IN THIS ISSUE

Prepared by:
Reem Tarek
Alaa Yahya
Mona Abo-Elseoud
Nadia Mostafa
Esraa Salah
Lobna Samy

Designed by:
Reem Tarek

Chief Editor
Fatma Hassan
Head of Egyptian Pharmacovigilance Center

Under supervision of
Abeer El behairy
Head of the Central Administration for Pharmaceutical Care

EPVC Mission

Pharmaceutical Vigilance administration is the way through which the processes for authorizing, Regulating , monitoring and evaluating the safety of any pharmaceutical product or medical device take place, in addition to disseminating any safety information for public health programs, healthcare professionals, and the Egyptian citizen.

The Pharmaceutical vigilance administration is an integral part of the Central Administration of Pharmaceutical Care that works on the enhancement of the pharmaceutical services to guarantee safe and effective use of medications in Egypt, under the patronage of the Egyptian Drug Authority.

Newsletter

June 2026

Volume 20 Issue 6

Safety Update: : Use of Insulin-Specific Syringe to Prevent Medication Errors during Insulin Administration

Background

The regulatory authority in Japan published the following safety update: Insulin is a high alert drug for managing diabetes. It is administered via subcutaneous injection using insulin vials and syringes. Precise dosing in units (U) is essential to prevent hypoglycemia, hyperglycemia, and long-term complications.
A critical medication error has been repeatedly reported: incorrect unit conversion when general-purpose syringes (marked in mL) are used instead of insulin-specific syringes (marked in UNITS). This results in doses far exceeding the intended dose, causing serious adverse events.
Although this safety alert references the Pharmaceuticals and Medical Devices Agency (PMDA) Medical Safety Information No. 73 (April 2026), insulin dosing errors associated with the use of non-insulin syringes have been widely reported in regulatory communications and clinical studies. These consistently highlight the risk of unit misinterpretation when insulin is administered using general-purpose (mL-marked) syringes instead of insulin-specific (unit-marked) syringes

Key Points for Safe Insulin Administration

- Always Use Insulin-Specific Syringes: Use syringes marked in units only. Never use general syringes marked in mL.
- Verify Syringe Markings: Before drawing, visually confirm UNITS markings on syringe.
- Create Safe Environment: Store insulin together with the appropriate insulin syringes, apply clear labels to insulin vials, and label general syringes as "Do Not Use for Insulin
- Patient Education: Teach the patients importance of insulin-specific syringes.
- Double-Check Always: Verify syringe type, dose, medication, and patient identity before injection.

Recommendations for Healthcare Professionals

Hospital Settings:

- Implement Set Dispensing system
- Place warning signs on insulin storage
- Make syringe verification mandatory
- Report errors to pharmacovigilance system

Pharmacy:

- Always dispense insulin-specific syringes with insulin
- Provide clear patient instructions
- Document syringe dispensing

Key Messages for Patients and Caregivers

- Always use insulin-specific syringe marked UNITS. Never use syringe marked mL.
- Before injection, VERIFY syringe is insulin-specific.
- Wrong syringe = wrong dose = severe hypoglycemia or hyperglycemia.
- Store insulin and syringes together.
- Ask pharmacist for help if unsure which syringe to use.
- Report any medication errors to your healthcare provider.

References

1. ***PMDA :*** *Click here*

Enhance Patient Safety : Through Awareness of Labeled Drug–Drug Interactions, Focus on Narrow Therapeutic Index Drugs: Evidence from Post-Marketing Case Reports

Introduction

Pharmacovigilance serves as the foundation of patient safety, leveraging systematic real-world data analysis to detect and mitigate adverse drug reactions (ADRs). Drug-drug interactions (DDIs) involving narrow therapeutic index (NTI) drugs present critical safety risks, particularly in polypharmacy.

Objectives

To evaluate the clinical burden of labeled DDIs for valproic acid (VPA) and methotrexate (MTX) using individual case safety reports (ICSRs) and recommend appropriate risk minimization awareness to reduce preventable drug-related problems.

Methods

A retrospective signal detection study was conducted using the WHO global database of adverse event reports for medicines and vaccines (VigiBase); two signals of disproportionate reporting (SDRs) were identified for reports with labeled DDIs: 25 VPA cases (88% serious) and 31 MTX cases (84% serious). Descriptive statistics characterized the temporal distribution, seriousness, and clinical relevance, with a focus on the significant 2025 reporting spike.

Results

Evaluation of global and domestic pharmacovigilance data, acknowledging underreporting, identified clinically important labelled drug–drug interactions involving valproic acid and methotrexate with relevant safety impact. The analysis demonstrated 25 valproic acid cases and 31 methotrexate cases. Descriptive statistics showed that 38.4% and 54.5% of valproic acid and methotrexate (MTX) cases, respectively, involved serious adverse drug reactions (ADRs) and treatment failure related to labelled DDIs. VPA interactions caused pharmacokinetic shifts, resulting in a 20% incidence of breakthrough seizures (e.g., with meropenem) and 18% drug-related toxicity (e.g., with lamotrigine/phenytoin/carbamazepine). MTX interacts primarily with salicylates, proton-pump inhibitors, and NSAIDs, demonstrating synergistic toxicity. Key adverse clinical outcomes included pancytopenia (25.8%), renal impairment (16%), and a 19.3% rate of contraindicated co-administration.

Conclusion

The PVGA published these analytical findings in its monthly newsletter to raise awareness with relevant stakeholders, healthcare providers, and patients of critical labeled drug–drug interactions (DDIs), particularly those involving narrow therapeutic index (NTI) products. Also recommends integration of an artificial intelligence (AI) tool, supports proactive risk-minimization strategies, optimizes therapeutic outcomes, reduces drug-related problems, and strengthens medication safety in routine clinical practice.

References

1. ***PubMed:*** *Click here*
2. ***PubMed:*** *Click here*

Local Case Safety Report: Hypocalcemia, Hyperparathyroidism and hypophosphatemia reported following administration of Denosumab

Cairo Regional Pharmacovigilance Center received an Individual Case Safety Report (ICSR) describing suspected adverse drug reactions associated with a medicinal product containing denosumab. The report concerned a 51-year-old female patient with end-stage renal disease (ESRD) on maintenance hemodialysis and a history of hypertension.
On 01 December 2025, the patient received a single subcutaneous injection of denosumab 60 mg for the treatment of primary osteoporosis. Baseline laboratory investigations performed in November 2025 demonstrated a total serum calcium level of 10.99 mg/dL and a serum phosphorus level of 4.9 mg/dL.
Following denosumab administration, a marked and persistent decline in mineral parameters was observed. Total serum calcium decreased from 10.99 mg/dL in November 2025 to 8.33 mg/dL on 22 December 2025 and further declined to 8.22 mg/dL in January 2026. Serum phosphorus also showed a substantial reduction, falling from 4.9 mg/dL to 1.6 mg/dL. On 22 December 2025, with only partial recovery to 2.2 mg/dL by January 2026. In parallel, parathyroid hormone (PTH) levels increased significantly from a baseline value of 71.3 pg/mL in June 2025 to 571 pg/mL in January 2026.
Dechallenge assessment was considered not applicable, as denosumab is a long-acting monoclonal antibody with pharmacological activity that may persist for up to six months following administration. Consequently, management of the adverse effects relied on appropriate corrective measures, including calcium and vitamin D supplementation, rather than drug withdrawal. At the time of reporting, the patient was experiencing significant biochemical disturbances necessitating close clinical and laboratory monitoring.

Background:

Denosumab is a human monoclonal IgG2 antibody produced in a mammalian cell line (Chinese hamster ovary cells) by recombinant DNA technology.It is a long-acting monoclonal antibody that remains active in the system for up to 6 months.
Mechanism of action Denosumab binds with high affinity and specificity to Receptor Activator of Nuclear Factor κB Ligand (RANKL) preventing activation of its receptor, RANK, on the surface of osteoclast precursors and osteoclasts. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function and survival, thereby decreasing bone resorption in cortical and trabecular bone.

Labeled information:

According According to Summary of product Characteristics (SmPC) of Denosumab, hypocalcemia is listed under the metabolism and nutrition disorders as an adverse reaction.
It is important to identify patients at risk for hypocalcaemia. Hypocalcaemia must be corrected by adequate intake of calcium and vitamin D before initiating therapy.
In the post-marketing setting, severe symptomatic hypocalcaemia (resulting in hospitalization, life-threatening events, and fatal cases) has been reported. While most cases occurred in the first few weeks of initiating therapy, it has also occurred later.
Renal Impairment and Its Impact on Calcium and Parathyroid Hormone Levels:Patients with severe renal impairment (creatinine clearance < 30 mL/min) or receiving dialysis are at greater risk of developing hypocalcaemia. The risks of developing hypocalcaemia and accompanying parathyroid hormone elevations increase with increasing degree of renal impairment. Severe and fatal cases have been reported. Adequate intake of calcium, vitamin D and regular monitoring of calcium is especially important in these patients.

Conclusion:

The administration of denosumab, a RANKL inhibitor, is consistently associated with clinically relevant disturbances in mineral metabolism, particularly hypocalcaemia, secondary hyperparathyroidism, and, less commonly, hypophosphataemia. The primary mechanism underlying these effects is the potent inhibition of osteoclast-mediated bone resorption, which significantly reduces the release of calcium from the bone into the systemic circulation. Consequently, the reduction in serum calcium triggers a compensatory increase in parathyroid hormone (PTH) secretion, leading to secondary hyperparathyroidism. This elevated PTH level further exacerbates phosphate wasting through increased renal excretion, thereby contributing to the development of hypophosphataemia.
Evidence from observational studies and clinical reports demonstrates that these metabolic disturbances may occur shortly after denosumab initiation and are more pronounced in patients with predisposing conditions such as chronic kidney disease, vitamin D deficiency, or impaired baseline mineral homeostasis. Furthermore, regulatory data and the FDA prescribing information confirm hypocalcaemia as a significant and potentially severe adverse effect of denosumab, underscoring the clinical importance of these biochemical changes.
In summary, the interplay between reduced osteoclastic activity, decreased serum calcium, compensatory PTH elevation, and increased phosphate excretion provides a well-established and coherent pathophysiological explanation for the occurrence of hypocalcaemia, secondary hyperparathyroidism, and hypophosphataemia following denosumab therapy.

Local Case Safety Report: Hypocalcemia, Hyperparathyroidism and hypophosphatemia reported following administration of Denosumab

Recommendations for Healthcare Professionals:

1.**Pre-treatment assessment and optimization**

• Correct hypocalcemia before initiation (contraindication if present).
• Assess and optimize vitamin D status prior to therapy, as deficiency increases the risk of hypocalcemia
• Evaluate baseline laboratory parameters, including:
- Serum calcium
- Phosphate and magnesium
- Renal function
- Parathyroid hormone (especially in CKD patients)
• Identify high-risk patients, particularly those with chronic kidney disease, low baseline calcium, or vitamin D deficiency.

2. Ensure adequate supplementation

• Provide routine calcium and vitamin D supplementation to all patients.
• Maintain supplementation throughout the treatment period, not only at initiation.

3. Laboratory monitoring during treatment

• Monitor serum calcium regularly, particularly:
- Before each dose
- During the early post injection period within 14 days of denosumab injection (when levels typically decline)
• Monitor phosphate and other electrolytes periodically, especially in high-risk patients.
• Monitor vitamin D levels intermittently to ensure adequacy.
• In CKD or high-risk patients, more frequent calcium monitoring is recommended (e.g. weekly for the first month then monthly).

4. Special precautions in high-risk populations

Use denosumab cautiously in patients with advanced CKD, and involve specialists when appropriate.

Concomitant use of calcimimetic drugs may worsen hypocalcemia risk in patients with advanced CKD

Assess for CKD–mineral and bone disorder (CKD-MBD) before treatment in these patients, as they are more prone to the risk of hypocalcemia. Treatment with denosumab in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.

Denosumab products may cause fetal harm when administered to pregnant women. Advise females of reproductive potential to use effective contraception during therapy, and for at least 5 months after the last dose of denosumab.

Denosumab safety and effectiveness have not been established in pediatric patients.

Implement closer monitoring protocols (e.g., frequent calcium testing) in these populations.

5.Patient education and safety measures

Educate patients to:
• Maintain adherence to calcium and vitamin D supplementation
• Recognize symptoms of hypocalcaemia (e.g., muscle spasms, paresthesia, seizures)
• Advise immediate medical evaluation if symptoms occur.

6.Multidisciplinary care approach (for high-risk patients)

• Evidence suggests that integrated or multidisciplinary care pathways (including endocrinology/nephrology input) can reduce the incidence of severe hypocalcaemia in high-risk populations.

References

1. **Denosumab SPC (EMA):** (click here)
2. **Injection instructions:** (click here)
3. **Denosumab and hypocalcemia :** (click here)
4. **Prolia.com :** (click here)
5. **Denosumab (NIH)** (click here)
6. **Laboratory Monitoring Recommendations:** (click here)

PVGA participated in the first edition of the Annual Police Pharmacist Conference for Strategic Pharmaceutical Care (PPC 2026)

In response to a prestigious invitation; EDA participated in the Pharmacist Conference for Strategic Pharmaceutical Care (PPC 2026) that was held on May 19, 2026.
The conference was organized by the Medical Services Sector under the patronage of the Assistant Minister of Interior; Major General Dr. Saeed El-Naggar.
The conference witnessed high-level participation from members of the Scientific Committee of the Medical Services Sector at the Ministry of Interior, deans of medical faculties across Egypt, university professors and academic staff, directors and deputy directors of healthcare institutions, as well as representatives from pharmacy syndicates and pharmacists from Police Hospitals and various healthcare institutions.

The participation of the Egyptian Drug Authority was represented by the General Director of the General Administration of Pharmacovigilance and the Director of the Regional Centers Unit, who joined a panel discussion about PV science and activities in the presence of pharmacy faculties and representatives from pharmaceutical companies. The session was moderated by Pharmacist Captain Norhan Ashraf.
During the conference, the PV Initiatives Coordinator delivered a comprehensive presentation titled "PV Landscape and reporting system" highlighting national pharmacovigilance activities and emphasizing the importance of adverse drug reaction (ADR) reporting in strengthening medication safety and protecting patient health.
The presentation also highlighted the progress achieved through the "BE Vigilant" initiative, launched by PVGA in 2025, and concluded with an open invitation for all healthcare institutions to join the initiative in support of building a successful model of integration among national healthcare entities to deliver safe and high-quality pharmaceutical care.
The session witnessed strong engagement and interactive discussions on the role of pharmacovigilance in ensuring drug safety and effectiveness.

Vigitest Competition 2026 – Round 2: Self-Paced Pharmacovigilance Challenge – Celebrating winners

We appreciate your engagement in Round 2 of VigiTest 2026, A big applause for the 27 participants who joined the self-paced game challenge in round 2.
Thank you for participating, and please join us in congratulating our top 3 winners on their achievement

Name	Title	Affiliation
Gannat Gamal	PV specialist	MOH
Dina Muhammed	PV specialist	EHA
Hala Mohamed	PV specialist	SMC

Vigitest Competition 2026 – Round 3 as a Live Pharmacovigilance Challenge
Following the successful launch of Vigitest in 2026 round 1 in the Live format competition & round 2 in the self-paced format game, where participants engaged through a Game based learning approach; we are excited to announce the Round 3 of the Vigitest competition in a dynamic live format for 2026.
Stay tuned for rapid-fire rounds and simulations that test your PV expertise in real-time.

How to Join Vigitest 2026

1. Register your participation by submitting your name through the Google Form linked below.
Scan the QR code or tap the link below, follow the instruction and answer the questions.

Orcopy the link:
https://docs.google.com/forms/d/e/1FAIpQLSetBbvH_U8JDZnJZzDIHm2383ZgJVgzwqrfQcjSh-AiEQBVYQ/viewform?usp=dialog

2. Once registered, you will receive **an invitation email one day before the competition**, including:

- Exact date and time of your competition round
- Instructions on accessing the live platform

Don't miss the opportunity to be part of the Vigitest Game 2026 – where knowledge meets action.

On Pharmacovigilance

Be Aware of Drug–Lab Test Interactions

Some medicines can affect laboratory test results, leading to false-positive, false-negative, or misleading findings. This may result in unnecessary investigations or incorrect clinical decisions.

Key Points:

Always inform the laboratory and healthcare provider about all medications being taken, including prescription drugs, over-the-counter medicines, herbal products, and supplements.

Review unexpected laboratory results in the context of the patient's medication history.

Consider the possibility of drug–laboratory test interactions before making clinical decisions based on abnormal test results.

Examples:

- High-dose Vitamin C (Ascorbic Acid) may interfere with glucose and urine tests.
- Biotin supplements can affect thyroid function tests and certain cardiac biomarker assays.
- Some antibiotics and other medicines may influence liver, kidney, or coagulation test results.

You can report any ADR on:

Email: pv.followup@edaegypt.gov.eg

Hotline: 15301

Website: (click Here)

Or report through your pharmacy / product distributor / company hotline — they are required to forward it to EDA.

Why Your Report Matters

Every report submitted to us counts when it comes to the safety of medicines and patients worldwide

Visit EDA website to find all medicine- related news, updates and alerts *Click here*

You will find all EPVC Newsletters and DHPCs here

You will also find all alerts regarding counterfeited and falsified products released by Central Administration of Operations *here*

One report counts

A call for reporting

Please remember that you can report safety information of medicines to EPVC using the following communication information:

What is Pharmacovigilance

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug- related problem.

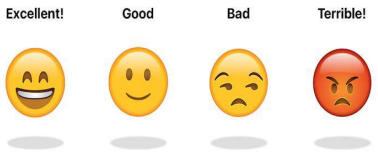
What is the Egyptian Pharmaceutical Vigilance Center?

With the increasing demand for patient's safety which is becoming more stringent, . The Egyptian Pharmaceutical Vigilance Center was established to be responsible for the safety monitoring of the pharmaceutical products throughout its lifecycle and it is the regulatory authority regarding Pharmacovigilance and its applications .

EPVC monitors the safety of all types of pharmaceutical products, including human medicines, biological products, supplements, cosmetics, veterinary medicines, medical devices, Biocides and pesticides

Participate with us

We invite you to take a quick survey on how much our communication with you is effective
We value your feedback! Help us enhance our communication by taking a quick survey. Your insights are crucial in ensuring we meet your expectations.
Survey Link: (Click Here)



Thank you for your valuable input

Communication information

The Egyptian Drug Authority (EDA)
Pharmaceutical Care Administration
The Egyptian Pharmaceutical Vigilance Center (EPVC)

Address: 21 Abd El Aziz AlSoud Street. El-Manial, Cairo, Egypt, PO Box: 11451
Hotline: 15301
Fax: +202 – 23610497
Email: pv.followup@edaegypt.gov.eg
Reporting link: (click Here)

هيئة الدواء المصرية (الرعاية الصيدلية)