



Pharmacovigilance NEWSLETTER



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The Aim of the newsletter:

- Dissemination of drug and vaccine safety information, trend of adverse events, adverse event evaluation, regulatory decisions, and pharmacovigilance enforcement activities.
- Sharing the progress of DGDA's Pharmacovigilance system towards WHO maturity level 3.
- Sharing the activities of the ADRM cell, Pharmacovigilance and COVID-19 Safety Surveillance cell and the outcomes of the National Pharmacovigilance Centre, DGDA and related committees.

Introduction

The Pharmacovigilance Newsletter provides the latest information on the safety of medicine, vaccines, and regulatory decisions of the DGDA. It is one of the important methods of communicating with pharmacovigilance stakeholders. The newsletter includes the status of adverse event evaluation with regulatory decisions and actions, including COVID-19 vaccines, reliance on other international regulatory authorities, introduction of Good Pharmacovigilance Practices (GVP) guidelines, training, coordination with different stakeholders, and so on.

Adverse Drug Reaction Monitoring in Bangladesh:

The Adverse Drug Reaction Monitoring (ADRM) Cell serves as the coordinating body for the national PV system in Bangladesh. From April 2023 to December 2024, the National Pharmacovigilance Centre of Bangladesh received a total of 2132 reports from different stakeholders. Out of these 2132 reports, there are 1801 ADR reports and 331 AEFI reports. All these reports were primarily evaluated by the ADRM cell. Out of these 2132 reports, 1191 were found complete, while 941 were deemed incomplete due to a lack of minimum information after follow up with the reporters. From September 2023 to January 2025, the ADRM cell organized a total of 07 workshops. So far, the committee has assessed 1191 complete reports in workshop; among those reports, 1024 were deemed to be not serious, and 167 to be serious.

*“*Serious adverse reaction: An adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a birth defect”. Ref. European Medicines Agency*

Table 1. ADRM Cell Meetings, Number of ADR & AEFI reports evaluated in the meetings

Serial No.	Name of the Month	No. of Report	Incomplete	Complete		
				Total	Not Serious	Serious
01	April to Aug, 2023	232	101	131	121	10
02	Sep, 23 to Feb, 24	713	451	262	249	13
03	Mar, 24 to April, 24	142	88	54	53	1
04	May, 24 to July, 24	286	118	168	159	9
05	Aug, 24 to Sep, 24	202	99	103	99	4
06	Oct, 24 to Nov, 24	299	58	241	241	0
07	December, 2024	258	26	232	102	130
Total		2132	941	1191	1024	167

The table above presents the number of ADRM Cell meetings, along with the corresponding number of Adverse Drug Reaction (ADR) and Adverse Events Following Immunization (AEFI) reports reviewed during these sessions. During this period, the Directorate General of Drug Administration (DGDA), in collaboration with development partners such as USAID MTaPS and the World Health Organization (WHO), conducted nationwide awareness programs and training sessions on pharmacovigilance.

Additionally, an electronic ADR/AEFI reporting system, known as the Pharmacovigilance Monitoring System (PViMS), has been developed and is now fully operational. As a result, the DGDA Pharmacovigilance Department is now receiving reports both electronically and in hard copy. This dual-channel reporting system has significantly contributed to the increased volume of ADR and AEFI reports received at DGDA.

Adverse Drug Reaction Advisory Committee (ADRAC) Meeting for ADE evaluation:

DGDA organized 16th and 17th Adverse Drug Reaction Advisory Committee (ADRAC) Meetings in 2023 & 2024 at DGDA with the reports related to drugs and vaccines (except COVID-19 vaccines). The Director General of DGDA and Chairman of ADRAC presided over the meetings. The 16th ADRAC meeting was held on the reports received from October 2022- March 2023, and the 17th meeting was on the report received from April 2023- April

2024. Out of 243 complete reports reviewed by a technical subcommittee, 31 serious ADE reports were forwarded to the 16th and out of 388 complete reports reviewed by a technical subcommittee, 24 serious ADE reports were forwarded to the 17th meeting of the Adverse Drug Reaction Advisory Committee (ADRAC) for regulatory recommendations.

Table 2. Classification of serious adverse drug reactions evaluated in the meeting of 16th & 17th ADRAC

WHO Causality Assessment Scale	Total Serious Adverse Event Reports	
	16 th ADRAC	17 th ADRAC
Certain	-	01
Possible	-	08
Probable/Likely	26	09
Unlikely	05	-
Unclassified	-	02
Unclassifiable	-	04
Total	31	24

Regulatory decisions taken by Adverse Drug Reaction Advisory Committee:

Meeting Info	Decisions
16 th meeting of ADRAC held on 21 st May 2023	Based on the information published in WHO Newsletter, Issue-1, 2023 (Signal), there is a potential risk of Acute Respiratory Distress Syndrome (ARDS) associated with the use of Hydrochlorothiazide, and a risk of Hypokalaemia linked to the use of Itraconazole. Therefore, a letter must be sent to the Marketing Authorization Holder (MAHs) instructing them to include relevant warnings in the Patient Information Leaflet (PIL) of both medicines.
	A letter must be sent to the relevant institutions to raise awareness and provide guidance that steroid-containing medicines should not be prescribed without consultation by a specialist physician, and should not be sold or used without a valid prescription.
	Letters will be sent to all medical and nursing educational institutions, pharmaceutical companies (MAHs), healthcare professionals (HCPs), professional medical associations, and the Bangladesh Medical Association (BMA), advising them to exercise utmost caution during the administration of injectable medicines, including antibiotics, and to closely monitor patients for any signs of hypersensitivity reactions.
	In order to increase the reporting of Adverse Drug Reactions (ADRs), necessary steps will be taken to raise widespread awareness among various medical colleges, hospitals, department heads, and institutional heads. This will include providing the required reporting forms, online links, instructions, and other relevant materials to facilitate easy ADR reporting to the Directorate General of Drug Administration (DGDA).
	Letters must be sent to the institutions that regularly submit reports, expressing appreciation for their continued contributions. The letters should also include necessary information for report evaluation and request their continued cooperation in submitting ADR reports in the future.
17 th meeting of ADRAC held on 11 th June 2024	A recommendation must be submitted to the Drug Control Committee (DCC) for the cancellation of the registration of Halothane as an inhalational anesthetic agent.
	A Safety Alert needs to be issued regarding the risk of aplastic anaemia associated with the use of Atezolizumab.

Information of the WHO Pharmaceuticals Newsletter, Issue No. 1, 2022. Total four alerts have been discussed in the meetings identified through literature review which were issued by other regulated country's NRA. One signal related to muscle spasms or cramps associated with Methotrexate, generated through the WHO VigiBase (A global individual case safety reports database.)

The committee has also recommended the safety information published in the Drug Safety

Alerts of 2024

Sl. No	Name of Medicine	Adverse Drug Reaction	Recommendation by ADRAC	Remarks
01	Halothane	Cough and respiratory distress leading to respiratory failure and death	Recommendation sent to Drug Control Committee (DCC) to cancel the registration.	17 th meeting of ADRAC held on 11 JUN 2024
02	Ciprofloxacin	Tendinitis, tendon rupture, peripheral neuropathy, central nervous system effects and exacerbation of myasthenia gravis	Update the PIL	17 th meeting of ADRAC held on 11 JUN 2024
03	Fluoroquinolone Antibiotics	Risk of suicidal thoughts and behaviour	Letter sent for the opinion of Associations of Physicians of Bangladesh (APB), Society of Surgeon & Infectious disease specialist	17 th meeting of ADRAC held on 11 JUN 2024

Workshop on GVP Guideline for MAHs

On November 18, 2024, a workshop focusing on the Good Pharmacovigilance Practices (GVP) Guideline for Marketing Authorization Holders (MAHs) was conducted. The event aimed to provide in-depth knowledge and practical guidance to representatives from pharmaceutical companies on adhering to international standards for pharmacovigilance. The workshop covered key elements of GVP, emphasizing the critical responsibilities of MAHs in ensuring drug safety, monitoring adverse drug reactions (ADRs), and maintaining compliance with regulatory requirements. The session also explored the role of MAHs in post-marketing surveillance, risk management, and the importance of transparent reporting systems.



Figure: Workshop on Good Pharmacovigilance Practices (GVP) Guideline for Marketing Authorization Holders

Induction Training for the newly joined DGDA officials on Pharmacovigilance:

On December 20, 2023, the Pharmacovigilance (PV) Department of the Drug Regulatory Authority (DGDA) organized an induction training session for 53 newly recruited Superintendent of Drugs (SD). The purpose of the training was to equip these SDs with essential knowledge and skills related to pharmacovigilance activities, ensuring they understand their roles in monitoring the safety and efficacy of pharmaceuticals in the market. The training covered key aspects of pharmacovigilance, including adverse drug reactions (ADRs), reporting mechanisms, regulatory frameworks, and the important in safeguarding public health.



Figure: Induction training for the newly joined 53 Superintendent of Drugs on Pharmacovigilance activities.

Implementation of the Good Pharmacovigilance Practices (GVP) Guideline for Marketing Authorization Holders (MAHs):

The Directorate General of Drug Administration (DGDA) organized three training programs on the newly formulated Good Pharmacovigilance Practices (GVP) Guidelines for the Marketing Authorization Holders (MAHs) in Dhaka, starting from September 2023. The training sessions included a comprehensive orientation, group work, presentations, and a Question-and-Answer (Q&A) session to help MAHs representatives understand their roles in accordance with the guideline. A copy of this guideline was distributed to all representatives and these programs were conducted with the technical assistance of WHO and the USAID MTaPS Program.

It is noteworthy that the GVP Guidelines for MAHs were developed and implemented by the DGDA in September 2023, with the endorsement of the Ministry of Health and Family Welfare (MoHFW). The development process involved active participation from representatives of the pharmaceutical industry as working committee members, and public consultations were held throughout the process. The guidelines are available on the DGDA website (<http://dgda.gov.bd>).



Figure: GVP guideline implementation Programs for MAHs

GVP Inspection:

The Pharmacovigilance Department of the Directorate General of Drug Administration (DGDA) plays a pivotal role in ensuring the safety and efficacy of pharmaceutical products in Bangladesh. As part of its efforts to uphold public health standards, the department conducts regular inspections of Marketing Authorization Holders (MAHs) to ensure compliance with the Good Pharmacovigilance Practices (GVP) Guideline and the Drug & Cosmetics Act 2023.

These inspections are integral to the oversight and regulation of the pharmaceutical sector, ensuring that MAHs adhere to the established standards for monitoring the safety of medicines. Following a structured and systematic approach, the DGDA has developed an annual inspection plan for the MAHs, which is designed to assess compliance with pharmacovigilance requirements, including the monitoring of adverse drug reactions, reporting protocols, and the proper handling of safety data.

The DGDA's Pharmacovigilance team has successfully conducted inspections of four prominent MAHs: Popular Pharmaceuticals Ltd., Healthcare Pharmaceuticals Ltd., Radiant Import & Export Ltd., and Janata Traders. These inspections not only assess the compliance of these companies with national regulations but also help identify areas for improvement and further alignment with international best practices in pharmacovigilance.

The inspections focus on a wide range of pharmacovigilance activities, including the establishment of robust safety reporting systems, the timely reporting of adverse events, the implementation of risk management plans, and the overall capacity of MAHs to ensure the safe use of medicines. Furthermore, the team evaluates whether the MAHs have the necessary resources and processes in place to handle pharmacovigilance obligations effectively.

Through these diligent inspection processes, the DGDA continues to strengthen its regulatory framework, ensuring that marketing authorization holders uphold the highest standards of pharmacovigilance and contribute to the safe and effective use of medicines across the country.

The DGDA reviews the procedures, training programs, and guidelines implemented by the MAHs, as well as the practices they undertake. The inspection also assesses awareness of pharmacovigilance and the reporting of adverse events, including practical demonstrations. These efforts aim to ensure that the pharmacovigilance systems of the organizations comply with the GVP Guidelines and the Drug and Cosmetics Act 2023. Furthermore, the DGDA provides recommendations or assistance to strengthen the safety reporting and monitoring systems.



Healthcare



Popular Pharmaceuticals



Radiant Export & Import



Janata Traders

Figure: GVP Inspection at different MAHs

Strategy Paper Development for Increasing Non-EPI Vaccine Reporting:

The Directorate General of Drug Administration (DGDA) in Bangladesh has been actively working towards achieving the World Health Organization (WHO) maturity level III in vaccine safety surveillance. As part of this ongoing effort, DGDA has developed two key strategies in response to recommendations from a WHO assessor. These strategies aim to strengthen the country's post-vaccination surveillance and align with the WHO's South-East Asia Regulatory Network (SEARN) Action Points 10 and 11.

The first strategy is the National Non-EPI Vaccine Safety Surveillance Strategy-2024, which focuses on monitoring and ensuring the safety of vaccines that are not part of the routine Expanded Program on Immunization (EPI). The second strategy is the National Strategy for Integrating Post-Vaccination Vigilance, which emphasizes the integration of vaccination vigilance into broader health surveillance systems to enhance the detection and management of any adverse events following immunization.

Both of these strategies were developed with the technical support of WHO and guidance from two WHO consultants based in Bangladesh. Their expertise ensured that the strategies are comprehensive and tailored to the specific needs of the country's vaccination program.

To ensure that these strategies are robust and well-aligned with the needs of all relevant stakeholders, DGDA organized three consultative workshops. These workshops were held to gather feedback from key stakeholders, including health care professionals, government officials, and public health experts, to refine the strategies and ensure their effectiveness.

In line with SEARN Action Point 10, which calls for strategies to stimulate the reporting of vaccine safety concerns, and Action Point 11, which focuses on supporting the integration of vigilance systems, the strategies aim to create a more responsive and integrated post-vaccination monitoring system in Bangladesh. By involving stakeholders and aligning with WHO recommendations, DGDA is working to strengthen the country's capacity to detect, report, and manage adverse events, ultimately ensuring the safety and effectiveness of vaccines for the Bangladeshi population.

These initiatives represent a significant step toward improving vaccine safety surveillance and are expected to contribute to achieving WHO maturity level III, a goal that will further enhance the country's ability to ensure the safety of vaccines and protect public health.



Figure: Workshop on National non-EPI Vaccine Safety Surveillance Strategy-2024 & National Strategy for Integrating Post-Vaccination Vigilance

Dissemination on Good Pharmacovigilance Practices (GVP) Guideline for Pharmaceutical Industries (MAHs)

On November 26, 2024, at 10:30 AM, the Directorate General of Drug Administration (DGDA) hosted a workshop titled "Dissemination of Good Pharmacovigilance Practices (GVP) Guidelines for Pharmaceutical Industries (MAHs)" in the department's conference room. This training aimed to educate representatives from drug manufacturers, importers, and marketers about the importance of adhering to the Good Pharmacovigilance Practices (GVP) guidelines, a cornerstone of ensuring drug safety and regulatory compliance. The workshop highlighted the responsibilities of Marketing Authorization Holders (MAHs) in pharmacovigilance, with a focus on effective monitoring, reporting, and management of adverse drug reactions (ADRs), as well as their critical role in post-market surveillance.

It provided crucial insights into the regulatory and safety obligations of drug manufacturers, importers, and marketers. It reinforced the importance of a robust pharmacovigilance system to ensure the safety of pharmaceuticals in the market and highlighted the vital role of MAHs in monitoring and managing the safety profiles of their products. Through such initiatives, the DGDA aims to foster a culture of safety, regulatory compliance, and continuous improvement within the pharmaceutical industry, ultimately contributing to the protection of public health.



Figure: Workshop on Dissemination on Good Pharmacovigilance Practices (GVP) Guideline for Pharmaceutical Industries (MAHs)

World Patients Safety Day-2024 celebration:

On September 17, 2024, the Directorate General of Drug Administration (DGDA) marked World Patient Safety Day by hosting a significant roundtable discussion aimed at raising awareness and fostering dialogue on patient safety. The event was inaugurated by the Director General of DGDA, who served as the chairperson, leading the discussion on the critical issues surrounding patient safety and its implications for healthcare in Bangladesh.

The discussions focused on various aspects of patient safety, including the role of regulatory bodies, healthcare providers, the pharmaceutical industry, and other stakeholders in ensuring the safe use of medicines and medical practices. Key topics included the importance of quality control in pharmaceutical products, safe prescribing practices, ensuring access to accurate information for both healthcare professionals and patients, and strategies to minimize errors in healthcare settings.



Figure: Roundtable discussion session at the DGDA conference room

The roundtable brought together a diverse group of esteemed participants, including representatives from the Bangladesh Association of Pharmaceutical Industries (BAPI), hospital management, Bangladesh Chemist and Druggist Samity (BCDS), the Regulatory Affairs Society of Bangladesh (ARAB), USAID's MTaPS Program, the World Health Organization (WHO), and the pharmaceutical industry. This collaboration among key stakeholders provided a platform for sharing insights, discussing challenges, and exploring solutions to improve patient safety in the country.

The participation of WHO and USAID's MTaPS Program highlighted the global and regional commitments to improving patient safety and the alignment of Bangladesh's efforts with international standards and best practices. Through the collaboration and shared expertise, the event underscored the need for continued advocacy, education, and regulatory strengthening to protect patients and enhance the quality of healthcare in Bangladesh.

By commemorating World Patient Safety Day in such a meaningful way, DGDA reinforced its commitment to safeguarding public health, ensuring that patient safety remains a top priority in healthcare and pharmaceutical practices across the nation. The roundtable discussion not only served as an important platform for dialogue but also as a catalyst for ongoing initiatives aimed at improving patient safety standards in Bangladesh.

This year's theme, "Improving Diagnosis for Patient Safety", accompanied by the slogan "Get it Right, Make it

Safe!", underscored the critical importance of accurate and timely diagnosis in enhancing patient safety and achieving better health outcomes.

To disseminate information and promote awareness on enhancing diagnostic practices and safe medication use, a rally was organized featuring festoon balloons and long banners. The banners were prominently displayed in front of the DGDA headquarters and various sections of the office.



Figure: Rally on World Patient Safety Day, 2024