

PHARMACOVIGILANCE NEWSLETTER



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VigiMobile: Provincial Adverse Events Collection Tool

In a significant step toward strengthening pharmacovigilance in Pakistan, the Drug Regulatory Authority of Pakistan (DRAP) has adopted the VigiMobile application as a provincial tool for the collection of Adverse Drug Reactions (ADRs). Developed in collaboration with the Uppsala Monitoring Centre (UMC), Sweden, VigiMobile is a customizable web-based application that enables healthcare professionals and the public to report adverse events related to medicines and vaccines easily using any digital device. The application allows reports to be completed even in offline mode and submitted once an internet connection becomes available.

Through this initiative, DRAP has decentralised the adverse event reporting mechanism in Pakistan. Reports submitted via

VigiMobile and UMC web-based reporting forms are automatically routed to the respective Provincial Pharmacovigilance Centres based on the reporter's location, effectively making VigiMobile the province's own reporting tool. Available in both English and Urdu, the platform enhances accessibility and user-friendliness for patients, healthcare professionals, and the public, with plans underway to expand support to additional regional languages.



Visit of the WHO Consultant Dr Jean-Christophe Delumeau to Pakistan for Strengthening the Pharmacovigilance System.

Dr. Jean-Christophe Delumeau, ISO-P Executive Board Member and WHO consultant, visited Pakistan for two weeks in November 2025 to support the strengthening of the National pharmacovigilance system and assist the Drug Regulatory Authority of Pakistan (DRAP) in preparation for the World Health Organisation (WHO) World Listed Authority (WLA) Maturity Level III assessment. His visit focused on capacity building, stakeholder engagement, and strengthening regulatory processes related to medicine and vaccine safety monitoring across the country.

During the first phase of the visit (3–6 November 2025), DRAP, in collaboration with WHO, organised a multi-stakeholder technical workshop in Islamabad aimed at advancing medication safety and strengthening the pharmacovigilance framework in Pakistan. The workshop brought together representatives from the National Pharmacovigilance Centre (NPC), DRAP, the Federal Directorate of Immunisation, the Common Management Unit overseeing TB, Malaria and HIV programmes, Provincial Health departments, Healthcare commissions, and VigiFlow Focal Persons from hospitals. The event was inaugurated by honorable Federal Minister of Health, Syed Mustafa Kamal, who also launched the #MedSafetyWeek awareness campaign and emphasised the importance of proactive vigilance, public engagement, and stronger coordination between federal and provincial authorities to enhance medicine and vaccine safety surveillance.

Dr Delumeau conducted interactive sessions with participants, combining strategic stakeholder mapping with hands-on technical training. The workshop, facilitated with technical input from the Uppsala Monitoring Centre (UMC), covered key areas such as the evolution of pharmacovigilance systems, benefit–risk assessment, risk management planning, safety communication, and practical use of the VigiFlow database. These activities highlighted Pakistan's continued commitment to strengthening medicine safety monitoring and progressing toward the WHO World Listed Authority (WLA) Maturity Level III benchmark for a mature and functional regulatory system.

In addition, several technical capacity-building sessions were conducted for officers of the National Pharmacovigilance Centre and DRAP. These included training on the assessment of Risk

Jean Christophe's Visit to Pakistan



Management Plans (RMPs) and Periodic Benefit–Risk Evaluation Reports (PBRERs), harmonisation of Standard Operating Procedures and pharmacovigilance working manuals, and strengthening of the Quality Management System. A virtual, coached-audit on Good Pharmacovigilance Practices (GVP) inspection was also conducted to enhance regulatory inspection capacity.

As part of his mission, Dr. Delumeau also held meetings with key stakeholders, including the Federal Directorate of Immunisation, the Polio Eradication Programme, the Provincial Pharmacovigilance Centre in Islamabad, the Common Management Unit, and the Ministry of National Health Services, Regulations and Coordination. During these engagements, he encouraged stakeholders to actively utilise the VigiFlow database, strengthen adverse event reporting, and play a proactive role in Pakistan's pharmacovigilance system.

Overall, the visit marked an important milestone in strengthening collaboration among national and international partners and further advancing Pakistan's pharmacovigilance framework to ensure safer medicines and vaccines for the population.

Title of training	Date & Venue	HCPs trained
Multi-Stakeholder Technical Workshop on Strengthening Pharmacovigilance Systems in Pakistan	03-6th November 2025, Islamabad	97
One-day Workshop on Assessment of Risk Management Plans and Periodic Benefit-Risk Assessment Reports	7th November, 2025, Islamabad	11
One-day Capacity Building Workshop for the members of the Pharmacovigilance Risk Assessment Expert Committee.	10th November, 2025, Islamabad	21
One-day Workshop on Harmonisation of Standard Operating Procedures and Working Manual for Pharmacovigilance	11th of November, 2025, Islamabad	15
Workshop on Quality Management System and Good Pharmacovigilance Practices (GVP) Inspection	12-13th November, 2025, Islamabad	15



Capacity Building Training Session for members of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC).

After completion of its three-year tenure, the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) was reconstituted by the Drug Regulatory Authority of Pakistan (DRAP) in accordance with Rule 9 (1) of the Pharmacovigilance Rules, 2022. In order to impart necessary training to the members, the Drug Regulatory Authority of Pakistan, in collaboration with the World Health Organisation, organised a one-day interactive workshop for members of the newly constituted Pharmacovigilance Risk Assessment Expert Committee (PRAEC) on 10th November 2025. The session was attended by senior officials, including Dr. Obaidullah, CEO-DRAP and Ellen Thom, Deputy WR, WHO, who welcomed the newly appointed PRAEC members and highlighted their pivotal role in strengthening pharmacovigilance oversight in Pakistan. The CEO-DRAP emphasised the importance of adopting a risk-based approach for proactive vigilance of therapeutic goods and

reiterated DRAP's commitment to ensuring the availability of safe and effective medicines and vaccines. The importance of fostering a no-blame culture for reporting adverse drug reactions (ADRs) was also underscored.

During the session, Dr. Akhtar Abbas Khan briefed participants on the current pharmacovigilance structure in Pakistan, relevant regulatory provisions including the Pharmacovigilance Rules, roles and responsibilities of PRAEC, and the current status of ADR reporting. Dr Delumeau shared global insights on the functioning of pharmacovigilance committees within stringent regulatory authorities, emphasising PRAEC's critical role in risk assessment, risk communication, and awareness among healthcare professionals and the public. PRAEC members reaffirmed their commitment to advancing medication and patient safety in collaboration with NPC-DRAP.



Composition of Pharmacovigilance Risk Assessment Expert Committee

S#	Name & Designation	Position
1	Prof. Dr. Moosa Khan, Dean, Basic Medical Sciences and Professor & Chairman, Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad	Chairman
2	Dr. Akhtar Abbas Khan, Director, Division of Pharmacy Services, DRAP.	Co-Chair
3	Mr. Abdul Mateen, Deputy Director, National Pharmacovigilance Centre, Division of Pharmacy Services, DRAP.	Secretary
4	Prof. Dr. Furqan Hashmi, Professor, Pharmacy Practice, University College of Pharmacy, University of the Punjab, Lahore	Member
5	Prof. Dr. Abdul Jabbar Shah, Professor & Chairperson, COMSATS University Abbottabad	Member
6	Mr. Rehan Anjum, Manager Pharmacy, Shaukat Khanum Cancer Hospital and Research Centre, Peshawar	Member
7	Dr. Sajjad Ali, Consultant, Internal Medicine, Shifa International Hospital, Islamabad	Member
8	Dr. Mohammad Imran Younus, Associate Professor, Health Services Academy, Islamabad	Member
9	Dr. Samina Rehman, HOD/Professor of Forensic Medicine and Toxicology, Bolan Medical College, Quetta	Member
10	Ms Nazima Asghar, Clinical Pharmacy & Pharmacovigilance Officer and Hospital Pharmacist, Holy Family Hospital, Rawalpindi	Member
11	Dr. Faiza Bashir, Director (Research), National Institutes of Health, Islamabad	Member
12	Dr. Noor-us-Saba, Ex-Director of Biological Evaluation & Research Division, DRAP, Islamabad	Member
13	Dr. Farhana Badar, Senior Biostatistician and Cancer Epidemiologist, Shaukat Khanum Memorial Cancer Hospital and Research Centre, Lahore	Member

6th Meeting of Pharmacovigilance Risk Assessment Expert Committee (PRAEC)

The 6th meeting of the PRAEC was held on 31st December 2025 at the headquarters of the Drug Regulatory Authority of Pakistan (DRAP), Islamabad. The meeting was chaired by Dr. Moosa Khan, Dean, Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad, and co-chaired by Dr. Muhammad Akhtar Abbas Khan, Head of the National Pharmacovigilance Centre (NPC) / Director, Division of Pharmacy Services. Mr. Abdul Mateen, Deputy Director (Pharmacovigilance), served as the Secretary of the meeting. Representatives from the Provincial Pharmacovigilance Centres of Punjab and Islamabad, along with members of the Common Management Unit, also attended the meeting.

Officers from the National Pharmacovigilance Centre (NPC) briefed the newly nominated members of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) on the Terms of Reference (ToRs) and the working mechanism of the committee in light of the Pharmacovigilance Rules, 2022. The committee was also



presented with the updated status of pharmacovigilance activities in the country, including the establishment of pharmacovigilance centres across all provinces, the number of adverse drug reaction (ADR) reports submitted by various stakeholders, and the proposed way forward to further strengthen the national pharmacovigilance system.

Subsequently, four domestic cases were presented and discussed in detail. These included two cases related to the revision of registration specifications of ceftriaxone injection and the review of the drug formulation of A-Care injection, which had been referred by the Punjab Pharmacovigilance Centre. In addition, two other domestic safety signals—renal impairment associated with entrectinib and myocardial infarction associated with pertuzumab—were reviewed. The Marketing Authorisation Holders (MAHs) and the National Pharmacovigilance Centre were advised to continue close monitoring of these adverse drug reactions.

In addition to the domestic cases, seven cases based on reliance on reference regulatory authorities were also discussed. Following deliberations, the committee made the necessary recommendations to the Registration Board and the respective MAHs regarding the revision of product labels and Summary of Product Characteristics (SmPCs).

Cases discussed in the 6th meeting of PRAEC

1. Proposal for Revision of Registration Specifications for Injection Ceftriaxone
2. Request for Review of Drug Formulation and Comparative Clinical Assessment of Inj A-Care (Atracurium) 50mg/5ml
3. Safety Signal of Renal Impairment with Entrectinib
4. Safety Signal of Myocardial Infarction with Pertuzumab
5. Isotretinoin: Risk of Sacroiliitis
6. Mesalazine: Risk of idiopathic intracranial hypertension
7. Thiopurines: Risk of Intrahepatic cholestasis of pregnancy
8. Finasteride, Dutasteride: Potential risk of suicidal thoughts
9. Sulfamethoxazole, trimethoprim: Risk of circulatory shock
10. Semaglutide: Risk of non-arteritic anterior ischemic optic neuropathy (NAION)
11. Cetirizine, levocetirizine: Risk of severe itching after discontinuation of long-term use



Safety communication

International Safety Issues.

Risk of Sacroiliitis with Isotretinoin



Health Canada, through its InfoWatch Newsletter (March 2025), reported a possible association between Isotretinoin and Sacroiliitis. The safety review assessed 24 international cases, of which 23 were considered possibly linked to isotretinoin use, with an average patient age of 20 years and no reported deaths. Evidence from 18 scientific publications also supported this association, although no clear biological mechanism was identified. It was informed that Health Canada will work with manufacturers to update the Canadian Product Monograph to include this potential risk, noting that symptoms generally improved after discontinuation of isotretinoin and appropriate treatment.

The case was discussed in the 6th meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC), held on 31st December 2025, which decided under the Rule 10(1)(h)(iv) of the Pharmacovigilance Rules, 2022 that registration holders of Isotretinoin-containing medicines must update the SmPC/label to include the risk of Sacroiliitis, in line with the Health Canada Product Monograph.



Isotretinoin is a prescription drug used for the treatment of severe forms of acne in patients 12 years of age and older, when the acne fails to respond to other treatments.



Healthcare professionals and patients are informed that isotretinoin may be associated with Sacroiliitis. **Patients** experiencing persistent lower back, hip, or buttock pain should consult their doctor and are also advised not to discontinue treatment without medical advice. Any suspected adverse drug reactions should be reported to the National Pharmacovigilance Centre, Drug Regulatory Authority of Pakistan.

Risk of Idiopathic Intracranial Hypertension with Mesalazine

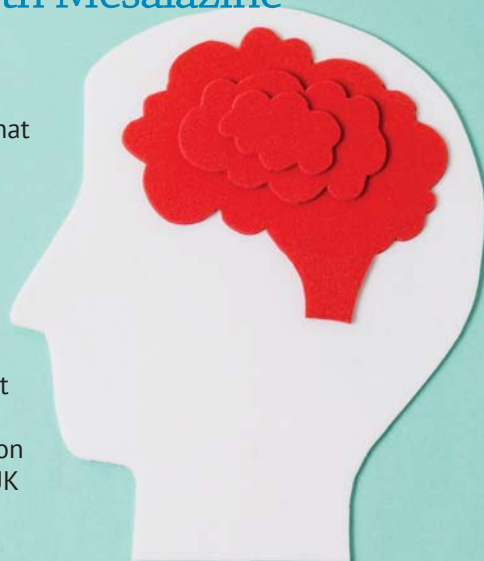


The Health Products Regulatory Authority (HPRA) of Ireland in its June 2025 Drug Safety Newsletter reported that product information for Mesalazine has been updated to include the risk of Idiopathic Intracranial Hypertension (pseudotumor cerebri), based on recommendations from the European Medicines Agency Pharmacovigilance Risk Assessment Committee (PRAC) following review of literature and spontaneous reports showing temporal association and positive de-challenge/re-challenge in some cases.

Similarly, the Medicines and Healthcare products Regulatory Agency of the United Kingdom (MHRA-UK), in a Drug Safety Update on 4th December 2025, informed that very rare cases of IIH with mesalazine have been reported and recommended adding warnings to product information. The benefit-risk balance remains unchanged. The review was endorsed by the UK's independent Pharmacovigilance Expert Advisory Committee (PEAG) of the Commission on Human Medicines (CHM), which agreed with the

recommendations.

In the 6th meeting of PRAEC, it was decided that the SmPC/labels of all Mesalazine products in Pakistan should include the risk of Idiopathic Intracranial Hypertension in Warnings and Precautions, and also list it with frequency "not known," in an ADR section in line with the MHRA-UK decision.

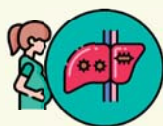


Mesalazine (5-aminosalicylic acid) is an intestinal anti-inflammatory used to treat mild to moderate Ulcerative Colitis (acute and maintenance) and Crohn's Disease when limited to the colon, including prevention of recurrence.



Healthcare professionals are informed that Idiopathic intracranial hypertension (IIH) has been very rarely reported with mesalazine. Monitor patients for severe or recurrent headaches, visual disturbances, or tinnitus. Promptly involve relevant specialties (neurology, neurosurgery, ophthalmology) if IIH is suspected. Consider discontinuing mesalazine and start immediate management. Exercise caution in patients with a history of IIH. **Patients** are also informed that very rare cases of increased pressure in the skull (IIH) have been reported with mesalazine, which can rarely affect vision. Seek medical attention immediately if you notice worsening headaches, vision changes, ringing in the ears, dizziness, or neck/back pain.

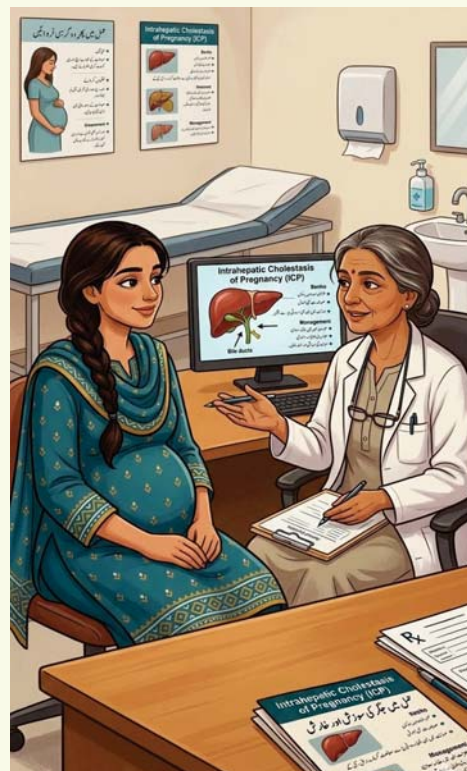
Risk of Intrahepatic Cholestasis of Pregnancy with Thiopurines



The MHRA-UK, on 15th May 2025, through a Drug Safety Update, highlighted that intrahepatic cholestasis of pregnancy (ICP) has been rarely reported in patients treated with thiopurines (azathioprine, mercaptopurine, thioguanine). It was also informed that thiopurine-associated ICP may occur earlier in pregnancy than non-drug-induced ICP, and bile acid levels may not always respond to ursodeoxycholic acid. Cases were reported mainly in IBD or transplant patients, and have occasionally been serious, including fetal death, though reporting bias may overrepresent severe outcomes. Early diagnosis and dose adjustment or discontinuation of thiopurines can reduce fetal risk. Assessment of maternal treatment benefits versus ICP risk is recommended. Patients should be educated on ICP symptoms, including intense itching without rash, nausea, and loss of appetite, and advised to seek prompt medical attention.

On 13th June 2025, the Saudi Food & Drug Authority (SFDA) also issued a safety communication updating thiopurine product information to include the risk of ICP. Healthcare professionals were advised to closely monitor pregnant patients on thiopurines and counsel them to report symptoms.

In its 6th meeting, the PRAEC-DRAP decided that registration holders are required to include the risk of ICP of pregnancy, with a frequency of “not known”, in the Adverse Drug Reactions and Warnings and Precautions sections of the SmPC/label of thiopurine-containing medicines registered in Pakistan, in line with the SmPC approved by MHRA.



Thiopurines (azathioprine, 6-mercaptopurine, and thioguanine) are used in cancer (mainly leukaemia), as immunosuppressants to treat inflammatory bowel diseases and to increase graft survival following organ transplant.



Healthcare professionals are informed that cholestasis of pregnancy has rarely been reported with thiopurines, which may occur early in pregnancy, and may not respond to ursodeoxycholic acid. Dose adjustment or withdrawal can help. Monitor ICP symptoms, involve hepatology if needed, and check serum bile acids to identify risk of preterm birth ($\geq 40\mu\text{M}$) or stillbirth ($\geq 100\mu\text{M}$). **Patients** should promptly consult their doctor or midwife if they experience cholestasis symptoms such as intense itching without rash, nausea, or loss of appetite and should not stop their medication without medical advice.

Risk of Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) with Semaglutide



On 6th June 2025, EMA-PRAC concluded its review of semaglutide (Ozempic®, Rybelsus®, Wegovy®) following concerns of a possible increased risk of non-arteritic anterior ischemic optic neuropathy (NAION). The PRAC recommended updating product information to include NAION as a “very rare” adverse effect (up to 1 in 10,000 patients), a condition that may cause vision loss. Results from epidemiological studies suggest semaglutide doubles the risk of NAION in adults with type 2 diabetes, corresponding to roughly one additional case per 10,000 person-years; clinical trials also indicate a slightly higher risk compared with placebo.

Following EMA-PRAC, the WHO also issued a safety alert on 27th June 2025, advising healthcare professionals and regulatory authorities about the risk of NAION. The WHO’s Advisory Committee on Safety of Medicinal Products (ACSoMP) recommended revising the semaglutide Risk Management Plan to include NAION as a potential risk and

any additional pharmacovigilance measures. Reports of NAION after semaglutide use have also been received from multiple countries via VigiBase, highlighting the serious global safety concern.

The PRAEC-DRAP in its 6th meeting decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 that Registration holders are required to include the risk of non-arteritic anterior ischemic optic neuropathy (NAION) in the Warnings and Precautions section and list it with a frequency of “very rare” in the Adverse Drug Reactions (ADRs) section of the SmPC/label of semaglutide-containing medicines registered in Pakistan.



Semaglutide, a GLP-1 receptor agonist, is used to treat diabetes and obesity. It lowers blood glucose by enhancing insulin release and helps weight management by reducing appetite, food intake, and cravings.



Healthcare professionals are informed that semaglutide carries a very rare risk of non-arteritic anterior ischemic optic neuropathy (NAION), affecting up to 1 in 10,000 patients. Treatment should be stopped if NAION is confirmed. NAION may cause vision loss, and healthcare professionals should monitor patients with pre-existing optic nerve disorders or vascular risk factors. **Patients** experiencing sudden or rapidly worsening vision should seek medical attention immediately.

Risk of Suicidal Thoughts with Finasteride and Dutasteride-containing medicines.



In its 5–8th May, 2025 meeting, the EMA-PRAC reviewed data on suicidal ideation and behaviours with finasteride and dutasteride containing products, including clinical trials, spontaneous reports, literature, and reports submitted by MAH. The PRAC confirmed a causal link between oral finasteride (1mg and 5mg) and suicidal ideation, and requires that it should be listed as an undesirable effect with frequency “not known”. The PRAC also concluded that sexual dysfunction, a known adverse effect of

finasteride, may contribute to suicidal ideation and will be reflected in product warnings. Finasteride 1mg product information will now advise patients to seek medical help for problems with sexual function that may affect mood, and a patient card will be included in the package. No update is required for cutaneous finasteride, as evidence of suicidal ideation is insufficient, and the benefit-risk balance remains favourable. While a causal link with dutasteride was not established, its mechanism is similar to finasteride, so information on mood changes will also be added as a precaution. Overall, PRAC concluded that the benefits of finasteride and dutasteride continue to outweigh their risks.

PRAEC-DRAP reviewed this case initially in its 2nd meeting in March 2023, following HSA Singapore and Health Canada reports. The case was again reviewed in light of the EMA-PRAC decision, and it was decided that registration holders are required to include the risk of suicidal ideation (suicidal thoughts) in the Adverse Drug Reactions section, with a frequency of “unknown”, for oral finasteride and dutasteride-containing medicines registered in Pakistan.



Finasteride (oral 1 mg tablet) is used to treat the early stages of androgenic alopecia in men aged 18 to 41 years. Finasteride 5mg tablets and dutasteride 0.5mg capsules are used for benign prostatic hyperplasia (BPH) in men.



Healthcare professionals are advised that finasteride may be associated with mood alterations, including depression and, rarely, suicidal ideation (frequency “unknown”), particularly in patients using 1 mg for hair loss. They should consider these risks when evaluating treatment and counsel patients to seek medical attention promptly if such symptoms occur. **Patients** on finasteride or dutasteride should immediately contact their doctor if they experience mood changes or suicidal thoughts.

Risk of Circulatory Shock with the Sulfamethoxazole and trimethoprim drug combination



The EMA-PRAC, in its 5–8th May, 2025 meeting, recommended updating the product information for sulfamethoxazole–trimethoprim (cotrimoxazole) drug combination to include “circulatory shock” under undesirable effects with frequency “Not known.” Cases of circulatory shock, often accompanied by fever and resistant to standard hypersensitivity treatment, have mainly occurred in immunocompromised patients. Patients should seek immediate emergency care if they experience symptoms such as fever, very low blood pressure, or rapid heart rate after taking the medicine.

The PRAEC in its 6th meeting decided that registration holders are required to include the risk of “circulatory

shock”, with a frequency of “not-known”, in the Adverse Drug Reactions (ADRs) section of the SmPC/label of the sulfamethoxazole–trimethoprim combination, in line with the decision of EMA-PRAC.



Sulfamethoxazole and Trimethoprim drug combination is a prescription antibiotic medicine indicated for the treatment of various bacterial infections.



Healthcare professionals are advised that circulatory shock with frequency “not known”, often with fever and unresponsive to standard hypersensitivity treatment, has been reported with the sulfamethoxazole–trimethoprim drug combination, mainly in immunocompromised patients. **Patients** should seek immediate medical attention if they develop symptoms such as fever, very low blood pressure, or rapid heart rate.

Risk of severe itching after discontinuation of long-term use of Cetirizine and Levocetirizine.



In May 2025, the US Food and Drug Administration (FDA) warned that patients discontinuing cetirizine (Zyrtec®) or levocetirizine (Xyzal®) after long-term use may rarely experience severe and widespread itching (pruritus). This has been reported mainly in patients who used these medicines daily for several months or years. The itching was not present before starting treatment and, in some cases, was serious enough to require medical intervention.



The PRAEC-DRAP, in its meeting held on 31st of December, 2025, recommended as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 that the National Pharmacovigilance Centre should issue a safety alert to inform healthcare professionals and patients, warning them of the risk of severe pruritus following discontinuation of long-term use of allergy medicines, namely cetirizine and levocetirizine, in line with the decision of the US FDA.



Cetirizine and levocetirizine are antihistamines used to treat seasonal and perennial allergic rhinitis and chronic hives in children and adults by blocking histamine



Healthcare professionals should inform patients, while prescribing cetirizine or levocetirizine, including those using these as OTC, about the risk of severe itching (pruritus) after stopping these medicines, especially after long-term use. Itching usually occurs within a few days after discontinuation after daily use for a few months to years. **Patients** experiencing severe itching should contact their healthcare professional, and those planning long-term use should discuss the benefits and risks before starting treatment.

Adverse Drug Reaction (ADR) Reporting Statistics

As of 31-03-2026, the following statistics summarise ADR reporting by various stakeholders across Pakistan, along with the top reporting hospitals.

S#	Name of Hospital	No of Reports	Top Reporter
1	Shifa International Hospital, Islamabad	451	Ms Bushra Anjum
2	Shaukat Khanum Memorial Cancer Hospital and Research Centre, Lahore	330	Ms Saba Mazhar & Mr Usama Qadri
3	Holy Family Hospital, Rawalpindi	138	Ms Nazima Asghar & Ms Mehwish Ilyas
4	Indus Hospital & Health Network, Karachi	126	Mr Muhammad Hamid Hanif
5	Services Hospital Lahore	82	Ms Aroosa Akber
6	Shaukat Khanum Memorial Cancer Hospital and Research Centre, Peshawar	67	Ms Madhia Kanwal & Mr Muhammad Asif
7	Pakistan Institute of Medical Sciences (PIMS) Hospital, Islamabad	64	Ms Sidra Sulehri
8	Ali Medical Centre, Islamabad	57	Ms Laiba Ishfaq
9	The Aga Khan University Hospital (AKUH), Karachi	38	Ms Qurat Ul Ain Amir Butt
10	Dr Akbar Niazi Teaching Hospital, Islamabad	36	Mr Muhammad Bilal Anwar

58,753 Total Reports in the VigiFlow database, DRAP	Stakeholder or Means of Reporting	No of Reports	43,933 Reports transferred to VigiBase, Uppsala Monitoring Centre.
	The Punjab PV Centre	1,544	
	Islamabad PV Centre	1,387	
	Sindh PV Centre	221	
	Khyber Pakhtunkhwa PV Centre	101	
	Azad Jammu and Kashmir PV Centre	31	
	Balochistan PV Centre	25	
	Gilgit Baltistan PV Centre	2	
	Federal Directorate of Immunisation	32,204	
	National TB Control Programme	28	
	National AIDS Control Programme	6	
	Pakistan Polio Eradication Programme-National Emergency Operations Centre	6	
	VigiMobile/ Med Vigilance E reporting	737	
	Pharmaceutical Companies	22,461	



43,933
Reports transferred to VigiBase, Uppsala Monitoring Centre.



Highlights



Dr Obaidullah, CEO of DRAP, chaired a meeting on strengthening medicine and vaccine safety surveillance, attended by FDI, CMU, and UN partners, including WHO, UNICEF, and UNDP.



CEO, DRAP, addressing participants of a four-day multi-stakeholder workshop on strengthening the pharmacovigilance system of Pakistan, attended by senior officials from the Ministry of NHR&C, Provincial Health Departments, Provincial Pharmacovigilance Centres & Drug Control Units, Healthcare Commissions, FDI, CMU, and representatives from public and private hospitals.



Dr Dapeng Luo, WHO Representative in Pakistan, delivering his address during the four-day multi-stakeholder workshop on strengthening Pakistan's pharmacovigilance system.



Dr Muhammad Akhtar Abbas Khan, Director Pharmacy Services Division, Head, NPC, DRAP, presenting about the Pharmacovigilance system of Pakistan



Mr Muhammad Sohail, Director General of the Directorate of Drugs Control, Punjab, addressing participants at the training on Medication Safety and High-Risk Medication Management to Prevent Avoidable Harm, held in Lahore on 25-26 August 2025



Dr Muhammad Akhtar Abbas Khan, Director Pharmacy Services Division, Head, NPC, DRAP; Mr Asadullah, Technical Officer, WHO; and Dr Jean-Christophe Delumeau interacting with participants of the multi-stakeholder workshop on strengthening Pakistan's pharmacovigilance system



Jean-Christophe Delumeau, ISoP Executive Board Member and WHO Consultant, delivering his address during multi-stakeholder workshop on strengthening Pakistan's pharmacovigilance system, held from 3-6 November 2025



Group Picture of Trainings on Medication Safety/ High Risk Medication Management to prevent avoidable harm, held on 24-25 September 2025 at Peshawar

Series of Trainings on Medication Safety/ High Risk Medication Management to Prevent Avoidable Harm

To strengthen the patient safety ecosystem in Pakistan, the Drug Regulatory Authority of Pakistan (DRAP), in collaboration with the World Health Organisation Country Office Pakistan, organised a series of two-day capacity-building workshops on Medication Safety and High-Risk Medication Management in Islamabad, Lahore, and Peshawar.

The initiative brought together healthcare professionals from Provincial Health Departments, Provincial Pharmacovigilance Centres, Healthcare Commissions, Provincial Drug Control Units, the Federal Directorate of Immunisation, Common Management Unit as well as representatives from public and private hospitals. The workshops aimed to enhance strategies for preventing avoidable harm associated with high-risk medications and to strengthen collaboration among key stakeholders in the healthcare system.

The sessions were facilitated by trainers and experts from DRAP, WHO, Provincial Drug Control Units, Provincial Pharmacovigilance Centres, Private Sector Potential Hospitals and Healthcare Commissions. Key topics discussed during the workshops included the pharmacovigilance system in Pakistan and international best practices, management of Look-Alike Sound-Alike (LASA) and high-alert medications, the strategic framework of the WHO's 3rd Global Patient Safety Challenge, prescription safety, and the implementation of patient safety indicators in tertiary care hospitals.

The primary objective of these workshops was to equip participants from the respective provinces with essential knowledge and practical skills to prevent avoidable medication-related harm in healthcare settings. Participants were also trained to ensure timely reporting of Adverse Drug Reactions (ADRs) through the VigiFlow database, in line with internationally defined timelines and reporting standards.

As part of the practical learning component, participants in Islamabad and Lahore attended virtual visits to Shifa International Hospital and Ghurki Trust Teaching Hospital. In Peshawar, participants conducted an in-person visit to Shaukat Khanum Memorial Cancer Hospital and Research Centre. During these visits, participants were introduced to international best practices in sterile preparation, storage, and administration of high-alert medicines, along with practical demonstrations of trigger tools, ADR reporting mechanisms, and safe dispensing practices.



The Chief Executive Officer of DRAP, Dr. Obaidullah, emphasised the importance of strong collaboration among stakeholders and the adoption of a proactive approach toward ADR reporting. He urged healthcare institutions across the country to actively utilise DRAP's standardised reporting tools to improve medication safety and ensure better patient outcomes.

Speaking on the occasion, Dr. Dapeng Luo, WHO Representative and Head of Mission in Pakistan, shared valuable insights into current challenges in medication safety. He highlighted the importance of the WHO's third Global Patient Safety Challenge: Medication Without Harm, which aims to reduce severe and avoidable medication-related harm worldwide through coordinated global action.

As a way forward, it was agreed that Provincial Pharmacovigilance Centres and Healthcare Institutions will further strengthen their procedures for medication safety, with particular emphasis on raising awareness and improved reporting of ADRs. These coordinated efforts are expected to reduce the burden on healthcare and public health systems while significantly improving patient safety across the country.



Title	Date & Venue	HCPs trained
02-day Capacity Building Training on Medication Safety/ High Risk Medication Management to Prevent Avoidable Harm	25-26th June 2025 at Islamabad	49
02-day Capacity Building Training on Medication Safety/ High Risk Medication Management to Prevent Avoidable Harm	25-26th August 2025 at Lahore	55
02-day Capacity Building Training on Medication Safety/ High Risk Medication Management to Prevent Avoidable Harm	24-25th September, 2025 at Peshawar	46

Capacity Building Workshop on Pharmacovigilance System Strengthening and VigiFlow Data Entry

The Drug Regulatory Authority of Pakistan (DRAP), in collaboration with the World Health Organisation, successfully organised a one-day training session on Pharmacovigilance System Strengthening and VigiFlow Data Entry on 22 December 2025 at United Medical & Dental College in Karachi.

The training was attended by 137 participants, including pharmacovigilance officers nominated by the Sindh Health Department from DHQ/Civil Hospitals and Taluka-level hospitals, as well as representatives from private sector hospitals across Sindh. The session aimed to strengthen the capacity of healthcare professionals in pharmacovigilance practices and enhance the quality and timeliness of adverse drug reaction (ADR) reporting.

The Chief Executive Officer of DRAP, Dr. Obaidullah (PhD, MPH), emphasised the pivotal role of Provincial Pharmacovigilance Centres and hospitals as the primary points for adverse event reporting. He reaffirmed DRAP's continued commitment to supporting Provincial Health Departments in strengthening pharmacovigilance activities across Pakistan.

During the session, officers from the National

Pharmacovigilance Centre, DRAP, shared valuable insights on key aspects of pharmacovigilance practices. The training covered topics such as the pharmacovigilance process, causality assessment, detection of safety signals, and risk management strategies, including the management of Look-Alike Sound-Alike (LASA) medications. Participants also engaged in interactive group activities that demonstrated the workflow from signal detection to risk management decision-making.

A dedicated technical session was conducted by experts from the Uppsala Monitoring Centre (UMC), focusing on the VigiVerse ecosystem. The session included a practical demonstration of the VigiFlow database, enabling participants to better understand the process of entering and managing ADR reports within the global pharmacovigilance system.

The training highlighted the importance of strengthening pharmacovigilance capacity at the provincial and hospital levels to ensure effective monitoring of medicine safety. Through continued collaboration between national and international partners, Pakistan is making progress toward improving medication safety and protecting public health.

Title	Dated	HCP trained
One-day Capacity Building Workshop on Pharmacovigilance System Strengthening and VigiFlow Data Entry	22nd of December 2025 at Karachi	137



فارماکوویجیلنس نیوز لیٹر

دلیہ: ۴

مئی: ۲۰۲۶

شمارہ: ۱

MedSafetyWeek کی دسویں مہم پر پاکستان میں فارماکوویجیلنس سسٹم کو مضبوط بنانے کا عزم۔



گزشتہ سالوں کی طرح سال ۲۰۲۵ میں بھی ڈرگ ریگولیٹری اتھارٹی آف پاکستان (ڈریپ) نے دنیا کے مختلف اداروں کے ساتھ مل کر ادویہ کے محفوظ استعمال سے متعلق بین الاقوامی مہم #MedSafetyWeek 2025 میں حصہ لیا۔ ۲۰۲۵ کو اس مہم کے دس سال پورے ہونے کی وجہ سے بھی مزید اہمیت دی گئی۔ گزشتہ دہائی کے دوران، یہ مہم ان گنت لوگوں تک پہنچی اور ادویات کی حفاظت کے حوالے سے عوامی شعور اجاگر کرنے میں بھی اہم رہی۔ اس سال کی عالمی مہم کا موضوع تھا "ہم سب مل کر ادویات کو مزید محفوظ بنانے میں مدد کر سکتے ہیں"، جو ادویات کی حفاظت کو یقینی بنانے میں اجتماعی کوششوں کی اہمیت پر زور دیتا ہے۔

#MedSafetyWeek 2025 کے آغاز پر، وفاقی وزیر صحت سید مصطفیٰ کمال نے ڈریپ کی تیار کردہ ایک آگاہی ویڈیو جاری کر کے اس جامع مہم کا آغاز کیا۔ یہ پراثر ویڈیو واضح کرتی ہے کہ صحت کے پیشہ ور افراد اور مرلیض کس طرح آسانی سے ڈریپ کو ادویہ سے ہونے والے مضر اثرات کی رپورٹ کر سکتے ہیں۔ وزیر صحت نے اس موقع پر صوبائی اور وفاقی سطح پر رابطہ بہتر بنانے اور عوامی صحت کے رد عمل کو مضبوط بنانے کے لیے مشترکہ لائحہ عمل پر زور دیا۔

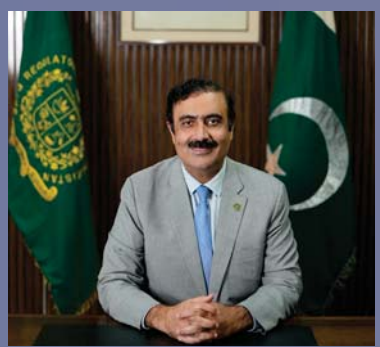
اس ویڈیو لانچ کی تقریب قومی فارماکوویجیلنس سنٹر (این پی سی) کی جانب سے عالمی ادارہ صحت (ڈبلیو ایچ او) کے کنسلٹنٹ ڈاکٹریان کرستوف ڈیویمو کی معاونت سے منعقدہ چار روزہ تربیتی سیشن کے دوران ہوئی۔ اس تربیتی ورکشاپ میں صوبائی فارماکوویجیلنس سنٹرز، وفاقی ادارہ برائے ایمنائزیشن (ایف ڈی آئی)، کامن ٹیمینٹ یونٹ (سی ایم یو) کے تحت قومی سپ ڈق، ملیز اور ایچ آئی وی کنٹرول پروگرامز، صوبائی محکمہ صحت، ہیلتھ کیئر کمیشنز اور ہیلتھ لوان کے نمائندگان نے شرکت کی۔ شرکاء نے دواؤں اور ویکسین سے متعلقہ خطرات کا جلد پتہ لگانے اور ان کو کم کرنے کے لیے ایک مربوط اور مؤثر قومی فارماکوویجیلنس نظام کے لیے مشترکہ طور پر ایک روڈ میپ ترتیب دیا۔

ڈریپ کے چیف ایگزیکٹو آفیسر ڈاکٹر عبید اللہ نے اس موقع پر مضر اثرات کی رپورٹنگ میں "الزام تراشی سے پاک کلچر" (نو۔ بلیم کلچر) کو فروغ دینے کی ضرورت پر زور دیا۔ انہوں نے کہا کہ فارماکوویجیلنس کے نظام کو مضبوط بنانا، مرلیضوں کی حفاظت اور ریگولیٹری عمدہ کارکردگی کے لیے ناگزیر ہے، اور اس مقصد کے حصول کے لیے قومی اور صوبائی سطح پر تمام اسٹیک ہولڈرز کو اپنا کردار ادا کرنا ہوگا۔

قومی فارماکوویجیلنس سنٹر کے سربراہ ڈاکٹر اختر عباس خان نے اس تربیتی سیشن کے منتظم کی حیثیت سے اپنے ساتھیوں اور شرکاء کی کاوشوں کو سراہا۔ اس مشترکہ کوشش کو پاکستان میں ایک محفوظ اور زیادہ ذمہ دار صحت کی دیکھ بھال کے نظام کی جانب ایک اہم سنگ میل قرار دیا جاسکتا ہے۔ سوشل میڈیا کی اس مہم میں ڈرگ ریگولیٹری اتھارٹی آف پاکستان نے بھی حصہ لیا۔ مزید برآں، ڈریپ نے پاکستان کی تمام علاقائی زبانوں میں ویڈیو پیغامات بھی تیار کیے ہیں تاکہ مضر اثرات کی رپورٹنگ میں بلاوجہ الزام نہ لگانا کے ثقافت کو فروغ دیا جاسکے، جو ڈریپ سوشل میڈیا پلیٹ فارمز کے ذریعے پوسٹ کیے گئے تھے۔

#MedSafetyWeek کی یہ مہم، جواب اپنی دوسری دہائی میں داخل ہو چکی ہے، عوام میں ادویات کی حفاظت سے متعلق آگاہی پھیلانے اور ڈریپ کے مختلف پلیٹ فارمز (وبی موبائل برائے ویکسین / برائے ادویہ اور ویدیو) کے استعمال کو فروغ دے کر ملک بھر میں فارماکوویجیلنس کلچر کو مضبوط بنانے میں معاون ثابت ہوگی۔

محفوظ رہیں، باخبر رہیں، رپورٹ کریں، آواز اٹھائیں۔



"مرلیضوں کی حفاظت کو یقینی بنانے اور فارماکوویجیلنس کو مضبوط بنانے کے لیے مضر اثرات کی رپورٹنگ میں بلاوجہ الزام نہ لگانا کے ثقافت کو فروغ دینا ضروری ہے۔ ڈریپ میں، ہم تمام اسٹیک ہولڈرز کی حوصلہ افزائی کرتے ہیں۔ خاص طور پر مرلیضوں اور صحت کی دیکھ بھال کرنے والے پیشہ ور افراد کو۔ مفتی واقعات کی اطلاع دیں۔ ہر رپورٹ اہمیت رکھتی ہے۔ آپ کی رپورٹ ادویات کو سب کے لیے محفوظ بنانے میں مدد کر سکتی ہے۔"

ڈاکٹر عبید اللہ، سی ای او، ڈریپ



ویڈیو دیکھنے کے لیے یہاں کلک کریں۔



مضر اثر کی اطلاع دینے کے لیے QR کو اسکین کریں، یہاں سے VigiMobile ایپلیکیشن بھی ڈاؤن لوڈ کی جاسکتی ہے۔