

PHARMACOVIGILANCE





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EDITOR'S NOTE

We wish to thank our numerous stakeholders who have been working tirelessly with the National Pharmacovigilance Centre (NPC) to ensure the safe use of medicines in Nigeria. The NPC remains committed to the regular publication of this quarterly newsletter as a platform for disseminating information on pharmacovigilance activities both nationally and globally. It also serves to educate stakeholders on medicine safety issues, promote the rational use of medicines, and strengthen the reporting of Adverse Drug Reactions (ADRs) and Adverse Events Following Immunization (AEFIs).

We encourage Health care Professionals and other stakeholders to continue to report all adverse drug reactions and AEFIs. Your valued comments and acknowledgement of receipt of this issue through our email addresses (pharmacovigilance@nafdac.gov.ng, fdic@nafdac.gov.ng) would be most appreciated.

Thank you for your relentless efforts in strengthening Pharmacovigilance System in Nigeria.

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Pharmacovigilance Inspections: Key Findings and Lessons for Marketing Authorization Holders

Between October 2024 and December 2025, the National Agency for Food and Drug Administration and Control (NAFDAC) conducted routine pharmacovigilance (PV) inspections to assess the compliance of Marketing Authorization Holders (MAHs) with national regulatory requirements.

A total of 24 companies were inspected, of which 15 were local pharmaceutical manufacturers. These inspections evaluated the performance and robustness of pharmacovigilance systems and their alignment with the **NAFDAC Good Pharmacovigilance Practice (GVP) Guidelines, 2021**, with the aim of strengthening post-marketing safety surveillance and safeguarding public health.



The inspections identified 33 observations, categorized as critical, major, and minor findings. Of these, 15 (45.5%) were critical, 11 (33.3%) were major, and 7 (21.2%) were minor.

Common Critical Findings	Common Major Findings	Minor Findings
Critical findings highlighted serious gaps in pharmacovigilance system governance and infrastructure. The most frequent issues included the absence of a functional pharmacovigilance system, lack of an adequately supported Qualified Person for Pharmacovigilance (QPPV), and the absence of a pharmacovigilance database for safety data management. In several cases, there was no documented back-up QPPV, no evidence of pharmacovigilance staff training, and no local pharmacovigilance audit	Major findings primarily related to system documentation and operational processes. Common issues included non-compliant Pharmacovigilance System Master Files (PSMFs), inadequate or missing standard operating procedures (SOPs) for critical PV processes such as individual case safety report (ICSR) management, and lack of key performance indicators (KPIs) to monitor PV system performance. Additionally, several MAHs demonstrated limited oversight of distributors and third-party vendors performing pharmacovigilance activities,	Minor findings were largely associated with documentation and procedural inconsistencies, such as typographical errors in PV documents, unclear SOP effective dates, lack of clarity on literature search frequency, and absence of procedures for escalation of safety issues.

conducted in the past five years. Other critical deficiencies included the absence of risk minimization activities, weak archiving and backup systems, lack of business continuity plans, and insufficient documentation of safety communication with stakeholders.	weak pharmacovigilance agreements, and insufficient documentation of training programs.	
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The inspection findings highlight the importance of establishing robust pharmacovigilance governance structures, including ensuring that the QPPV has sufficient authority and support to oversee PV activities. MAHs are to prioritize compliance with PSMF requirements, develop comprehensive PV SOP frameworks, and implement structured training and performance monitoring systems. Strengthening oversight of distributors and third-party partners involved in PV activities is equally critical to ensure consistent compliance with regulatory requirements. As pharmacovigilance systems continue to evolve, these inspections serve as an important reminder that effective medicine safety monitoring depends on well-structured systems, trained personnel, and strong regulatory compliance.

The inspection findings reveal critical gaps in pharmacovigilance governance, underscoring the need for more robust institutional structures. In particular, the role of the Qualified Person for Pharmacovigilance (QPPV) must be strengthened through adequate authority, resources, and organizational support to ensure effective oversight of PV activities.

Marketing Authorization Holders (MAHs) must enhance compliance with Pharmacovigilance System Master File (PSMF) requirements, establish comprehensive PV Standard Operating Procedure (SOP) frameworks, and implement structured training and performance monitoring systems to improve operational effectiveness.

Furthermore, weak oversight of distributors and third-party partners involved in PV activities highlights the need for stricter controls to ensure consistent adherence to regulatory standards.

These findings reinforce that effective medicine safety monitoring depends on well-governed systems, skilled personnel, and sustained regulatory compliance.

Trainings Conducted

Training for Qualified Persons for Pharmacovigilance (QPPVs)

The Pharmacovigilance Directorate conducted a comprehensive training program for approximately 270 Qualified Persons for Pharmacovigilance (QPPVs) as part of its ongoing efforts to strengthen pharmacovigilance systems in Nigeria. The training was designed to enhance the capacity and effectiveness of QPPVs in fulfilling their regulatory and professional responsibilities. The key objectives

of the training included equipping participants with a clear understanding of their roles and responsibilities as outlined in the NAFDAC Good Pharmacovigilance Practice (GVP) regulations and guidelines. In addition, the training aimed to sensitize QPPVs to NAFDAC's requirements for pharmacovigilance inspections, ensuring they are adequately prepared for regulatory assessments and compliance obligations. Furthermore, the program provided detailed guidance on pharmacovigilance processes, including adverse drug reaction reporting, signal detection, and risk management activities. Participants were also introduced to the various reporting tools and systems utilized by the National Pharmacovigilance Centre, NAFDAC, to facilitate timely and accurate safety reporting. The training clearly served as a strategic initiative to build capacity, promote regulatory compliance, and strengthen the national pharmacovigilance system through improved knowledge and performance of QPPVs.

Training on implementation of Pharmacovigilance in Health care Facilities at Abuja, September 17 to 18, 2025

The Pharmacovigilance Directorate organised a 2-day training for Health care facilities at Abuja from September 17 to 18, 2025 at Gracious Hotel, Garki Abuja and 1st Forty Hotel, Wuse II Abuja. The Training modules covered include the following:

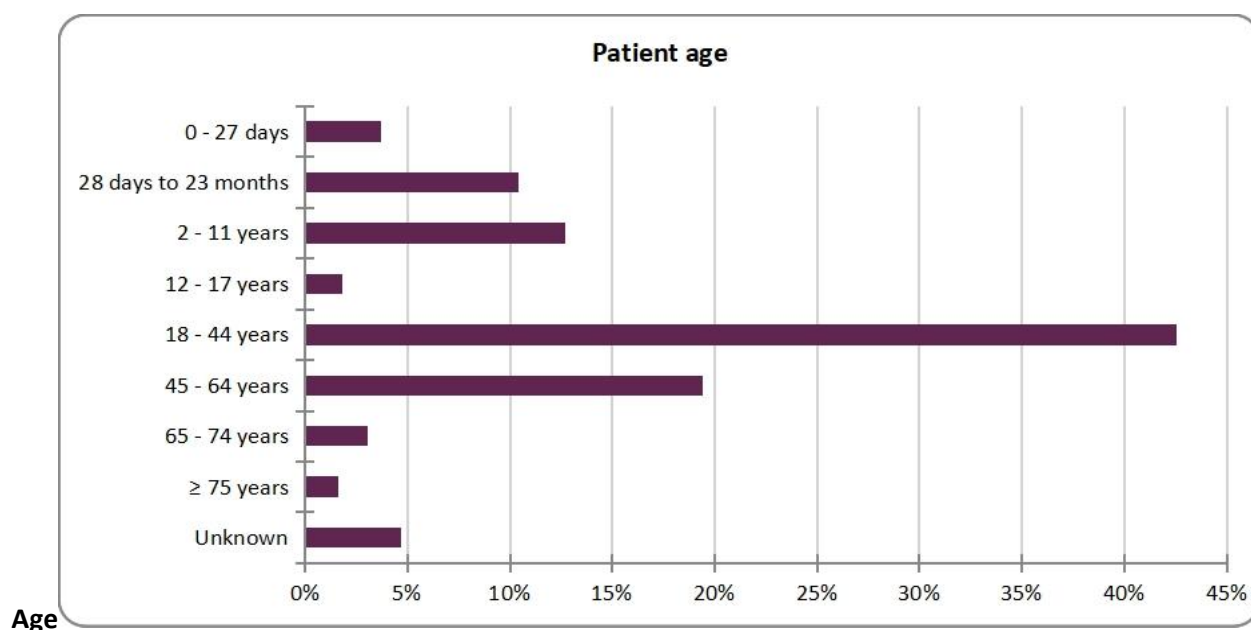
- Overview of Pharmacovigilance, National Pharmacovigilance Systems and Regulatory Frameworks
- Adverse Drug Reactions (ADRs) and Adverse Events Following Immunization (AEFIs)
- Definitions and Classifications
- Guide to Setting up a PV Committee/Unit
- Pharmacovigilance data collection and management
- Vaccine Safety in Pharmacovigilance
- Medication Errors and Pharmacovigilance
- Hands On Presentation on ADR / AEFI Detection/Reporting and Case Studies
- Health Facility Assessment and
- Health Facility Domestication of Standard Operating Procedures.



Training on implementation of Pharmacovigilance in Health care Facilities at Abuja, September 17 to 18, 2025

Pharmacovigilance Data Analysis for Quarter 4 2025

This report presents a comprehensive analysis of Adverse Drug Reaction (ADR) data, offering insights into the demographic, pharmacological, and clinical characteristics of reported events. The findings aim to highlight areas requiring strengthened pharmacovigilance efforts and improved data quality to enhance public health outcomes.

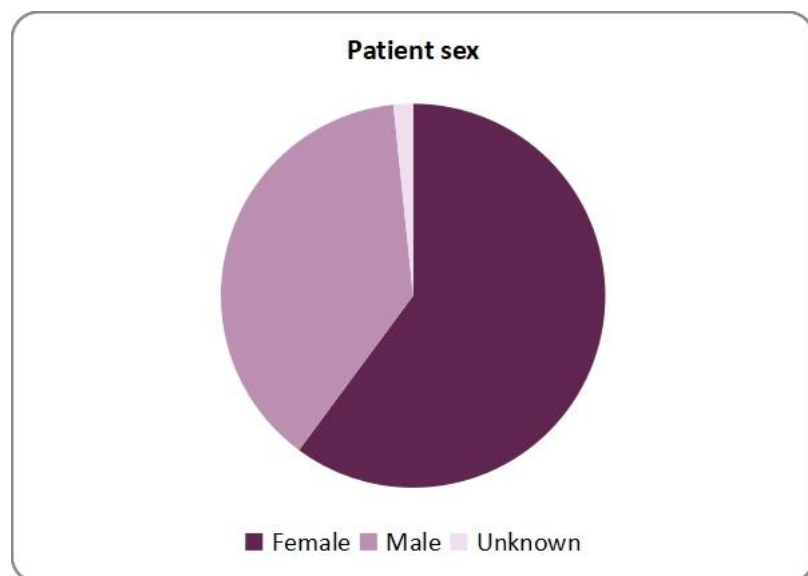


The data reveal that adults aged 18–44 years constitute the largest proportion of reported ADRs, accounting for 42.5% of all cases. The 45–64 years age group follows, contributing 19.4% of reports, further emphasizing the significant burden of ADRs within the adult population. Collectively, these two adult cohorts represent over 60% of all reported ADRs, underscoring the necessity for increased pharmacovigilance monitoring in this broad age range.

Among pediatric populations, children aged 2–11 years (12.7%) and infants aged 28 days to 23 months (10.4%) show notable contributions, indicating substantial medication exposure in these vulnerable groups. Neonates (0–27 days) account for a smaller but clinically significant 3.7%, highlighting their heightened vulnerability due to immature physiological systems and limited drug metabolism capabilities. Conversely, adolescents (12–17 years) exhibit a relatively low reporting rate of 1.8%, which may suggest either lower drug exposure or potential underreporting within this specific age bracket.

Surprisingly, older adults, particularly those aged 65–74 years (3.1%) and ≥ 75 years (1.6%), demonstrate comparatively lower reporting. This observation is counterintuitive, given that elderly populations are generally at a higher risk of experiencing ADRs due to factors such as polypharmacy, comorbidities, and age-related physiological changes affecting drug pharmacokinetics and pharmacodynamics. This discrepancy may indicate significant underreporting in older age groups or barriers to accessing reporting systems. Finally, 4.7% of reports lacked age information, pointing to existing gaps in data completeness that warrant improvement in pharmacovigilance documentation practices.

Sex



The analysis of reported ADRs by sex reveals a notable female predominance, with females accounting for 60.1% of all reports, compared to 38.2% for males. This observed disparity suggests that females are more frequently affected by or more likely to report adverse drug reactions during the study period. The minimal proportion of cases with unknown sex (1.6%) indicates a high level of data completeness for this variable, thereby strengthening the reliability of the observed sex distribution.

Reaction

Top Reported Preferred Term

Reported preferred terms (MedDRA)	Count	Percentage
PT: Pruritus	78	16.0%

PT: Rash	58	11.9%
PT: Pyrexia	54	11.0%
PT: Vomiting	43	8.8%
PT: Asthenia	37	7.6%
PT: Dizziness	36	7.4%
PT: Crying	25	5.1%
PT: Headache	24	4.9%
PT: Insomnia	17	3.5%
PT: Cough	14	2.9%
PT: Fatigue	13	2.7%
PT: Diarrhoea	11	2.2%
PT: Death	10	2.0%
PT: Nausea	10	2.0%
PT: Chest pain	9	1.8%
PT: Chills	9	1.8%
PT: Restlessness	9	1.8%
PT: Arthralgia	8	1.6%
PT: Lip swelling	8	1.6%
PT: Adverse drug reaction	8	1.6%
PT: Exposure during pregnancy	8	1.6%
PT: Abdominal discomfort	7	1.4%
PT: Abdominal pain	7	1.4%
PT: Malaise	7	1.4%
PT: Pain	7	1.4%

PT: Swelling	7	1.4%
PT: Decreased appetite	7	1.4%
PT: Palpitations	6	1.2%
PT: Peripheral swelling	6	1.2%

Clinical presentations are predominantly characterized by hypersensitivity and skin-related reactions, with pruritus (16.0 percent) and rash (11.9 percent) being the most frequently reported adverse events. This aligns with the high contribution from dermatological system organ classes and anti-infective medicines. Systemic symptoms are also highly prevalent, notably pyrexia (11.0 percent), which may be associated with infections, vaccines, or drug-induced febrile responses. Gastrointestinal symptoms, including vomiting (8.8 percent), nausea (2.0 percent), diarrhoea (2.2 percent), and abdominal pain or discomfort (1.4 percent each), reflect a significant burden consistent with the pharmacological profiles of commonly used antibiotics and antiretrovirals. Neurological and general symptoms further complicate the clinical picture, with reports of asthenia (7.6 percent), dizziness (7.4 percent), headache (4.9 percent), insomnia (3.5 percent), fatigue (2.7 percent), and restlessness (1.8 percent), indicating generalized weakness and central nervous system involvement. Paediatric involvement is highlighted by the presence of crying (5.1 percent) among the top reported terms, likely reflecting presentations in infants following vaccination or medication exposure. Other notable reactions include respiratory symptoms such as cough (2.9 percent), cardiovascular symptoms like palpitations (1.2 percent), and hypersensitivity indicators such as lip swelling (1.6 percent) and peripheral swelling (1.2 to 1.4 percent). The occurrence of death (2.0 percent) among the reported terms underscores the critical need for enhanced pharmacovigilance, prompt recognition of systemic and gastrointestinal symptoms, and targeted monitoring for hypersensitivity reactions, particularly with anti-infectives and antiretroviral therapies, while also paying close attention to paediatric-specific presentations.

Top Reported Active Ingredients

Reported active ingredients (WHODrug)	ATC Code	S/I	C	Total
AI: Dolutegravir;Lamivudine;Tenofovir disoproxil	Direct Acting Antivirals	171	7	178
AI: Sulfamethoxazole;Trimethoprim	Antibacterials for Systemic Use	11	9	20
AI: Isoniazid	Anti-infective for Systemic Use	9	8	17

AI: Artemether;Lumefantrine	Artemisinin-based Combination Therapy	6	11	17
AI: Azithromycin	Anti-infective for Systemic Use	16		16
AI: Amlodipine	Calcium channel blockers	4	9	13
AI: Metronidazole	Anti-infective for Systemic Use	4	8	12
AI: Prednisolone	corticosteroids for systemic use	4	8	12
AI: Imatinib	Antineoplastic agents	11		11
AI: Ceftriaxone	Anti-infective for Systemic Use	4	6	10
AI: Abacavir;Lamivudine	Direct Acting Antivirals	8	1	9
AI: Amoxicillin;Clavulanic acid	Anti-infective for Systemic Use	3	6	9
AI: Paracetamol	non-opioid analgesic and antipyretic	2	7	9
AI: Levofloxacin	Anti-infective for Systemic Use		8	8
AI: Tinidazole	Anti-infective for Systemic Use	7	1	8
AI: Ciprofloxacin	Anti-infective for Systemic Use	6	2	8
AI: Diclofenac	NSAID	5	3	8
AI: Omeprazole	Proton pump inhibitors		7	7

The analysis of top reported active ingredients (WHODrug) highlights the fixed-dose combination of dolutegravir/lamivudine/tenofovir disoproxil as the most frequently reported suspected/interacting (S/I) medicine in 171 reports and concomitant (C) medicine in 7 reports resulting in a total of 178 reports. This finding underscores the central role of antiretroviral therapy (ART) in ADR reporting, reflecting both its widespread use in HIV management and its known side-effect profile.

Among antibiotics, several agents feature prominently, including azithromycin (16 reports), sulfamethoxazole/trimethoprim (20 total), ceftriaxone (10 total), ciprofloxacin (8 total), and levofloxacin (8 total, mainly concomitant). This reinforces earlier findings that anti-infectives are major contributors to ADRs, consistent with their high utilization rates. Other notable medicines include isoniazid (17 total) and artemether/lumefantrine (17 total), indicating ADRs related to tuberculosis prophylaxis and antimalarial therapy, respectively. Imatinib (11 reports) also contributes, aligning with the earlier observation of contributions from antineoplastic agents. Amlodipine (13 total) represents cardiovascular drugs among the top reported ingredients. A number of medicines, such as metronidazole, prednisolone, paracetamol, omeprazole, and diclofenac, show higher proportions as concomitant (C) drugs, suggesting their frequent use as supportive or background therapies rather than primary suspected agents.

Seriousness



The data indicate that 24.7% (121 cases) of reported ADRs were classified as serious, while the majority, 75.3% (368 cases), were non-serious. This distribution signifies that although most reported ADRs are mild to moderate in nature and generally manageable, approximately one in four cases had significant clinical consequences. reports. The predominance of non-serious ADRs suggests that common reactions such as pruritus, rash, pyrexia, and gastrointestinal symptoms constitute the bulk of reports.

Seriousness Criteria

Seriousness criteria	Count	Percentage
Death	16	3.3%
Life threatening	26	5.3%
Caused/prolonged hospitalization	23	4.7%
Disabling/incapacitating	1	0.2%
Other medically important condition	61	12.5%

Among the serious ADRs, the criterion of "other medically important condition" was the most frequently reported, accounting for 12.5% of cases. This indicates that a significant proportion of serious events required clinical attention or intervention due to their potential to jeopardize the patient but did not necessarily result in immediate life-threatening outcomes or hospitalization. This highlights the importance of clinical judgment in identifying significant ADRs that may not fit into more rigid outcome-based definitions.

Life-threatening reactions constituted 5.3% of serious ADRs, while cases leading to or prolonging hospitalization accounted for 4.7%. These figures demonstrate that a meaningful proportion of ADRs had severe clinical implications, necessitating urgent medical care or inpatient management. Critically, death was reported as a seriousness criterion in 3.3% of cases, associated with imatinib, representing a vital safety signal. This finding reinforces earlier observations where death appeared among the top reported preferred terms, underscoring the urgent need for in-depth causality assessment and signal detection for these fatal outcomes. In contrast, only 0.2% of ADRs were classified as disabling or incapacitating, suggesting that long-term functional impairment was a relatively rare outcome in this dataset.

Temporal Trends (Year)

Year	Count	Percentage
Dec 2025	110	22.7
Nov 2025	200	41.1
Oct 2025	176	36.2

The temporal analysis of ADR reports reveals a distinct pattern across the three months studied. November 2025 recorded the highest number of ADR reports, with 200 cases, accounting for 41.1% of the total. This was closely followed by October 2025, which had 176 reports (36.2%). Conversely, December 2025 showed a noticeable decline, with only 110 reports (22.7%).

Top Ten Reporting States

State	Number of Report
Rivers	89
Lagos	81
Imo	59
Ogun	34
Kaduna	26
Kwara	24
Abia	20
Enugu	18
FCT	15
Akwa Ibom	12

The disparity in reporting may reflect significant underreporting, limited awareness of pharmacovigilance systems, or reduced access to healthcare services in low-reporting areas. Additionally, 6 reports were classified as "Unknown," highlighting gaps in data completeness regarding geographical information.

Top Ten Reporting Facilities

Facility	Number of Reports
University of Port Harcourt Teaching Hospital	63

Lagos State University Teaching Hospital (LASUTH)	20
Epe FMC/Epe CSCC	11
Medplus Pharmacy	10
Olorunda PHC	10
St. Joseph Catholic Hospital, Ohabiam	7
Eti-Osa CSCC	5
General hospital Awgu	5
General Hospital Ohafia	5
Bingham University Teaching Hospital, Jos	4

The data reveal a highly uneven distribution of ADR reports across healthcare facilities, with a few institutions contributing a large proportion of reports, while many others reported only one or a few cases. Most notably, "Unknown" facilities accounted for the largest share, comprising 241 out of 486 reports (approximately 49.6%). This represents a significant gap in data completeness, severely limiting the ability to trace reports back to specific healthcare settings and underscoring an urgent need for improved documentation and reporting practices at the source.

Interpretation and Implications of ADR Reporting Patterns

Adverse drug reaction (ADR) reporting demonstrates clear geographical, temporal, and clinical patterns, alongside notable system-level challenges. Geographically, reporting is heavily concentrated in a few urban, healthcare-rich states, while many regions—particularly in northern and rural areas—show low reporting rates. This likely reflects underreporting rather than a true absence of ADRs. Temporally, reporting peaked in November, remained high in October, and declined in December, suggesting possible seasonal or operational influences on reporting behaviour.

From a clinical perspective, most ADRs are non-serious and manageable; however, nearly one-quarter are serious, representing a significant burden on the healthcare system. Serious cases are largely categorized as medically important conditions, with a considerable proportion being life-threatening or requiring hospitalization. Fatal outcomes, though relatively low (3.3%), remain important and warrant detailed investigation. Reported reactions are predominantly systemic, dermatological, and gastrointestinal, with notable neurological and psychiatric involvement.

Drug-related patterns show that anti-infectives—particularly antiretroviral therapies such as dolutegravir-based regimens—dominate reports, reflecting both high utilization and safety relevance. Antineoplastic and immunomodulating agents are additional key contributors due to their inherent toxicity profiles. However, the distinction between suspected and concomitant drugs is not always clearly documented, affecting causality assessment.

Demographically, ADRs are more frequently reported in females than males, potentially due to both biological and behavioural factors. Adults aged 18–44 years account for majority of reports, while children represent a substantial minority. Elderly populations appear underrepresented, suggesting possible underreporting. Although sex data quality is high, gaps remain in age documentation.

From a health system perspective, ADR reporting is concentrated in tertiary hospitals and well-organized facilities, with minimal contributions from primary healthcare centers and community-level providers. A major limitation is poor data completeness, particularly the high proportion of reports lacking facility identification, along with some duplication and missing data issues.

Implications:

To strengthen pharmacovigilance, targeted efforts are needed to improve ADR reporting in low-performing regions, especially rural and northern areas. Capacity building through training and awareness among healthcare professionals is essential, alongside expanding reporting systems to primary healthcare facilities, pharmacies, and private providers. High-reporting institutions should be leveraged as centers of excellence for mentorship and system strengthening.

Improving data quality is critical—this includes addressing duplication, ensuring complete documentation (e.g., age and facility), and clearly distinguishing suspected from concomitant medications. Clinically, priority should be given to early detection and management of serious and life-threatening ADRs, with enhanced follow-up and signal detection, particularly for fatal cases. Monitoring should focus on high-risk drug classes such as antiretrovirals, anti-infectives, vaccines, and antineoplastic agents.

Finally, consistent year-round reporting should be encouraged by addressing seasonal fluctuations and identifying drivers of reporting peaks. Strengthening surveillance of common ADR patterns (systemic, dermatological, gastrointestinal) while improving reporting of less frequent reactions will enhance overall signal detection and patient safety outcomes.

Global Regulatory Updates

Product Information provides healthcare professionals, patients and the public with relevant information for the safe and effective use of a medicine. Maintaining drug product information is crucial for ensuring the right medication (at appropriate dosage) is prescribed to the right patient at the right time. With an up-to-date drug product information, Health care professionals can make informed decisions about medication therapy resulting to better patient outcomes. Some safety updates are presented below for the information of health care professionals and the public:

Potential risk of neurodevelopmental disorders (NDD) in children born to fathers treated with valproate monotherapy in the three months prior to conception

A retrospective observational study conducted in three Nordic countries suggested an increased risk of movement and mental developmental disorders (NDD) in children (aged 0 to 11 years) born to fathers treated with valproate monotherapy in the three months prior to conception compared to fathers treated with lamotrigine or levetiracetam monotherapy. Valproate must be initiated and supervised by a specialist experienced in the management of epilepsy or bipolar disorder; this is defined as a consultant psychiatrist or a consultant neurologist who regularly manages a bipolar disorder or complex epilepsy. It should not be used in girls and Women of Childbearing Potential (WCBP) unless other treatments are ineffective or not tolerated and it should be prescribed and dispensed according to the conditions of the valproate Pregnancy Prevention Program.

Prescribers should inform male patients of this potential risk and discuss with them the need to consider effective contraception, including for their female partner, throughout the duration of treatment with valproate and at least three months after discontinuation of treatment. Treatment with valproate in male patients should be regularly reassessed by prescribers to determine if valproate remains the most appropriate treatment.

For male patients planning to conceive a child, the prescriber should inform them of this potential risk and consider therapeutic alternatives depending on the clinical context. The patient information leaflet is to be given to patients when prescribing or dispensing valproate pending the provision of the new patient guide.

Suspension of marketing authorisations of medicinal products containing 17-hydroxyprogesterone caproate (17-OHPC)

The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (EMA PRAC) has suspended the marketing authorisations of medicinal products containing 17-hydroxyprogesterone caproate (17-OHPC) due to cancer risk: Given the findings from a pharmaco-epidemiological study and the results of the clinical trial and meta-analyses on 17-hydroxyprogesterone caproate (17-OHPC) as well as the limited data of efficacy in other indications, the benefit-risk balance of 17-OHPC containing products is no longer favourable in all authorized indications. 17-OHPC-containing medicines should no longer be prescribed or dispensed, and alternative treatment options should be considered for all indications. A Dear Healthcare Provider Letter on this was disseminated by NAFDAC.

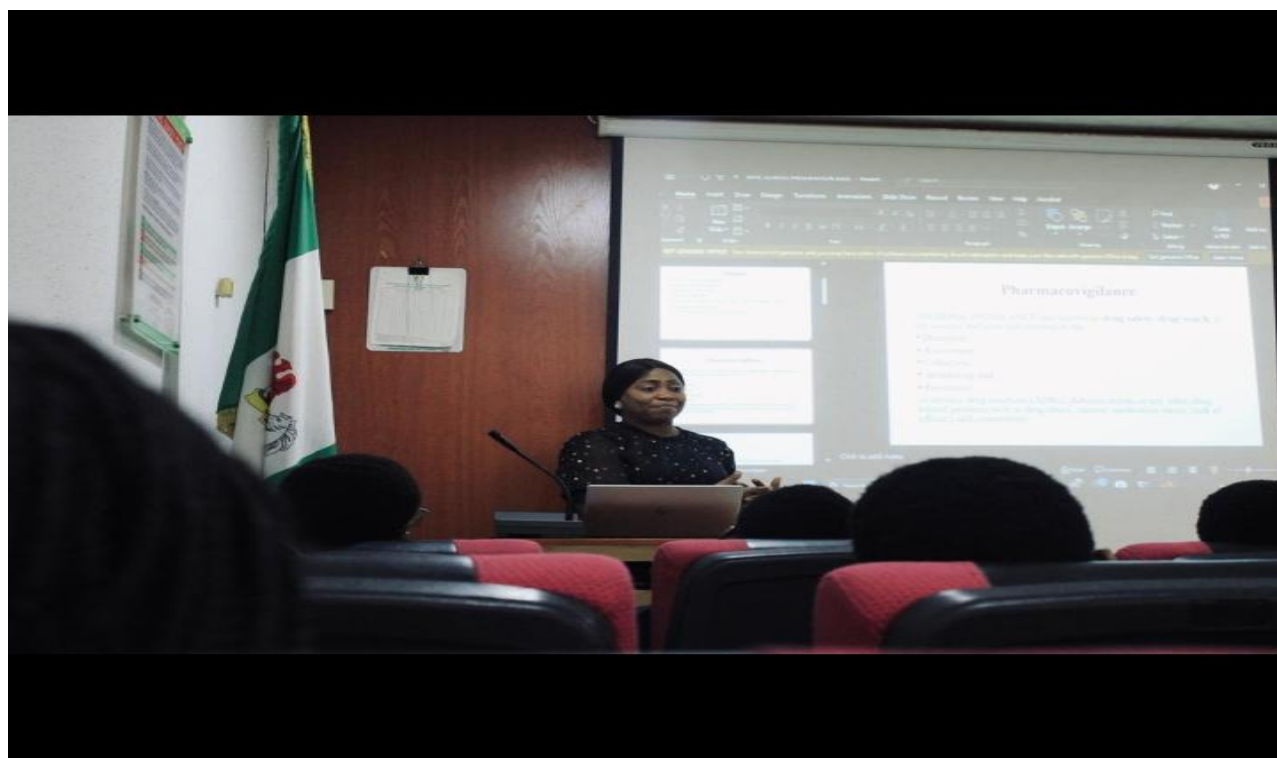
Carbamazepine 100 mg/5ml Oral Suspension Restriction of use in neonates:

Carbamazepine 100 mg/5ml Oral Suspension (OS) is no longer recommended for neonates (below 4 weeks of age for term babies or 44 weeks postmenstrual age for pre-term babies) due to the amount of propylene glycol (PG) in this formulation. There is no change proposed in the posology of any other formulation (such as tablets) or any other patient population.

During a procedure in another country for label update for the Oral Suspension, the process triggered an assessment of the amount of propylene glycol in the product. Propylene Glycol, an excipient used in this product formulation, was found to be above the threshold of (1 mg/kg/day) for neonates (refer to respective EMA guideline "*Excipients in the labelling and package leaflet of medicinal products for human use*"). The benefits do not outweigh the potential risks due to the amount of propylene glycol and therefore Carbamazepine 100 mg/5ml Oral Suspension use is no longer recommended in neonates.

Advocacy Visits and Landmark Meetings

As part of ongoing efforts to improve Pharmacovigilance (PV) awareness and promote medicine safety, officials from the Pharmacovigilance Advocacy & Public Health Collaboration Division conducted a sensitization on Pharmacovigilance activities to a group of secondary school students of Jewels leading light Academy Abuja, on 2nd, December 2025. The sensitization was led by Mrs. Asase Georgina (Chief Regulatory Officer). The visit aimed to educate students on the importance of medicine safety, adverse drug reaction (ADR) reporting and the role of Pharmacovigilance in protecting public health. An age-appropriate presentation on drug safety and the role of Pharmacovigilance was delivered to the students at the NAFDAC Headquarters, Abuja. The presentation was designed to engage the students through a dramatic and relatable approach to Pharmacovigilance, making the key messages easily understood. Following the presentation, a question-and-answer session was held. Participants asked thoughtful After a question & answer session, Information, Education, and Communication (IEC) materials were handed over to the school staff.



Highlights from Lagos State

In October 2025, the office focused on regulatory inspections, training, health facility assessment and preparatory activities for international benchmarking. Advocacy visits were conducted in the following healthcare facilities in Lagos namely: Healing Stripes Hospital (Oniru), Coptic Hospital (Victoria Island), and Diamed Multispecialist Hospital (Lekki Phase 1). They reinforced awareness on pharmacovigilance practices, adverse drug reaction reporting and available reporting tools. These are aimed at improving frontline reporting of adverse drug reactions (ADRs) and adverse events following immunization (AEFIs). In furtherance of regulatory compliance monitoring, one (1) Healthcare Facility GVP assessment was conducted at Mainland Hospital (Infectious Disease Hospital), Lagos, providing an opportunity to evaluate institutional pharmacovigilance structures and reporting practices.

The month also recorded extensive staff participation in capacity-building programmes, including:

- ❖ MedSafety Week Training ("Be the Link: Strengthening Our Collective Responsibility to Make Medicines Safer")
- ❖ TAF/3TC/DTG Step-down Training at APIN, LUTH and
- ❖ Training on ADR & AEFI Reporting using the Med Safety App.

GVP assessments were conducted in two (2) hospitals: St. Nicholas Hospital and Marigold Hospital to reinforce on-ground regulatory presence.



Advocacy Visit to Randle General Hospital Surulere, Lagos State.



Health Facility Good Pharmacovigilance Practice Training At Diadem Multispecialist Hospital Lekki, Lagos State.



Medsafety Week: Good Pharmacovigilance Practice Training At Agege (Sango) Primary Health Center, Lagos State.

Call for Reporting

Healthcare providers and consumers are advised to report adverse events and quality problems they experience with the use of medical products through the following channels:

- ✓ To the nearest NAFDAC office
- ✓ By e-mail to pharmacovigilance@nafdac.gov.ng.

•via e-Reporting platform available on the NAFDAC website www.nafdac.gov.ng or through the following link: <https://vigiflow-eforms.who-umc.org/ng/adr>

•via Med Safety App available for download on Android and IOS stores.

Conclusions

Participation in the WHO Global Benchmarking Tool (GBT) underscored Nigeria's ongoing efforts to align with global regulatory maturity standards.

Despite extensive activities, there is a persistent gap in reporting culture among healthcare professionals. Consequently, the Directorate continues to emphasize intensified advocacy, targeted sensitization, and digital reporting adoption (Med Safety App, e-reporting platforms) as key priorities moving into 2026.

The fourth quarter of 2025 was characterized by sustained regulatory activities, stakeholder engagement, capacity building, and strategic alignment with global pharmacovigilance standards. The National Pharmacovigilance Centre maintained a strong continued commitment to strengthening medicine safety monitoring systems, stakeholder collaboration across all States and participation in both local and international technical engagements thereby sustaining its mandate of safeguarding public health while reinforcing systems for medicines safety monitoring across its jurisdiction. The Pharmacovigilance Directorate remains committed to strengthening pharmacovigilance systems, enhancing regulatory compliance, and ensuring the safety of medicines and vaccines through proactive surveillance and stakeholder collaboration.