural Language Processing

Sze Gee Lim¹, Maizatul Akmar Ismail²

¹ Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

² Faculty of Computer Science and Information Technology, Universiti Malaya, 50603 Kuala Lumpur, Malaysia

Abstract

Introduction: Adverse drug reactions (ADRs) pose serious risks to patient safety and contribute significantly to the healthcare burden. In Malaysia, over 30,000 ADR reports are processed annually. Manual pharmacovigilance workflows remain labour-intensive, time-consuming, and inconsistent, particularly in mapping case narratives to predefined ADR terms.

Objective: This study aimed to develop and evaluate an automated natural language processing (NLP) approach for multi-label ADR classification to improve pharmacovigilance efficiency within regulatory workflows.

Methods: We developed the first domain-specific NLP pipeline using Malaysia's QUEST database (2015-2019) to identify and classify 80 predefined skin and subcutaneous tissue ADRs from 28,980 annotated case narratives. Two machine learning models, Multinomial Naive Bayes and Bidirectional Encoder Representations from Transformers (BERT), were evaluated under baseline, improved (threshold calibration and medical term integration), and augmented (ChatGPT-generated synthetic data) configurations. The best-performing model was deployed as a web-based application and reviewed by pharmacists using recent case narratives.

Results: Micro-F1 score reflects the combined precision and recall across ADR terms. Naïve Bayes had low baseline scores (0.36–0.54), improved substantially under improved configurations (0.75–0.77), and remained stable after augmentation. BERT performed consistently well across all configurations, with scores ranging from 0.85 to 0.87. As the best-performing model, it increased label coverage from 15 (baseline) to 74 (augmented). Pharmacist review confirmed at least one correct ADR among the top five predictions.

Conclusion: This study introduces a practical artificial intelligence (AI) framework for streamlined ADR classification, supporting real-world pharmacovigilance workflows and providing a regulatory-aligned foundation, with future expansion to other System Organ Classes and potential integration of causality assessment.

Keywords: Adverse drug reactions, pharmacovigilance, natural language processing, multi-label classification, machine learning

NMRR ID: NMRR ID-25-01404-FFD

Corresponding author: Sze Gee Lim

Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Email: lsgee@npra.gov.my

Abstract 2

Microbial Contamination Trends and GMP Compliance in Malaysian Traditional Medicines and Health Supplement (TMHS) Hard-Shell Capsules: A Five-Year Retrospective Analysis

Xin Yun Yah¹, Muhammad Amirul Amil¹, Jun Hao Koo¹, Norizzati Adila Salam¹, Muhammad Mawardi Zakaria¹

¹ Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Abstract

Introduction: Despite stringent regulations, persistent Good Manufacturing Practice (GMP) non-compliance raises public health concerns regarding the safety of traditional medicines and health supplements (TMHS). The growing demand for TMHS in Malaysia highlights critical vulnerabilities involving microbial contamination in hard-shell capsule products.

Objective: To evaluate microbial contamination risks in Malaysian TMHS hard-shell capsule production by analysing post-marketing product recall data to characterize patterns, and specific contamination risks.

Methods: A retrospective analysis was conducted using the National Pharmaceutical Regulatory Agency (NPRA) internal post-marketing surveillance and product recall database for the five-year period between 2020 and 2024.

Results: Analysis of 8,930 products revealed a TMHS recall rate of 4.73%, over four times the pharmaceutical recall rate of 1.09%. Among 245 TMHS recalls, 68 (27.76%) hard-shell capsule products were withdrawn specifically due to microbial contamination, primarily failing Total Aerobic Microbial Count (73.53%), Bile-Tolerant Gram-Negative Bacteria (42.65%), and Total Yeast and Mould Count (22.06%). The scale of public exposure was vast, with affected batches exceeding 11.97 million capsules cumulatively. A pattern of recurrent non-compliance was observed, with 25% of microbial recalls originating from a single manufacturer.

Conclusion: TMHS hard-shell capsule products face disproportionate microbial contamination risks driven by systemic quality management deficiencies. The high recall volume combined with and repeated non-compliance by certain manufacturers, emphasizes the urgent need for regulatory bodies to shift from reactive post-marketing surveillance to proactive, risk-based enforcement.

Keywords: Good Manufacturing Practice, microbial contamination, hard-shell capsules, traditional medicine and health supplements, product recall

NMRR ID: NMRR ID-25-00286-OTP

Corresponding author: Xin Yun Yah

Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Email: yahxinyun@npra.gov.my

Abstract 3

Driving Regulatory Efficiency with LC-HRMS for Nitrosamine Analysis

Sara Khalida Jamal Khair¹, Nur Baizura Bujang¹, Ahmad Zariq Syafiq Zaire¹, Muhammad Amirul Shafiq Mohamad Noor¹, Nur Amani Shaari¹, Ahmad Yusri Mohd Yusop¹

¹ Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Abstract

Introduction: Detecting N-Nitrosodimethylamine (NDMA) in extended-release (XR) metformin tablets is challenging due to ultra-trace limits and the potential for false-positive identifications. Conventional screening methods using low-resolution mass spectrometry often struggle with complex matrix effects caused by the hydrophilic polymer used in tablet coatings and isotopic interference from ¹⁵N-Dimethylformamide (DMF).

Objective: This study aims to develop and validate a robust liquid chromatography-high-resolution mass spectrometry (LC-HRMS) workflow as an orthogonal tool to distinguish true NDMA presence from DMF and enhance regulatory decision-making.

Methods: An LC-HRMS method was developed using a quadrupole time-of-flight (QTOF) in APCI positive mode. Separation was optimised on an HSS T3 column to discriminate the exact mass of NDMA (m/z 75.0553) from the isobaric ¹⁵N-DMF (m/z 75.0571). The protocol incorporated a biphasic liquid-liquid extraction (dichloromethane/water) to disrupt the XR polymer gel, followed by nitrogen evaporation. Validation was performed in accordance with ICH Q2(R2) guidelines.

Results: The method successfully separated NDMA from DMF, achieving good sensitivity with a limit of quantitation of 0.04 ppm in sample, mean recovery of 99.01% and precision of 2.5% RSD ($r^2 > 0.995$). LC-HRMS analysis confirmed product non-compliance at 0.70 ppm, significantly higher than 0.44 ppm detected by GC-MS/MS screening. This exceeds the 0.048 ppm limit by over 14-fold.

Conclusion: This LC-HRMS workflow is a critical orthogonal tool for confirming NDMA in complex formulations, resolving matrix-driven discrepancies and revealing the true extent of contamination. By ensuring definitive data, it minimizes unnecessary investigations, accelerates enforcement, and ultimately facilitates effective post-market surveillance while enhancing patient safety.

Keywords: NDMA, nitrosamine analysis, impurity profiling, orthogonal confirmation, LC-HRMS

NMRR ID: NMRR ID-26-00904-PK7

Corresponding author: Sara Khalida Jamal Khair

Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Email: sarakhalida@npra.gov.my

Abstract 4

A Retrospective Analysis of Functional Training at the National Pharmaceutical Regulatory Agency (NPRA) from 2020 to 2025

Jamilatul Wahidah Jamal Rodzi¹, Sharifah Nor Sazlin Syed Zainuddin¹

¹ Centre of Regulatory Coordination & Strategic Planning, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Abstract

Introduction: The pharmaceutical regulatory landscape is rapidly evolving due to advanced therapeutics innovations. Continuous adaptation of workforce training is essential to ensure role-specific competencies.

Objective: To examine functional training trends at the National Pharmaceutical Regulatory Agency (NPRA) over a six-year period, and to assess their alignment with evolving regulatory demands.

Methods: A retrospective trend analysis was conducted using NPRA training records (n=850) from 2020 to 2025. Training sessions were manually categorized into relevant competency domains. Descriptive statistics and cross-tabulation analyses were performed using Microsoft Excel to evaluate trends in training locations.

Results: Training was categorised into six domains: (i) Laboratory analysis & technical skills (35.1%), (ii) Good practice (GxP), inspection & quality systems (22.9%); (iii) Product evaluation & regulatory affairs (21.4%); (iv) Advanced therapies, vaccines, & biologics (10.1%); (v) IT, digital transformation & AI (6.0%); and (vi) Pharmacovigilance & post-market surveillance (4.5%). Local training was dominated by domain (i) (93.3%), and conducted mainly through internal NPRA programmes, with some external training at universities and government agencies. The overseas training focused largely on domains (ii) and (iv) and was organised by international regulatory agencies and universities. Overall, topic complexity increased across all domains, most notably in domain (v), which progressed from basic cloud literacy in 2020 to Python, AI prompting, and data mining by 2025.

Conclusion: The NPRA demonstrates a dynamic and adaptive training strategy that ensures workforce competencies remain aligned with evolving regulatory requirements, thereby safeguarding the safety, efficacy, and quality of therapeutic substances in the local market.

Keywords: Functional training, competency development, workforce strategy

NMRR ID: NMRR ID-26-00838-VBN

Corresponding author: Jamilatul Wahidah Jamal Rodzi

Centre of Regulatory Coordination & Strategic Planning, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Email: jamilatul@npra.gov.my

Abstract 5

Risk Minimisation Measures for Sodium Valproate: Insights into Malaysian Pharmacists' Knowledge and Practice

Rema Panickar¹, Wan Noor Ardila Wan Abhar², Tuan Mazlelaa Tuan Mahmood², Sabariah Pakeer Oothuman¹

¹ Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

² Faculty of Pharmacy, Universiti Kebangsaan Malaysia, Kampus Jalan Raja Muda Abdul Aziz, 50300 Kuala Lumpur, Malaysia

Abstract

Introduction: Sodium valproate (VPA) poses significant teratogenic risks, prompting regulatory agencies worldwide to implement risk minimisation measures (RMMs). In 2020, Malaysia's National Pharmaceutical Regulatory Agency (NPRA) introduced RMMs including new contraindications, a pregnancy prevention programme and risk communication. This study evaluates the impact of these measures on pharmacy practice.

Objective: To assess Malaysian government pharmacists' knowledge and practice regarding updated VPA RMMs, and identify factors predicting good knowledge.

Methods: A nationwide, cross-sectional web-based survey was conducted among pharmacists in Malaysian Ministry of Health facilities (May-June 2024). Data were collected via self-administered questionnaires, and analysed using descriptive statistics and multivariate logistic regression. Knowledge was categorised using Bloom's cut-off points.

Results: Among 456 respondents, majority demonstrated moderate (50%) to high (18.4%) knowledge. While NPRA (55.3%) was the primary source for VPA-specific safety information, pharmacists relied heavily on mobile applications (64.3%) for general updates. The boxed warning was the most recognised RMM (86.2%), while patient cards were the most provided material (46.3%). Newly initiated patients more frequently received pharmacist interventions, including patient cards (50.9%), and counselling on teratogenic risks (47.1%) or contraception (30.9%). Strongest predictors of "Good Knowledge" included working in health clinics (aOR 1.77, 95% CI 1.11–2.83, p=0.018) and in the East Coast region (aOR 2.85, 95% CI 1.40–5.79, p=0.004).

Conclusion: Malaysian pharmacists possess moderate-to-high knowledge and demonstrate satisfactory practice regarding updated VPA risks. However, our findings highlight a need for strengthened training and cohesive national strategies. To bridge information gaps in hospitals, regulatory strategies should shift toward digital solutions and packaging-based interventions.

Keywords: Sodium valproate, risk minimisation, teratogen, pregnancy, pharmacovigilance

NMRR ID: NMRR ID-24-00580-HTK

Corresponding author: Rema Panickar

Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Email: rema@npa.gov.my

Abstract 6

First-Line Anti-Tuberculosis Drugs in Malaysia: A Descriptive Analysis of the Adult Safety Profile from the National Pharmacovigilance Database

Vidhya Hariraj¹, Farah Faridah Jamaludin¹, Nur Dayana Nisbar², Norshazareen Abd Manab¹,
Norleen Mohamed Ali¹

¹ Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

² National Institute of Health Malaysia (NIH), Jalan Setia Murni U13/52, Seksyen U13, Setia Alam, 40170 Shah Alam, Selangor, Malaysia

Abstract

Introduction: The Malaysian National Strategic Plan for Tuberculosis (TB) Control (2016 - 2020) envisioned a TB-free country by year 2035 (<1 case/1,000,000 population). However, treatment success largely depends on patient adherence which may be affected by adverse drug reactions (ADR).

Objective: To describe and compare ADRs of first-line anti-tuberculosis drugs among adults in Malaysia.

Methods: We conducted a retrospective analysis of spontaneous ADR reports from the Malaysian pharmacovigilance database (January 2018 - June 2025) for rifampicin, isoniazid, pyrazinamide, ethambutol, rifampicin-isoniazid, and rifampicin-isoniazid-pyrazinamide-ethambutol, and combined them to compare adverse events (AEs) according to System Organ Classes (SOCs).

Results: 3 763 reports comprising of 6 544 adverse events (AEs) were identified. Out of this, 3 491 reports (92.8%) involving 4 884 AEs were related to three SOCs in descending order: Skin and Subcutaneous Tissues Disorders (2 048, 54.4%), Investigations (1 003, 26.7%) and Gastrointestinal Disorders (440, 11.7%) for all first-line antituberculosis drugs. From 3 491, Rifampicin-Isoniazid-Pyrazinamide-Ethambutol (EHRZ) was the most reported (1 479, 42.4%), followed by Rifampicin (664, 19.0%) and Isoniazid (545, 15.6%). 679 (33.2%) of cutaneous ADR reports were categorised as serious, of which 252 reports (37.1%) were SCARS (Severe Cutaneous Adverse Reactions) predominantly, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) (198, 78.6%).

Conclusion: The reported pattern in Malaysia aligns with the known safety profile of first-line anti-tuberculosis drugs. However, there was a high number of DRESS syndrome reports for first-line anti-tuberculosis drugs. This emphasizes the need for early detection and management strategies of DRESS syndrome presentations among patients to increase treatment success.

Keywords: First-line anti-tuberculosis drugs, severe cutaneous adverse drug reactions, drug reaction with eosinophilia and systemic symptoms, rifampicin, isoniazid

NMRR ID: NMRR ID-24-00786-KLO

Corresponding author: Vidhya Hariraj

Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Email: vidhya@npra.gov.my

Abstract 7

Cold Chain Management and Knowledge of Person-In-Charge (PIC) for Time- and Temperature-Sensitive Pharmaceutical Products (TTSP) at Licensed A Premises in Klang Valley, Malaysia

Chie Wei Sim¹, Chun Wei Lim¹, Nur Azimah Mohd Taman¹

¹ Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Abstract

Introduction: Time- and temperature-sensitive pharmaceutical products (TTSP) require controlled storage and distribution to maintain their quality; however, local data on handling practices is scarce.

Objective: To identify the availability of cold-chain equipment (storage and distribution devices), temperature monitoring devices and practices, and to assess the person-in-charge (PIC) knowledge among TTSP handlers in Klang Valley, Malaysia.

Methods: A cross-sectional, on-site survey using a validated English questionnaire was conducted from October 2022 to January 2023 among randomly selected Licensed A premises operating as TTSP importers, wholesalers and/or retailers. Descriptive statistical analyses were performed using SPSS.

Results: Of 351 premises approached, 268 consented, and 218 handled TTSP; 78.0% were retailers. Among TTSP handlers, 77.0% used household or commercial refrigerators, and 87.2% had temperature-monitoring devices. However, only 13.1% performed temperature mapping within the past three years, and 25.8% reported calibration within the previous 12 months. Most premises (86.8%) documented temperatures in the past three months, mainly using manual records (93.2%). Backup generators, alarm systems, and contingency plans were largely absent (78.6%, 83.0%, and 84.0%, respectively). Of the 66 premises distributing TTSP, 81.8% used shipping containers, but only 21.2% had qualified them. Awareness of the GDP Guideline (2018) was 44.8%, and 88.4% reported no TTSP-related training in the past five years.

Conclusion: Cold chain and GDP compliance among TTSP handlers in the Klang Valley was inconsistent, with gaps in equipment qualification, calibration, contingency planning, and training. Greater GDP awareness, targeted TTSP training, and a risk-based regulatory approach may improve compliance and product quality.

Keywords: Cold chain, Good Distribution Practice, regulatory compliance, time- and temperature-sensitive pharmaceutical products

NMRR ID: NMRR-21-1921-58922

Corresponding author: Chie Wei Sim

Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Email: sim@npra.gov.my

Abstract 8

Ensuring the Safe Glow: In silico ADMET Predictions and HPLC-PDA Method Development and Validation for Triclosan Quantification in Cosmetics

Muhammad Amirul Amil¹, Malissa Wani Mohammad Amini¹, Luqmanul Hakim Khudzri¹, Shahirah Atiqah Osman¹, Kok Zheng Gan¹, Nur Baizura Bujang¹, Ahmad Yusri Mohd Yusop¹

¹ Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Abstract

Introduction: Triclosan, a common antimicrobial in cosmetics, raises concerns due to bioaccumulation, and potential health risks such as hormone disruption, skin irritation, and antimicrobial resistance. Additionally, regulatory limits exist in the EU, US, and Malaysia. However, quantification in complex cosmetic matrices remains challenging due to the lack of validated methods.

Objective: To develop and validate high-performance liquid chromatography with photodiode array detection (HPLC-PDA) method for triclosan determination in various cosmetic matrices, complemented by in silico evaluation of its absorption, distribution, metabolism, excretion, and toxicity (ADMET) properties.

Methods: The ADMET properties of triclosan were assessed using SwissADME, pkCSM, and ProTox 3.0. Cosmetic samples, i.e., creams, gels, liquids, and bar soaps, were extracted with acetonitrile:water (3:1, v/v). Quantification was performed using an HPLC-PDA with detection at 280 nm and a 10-minute runtime. Method validation followed ICH Q2(R2) guidelines, assessing system suitability, linearity, limit of detection (LOD), limit of quantification (LOQ), specificity, accuracy, and precision.

Results: In silico analysis suggested moderate oral bioavailability and high plasma protein binding, consistent with bioaccumulation potential. Chromatographic performance was satisfactory, with a tailing factor of 1.35 and 7,590 theoretical plates. Linearity was observed from 3–100 µg/mL ($r^2 = 0.9987$), with LOD and LOQ of 1 and 3 µg/mL, respectively. Accuracy ranged from 90–110%, and precision was below 5% RSD.

Conclusion: In silico analysis provided mechanistic insights into triclosan's ADMET characteristics, while validated HPLC-PDA method enabled accurate quantification across cosmetic formulations. These approaches offer a comprehensive strategy for exposure assessment, quality control, and regulatory compliance in cosmetics.

Keywords: Triclosan, HPLC-PDA, method validation, ICH Q2(R2), cosmetic

NMRR ID: NMRR ID-24-03758-MXF

Corresponding author: Muhammad Amirul Amil

Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Email: amirulamil@npra.gov.my

Abstract 9

Stakeholder Acceptance and Regulatory Concerns Regarding the Sale of Drugs (Investigational Products for Clinical Trials) Regulations in Malaysia

Khim Boon Tee¹, Illayaraja Krishnan¹, Shin Yee Tan¹, Wei Xin Lee¹, Nursafira Khiril Amir¹, Zakiah Bakar Ali¹, Nur Atiqah Kamal Rodin¹, Syazwani Sirdar Ali¹, Rosliza Lajis¹, Azuana Ramli², Zaryl Harza Zakaria¹

¹ Centre of Product and Cosmetic Evaluation, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

² Pharmaceutical Services Programme, Ministry of Health, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Abstract

Introduction: Malaysia currently manages clinical trials via non-binding guidelines. Following a 2023 WHO assessment that identified critical regulatory gaps, the Sale of Drugs (Investigational Products for Clinical Trials) Regulations (SODIP) was proposed to establish an enforceable legal framework for participant safety and data integrity.

Objective: To evaluate stakeholder acceptance and identify regulatory concerns regarding the proposed SODIP 2025 framework and its perceived impact on Malaysia's clinical research ecosystem.

Methods: This descriptive cross-sectional study employed a two-stage hybrid methodology between March and November 2025. Stage 1 comprised five stakeholder engagement sessions involving 168 participants (sponsors, ethics committees, investigators and trial participants) who completed structured questionnaires. Stage 2 utilized an online Unified Public Consultation (UPC) where 19 respondents submitted 116 qualitative comments. Data were analysed to assess acceptance across 16 key regulatory concepts.

Results: High engagement was noted among investigators (n=76) and sponsors (n=29). Quantitative data showed strong acceptance for Clinical Trial Authorisation, product labelling, and reliance on reference authorities. Qualitatively, while the legal framework was supported, primary concerns included "approval timeline" and "increased regulatory burden." Notably, investigators expressed concerns regarding the impact of new fees on Investigator-Initiated Trials (IITs). Over 80% of participants supported a centralized regulatory database for real-time safety and approval tracking.

Conclusion: The study demonstrates broad stakeholder support for SODIP to align Malaysia with international GCP standards. However, implementation must address the identified concerns, specifically administrative delays and the financial burden on IITs to ensure the framework strengthens oversight without compromising Malaysia's global competitiveness in clinical research.

Keywords: Clinical trial authorisation, regulatory framework, stakeholder perspectives, investigational medicinal products

NMRR ID: NMRR ID-25-01425-XJT

Corresponding author: Khim Boon Tee

Centre of Product and Cosmetic Evaluation, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Email: tkboon@npra.gov.my

Abstract 10

Enhancing Regulatory Efficiency in Evaluating the Need for Bioequivalence Study Inspections: A 5-Year Retrospective Review of Process Improvements

Nabila Mohd Shaffie¹, Sharifah Mastura Ahmad Fuad¹, Mohd Azwadi Kamarudin¹, Nur Maisarah Mohd Jaafar¹, Khairulanwar Burhanuddin¹

¹ Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Abstract

Introduction: In July 2020, NPRA introduced the Evaluation on the need for the BE Study Inspection (BEDE), a risk-based regulatory tool to determine the need for bioequivalence study inspections. Early implementation faced operational bottlenecks and prolonged timelines, highlighting the need for systematic, data-driven process refinements to enhance regulatory efficiency while maintaining risk-based oversight.

Objective: To assess the impact of staged process refinements to the BEDE framework implemented between 2020 and 2025 on regulatory efficiency and turnaround time compliance.

Methods: A retrospective interrupted time series analysis (ITSA) was conducted on 1,100 BEDE applications. Two primary intervention points were evaluated: (1) implementation of stratified evaluation pathways (Auto-exemption, Expedited, and Full Evaluation) in February 2022; and (2) comprehensive process refinements in October 2024, involving updated risk-scoring, streamlined decision-making frameworks, digitalised communication, and automated screening tools. Outcomes included processing timelines and compliance with target turnaround times [TAT].

Results: The analysis demonstrated a progressive enhancement in regulatory efficiency across the study period. The comprehensive process refinements implemented in October 2024 resulted in a 67% reduction in mean evaluation-to-decision timelines, from 137.14 to 44.81 working days. Compliance with the 45-working-day evaluation target increased nearly five-fold, from 14.43% to 67.25%. At the screening stage, 66.33% of applications were completed within the 30-working-day target following the intervention. These improvements were immediate and sustained, without compromising risk-based regulatory oversight.

Conclusion: Staged, data-driven refinements to the BEDE process significantly enhanced regulatory efficiency and TAT compliance. Future directions include leveraging artificial intelligence to strengthen risk-based predictive modelling and further streamline bioequivalence study inspection oversight.

Keywords: BEDE, bioequivalence study inspection, regulatory inspection, risk-based assessment, regulatory strengthening

NMRR ID: NMRR ID-26-01-01394-AY3

Corresponding author: Nabila Mohd Shaffie

Centre of Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti (Jalan Prof Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia

Email: nabilashaffie@npra.gov.my

ACKNOWLEDGEMENT

The Organising Committee of the National Regulatory Conference 2026 would like to express our deepest appreciation and heartfelt gratitude to:

YB Datuk Seri Dr. Haji Dzulkefly bin Ahmad
Minister of Health Malaysia

YBhg. Datuk Seri Hasnol Zam Zam bin Ahmad
Secretary General, Ministry of Health Malaysia

YBhg. Datuk Dr. Mahathar bin Abd Wahab
Director General of Health, Malaysia

YBrs. Dr. Azuana binti Ramli
Deputy Director General of Health (Pharmaceutical Services), Ministry of Health Malaysia

Plenary Speakers

Judges

Abstract Reviewers

Presenters

Moderators

Participants

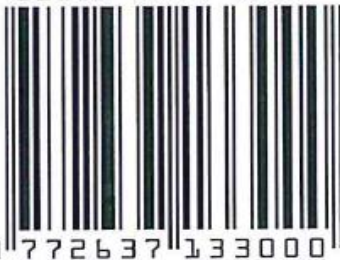
**and ALL who have contributed
and assisted in one way or another**

We extend our heartfelt gratitude to everyone who has contributed to the success of the National Regulatory Conference 2026. Your support, in every way, has been invaluable.

Thank you for being part of this event. We hope it has been a rewarding experience for you, and we look forward to welcoming you again at our next conference!



eISSN 2637-1332



9 772637 133000

