IN THIS ISSUE

Prepared by:

Reem Tarek
Maram Hany
Alaa Abd Elghany
Monica Magdy
Lobna Samy

Designed by:

Reem Tarek

Chief Editor

Maha Mohamed

Head of Egyptian Pharmacovigilance Center

Under supervision of

Yassin Ragaey

Assistant to EDA chairman for Media Affairs and Investment Support and Supervisor of the Central Administration for Pharmaceutical Care

EPVC Mission

Pharmaceutical Vigilance administration is the way through which the processes for authorizing, Reguing, 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

January 2026

Volume 20 Issue 1

Label Update: Mesalazine and idiopathic intracranial hypertension

- The regulatory authority in UK published the following label update whose key message is:

Idiopathic intracranial hypertension (IIH) has been very rarely reported in patients treated with mesalazine. Following a recent review, warnings for idiopathic intracranial hypertension are being added to the product information for all mesalazine products.

Background

Mesalazine is an aminosalicylate and is licensed for the treatment of inflammatory bowel disease such as ulcerative colitis and Crohn's disease.

The majority of patients presenting with IIH have symptoms that include the following. It should be noted that none of these symptoms alone are unique to IIH .

- A headache that is progressively more severe and frequent; the type of headache can be highly variable
- Transient visual obscurations (unilateral or bilateral darkening of the vision typically lasting seconds)
- Pulsatile tinnitus
- Back pain
- Dizziness
- Neck pain
- Visual blurring
- Cognitive disturbances
- Radicular pain
- Typically horizontal diplopia

Diagnosis may be achieved through blood pressure monitoring and ophthalmology examination. However, where diagnostic uncertainty remains, experienced clinicians should be consulted, who may consider brain imaging and/or lumbar puncture.

In Egypt, the Summary of Product Characteristics (SmPC) for all mesalazine-containing products will be updated to include warning about the risk of idiopathic intracranial hypertension.

Advice for Healthcare Professionals:

- Idiopathic intracranial hypertension (IIH) has been very rarely reported in patients receiving mesalazine
- The number of reports in the UK is very low
- Patients using any form of mesalazine should be warned to look for signs and symptoms of IIH including severe or recurrent headache, visual disturbances or tinnitus
- Remain vigilant of signs and symptoms of IIH in patients taking mesalazine and act promptly with a multidisciplinary approach, involving clinicians managing the patient's mesalazine as well as neurology, neurosurgery and ophthalmology teams as appropriate
- If symptoms of IIH occurs, discontinuation of mesalazine should be considered and management of the symptoms should begin immediately
- Caution is advised when prescribing for patients who have previously diagnosed or suspected IIH

Advice for Healthcare Professionals to Provide to Patients:

- There have been very rare reports of increased pressure within your skull known as idiopathic intracranial hypertension (IIH) in some patients receiving mesalazine
- IIH is not normally life threatening; however, in rare cases can cause serious vision problems which must be monitored and treated where possible
- Tell your doctor immediately if you experience progressively more severe and recurrent headache, disturbed vision, ringing or buzzing in the ears, back pain, dizziness, or neck pain, as these could be symptoms of IIH

References

1. MHRA: (click here)

Local Case Safety Report: Hidden Risk on the Plate: Food–Drug Interaction between Warfarin

Reason for publishing

In September 2025, the Regional Center of Pharmacovigilance in Cairo received 1 report, for a A 39 year old male patient with a history of Coronary Artery Bypass Graft (CABG) and aortic valve replacement 5 years earlier had been maintained on oral warfarin 3 mg once daily. In September 2025, the patient consumed a large amount of green vegetables and liver, after which he developed an ischemic stroke on 8 September 2025, requiring hospitalization. The event was managed with aspirin and increasing the warfarin dose from 3 mg to 5 mg, and the patient subsequently recovered. Given the temporal relationship, absence of concomitant medications, and the known effect of vitamin K–rich foods on warfarin anticoagulant activity, a possible drug–food interaction between warfarin and green vegetables was considered as a contributing factor.

Background:

Warfarin is an anticoagulant medication primarily used as a blood thinner. It works by decreasing the clotting ability of the blood.

Therapeutic indications: Coronary occlusion; deep vein thrombosis; pulmonary embolism; peripheral vascular thromboembolic states; mesenteric and retinal thromboembolism.

Labeled information: "Summary of product Characteristics (SmPC)"

Mechanism of Action:

Warfarin is a synthetic 4-hydroxycoumarin derivative which acts by preventing the formation of active procoagulation factors II, VII, IX and X in the liver by inhibiting the vitamin K-mediated gammacarboxylation of precursor proteins.

Full therapeutic activity is not achieved until circulating coagulation factors have been removed by normal catabolism.

This occurs at different rates for each factor, with factor VII having the shortest half-life. Warfarin has no direct thrombolytic effect, though it may limit the extension of existing thrombi.

Warfarin Dose Initiation and Maintenance:

Adults:

- 10 to 15 mg daily, according to age and body weight, and adjusted with relation to the results of daily control tests until the desired level of anticoagulant activity is achieved - usually three to six days after the initiation of treatment.
- Control tests should be made at regular intervals and the Warfarin maintenance dosage must be adjusted according to the results obtained.
- Concomitant heparin therapy affects the results of control tests and should be discontinued at least six hours before the first test is carried out.

- In emergencies, anticoagulant therapy should be initiated with heparin and warfarin together. Where there is less urgency, as in patients disposed to or at special risk of thromboembolism, anticoagulant therapy may be initiated with warfarin alone.

Children:

- Infants, especially neonates, may be more sensitive to the effects of anticoagulants in general, due to vitamin K deficiency.

Elderly:

- The elderly may be more susceptible to the effects of warfarin, resulting in increased risk of hemorrhage. Lower maintenance doses, weight for weight, than those usually recommended for adults may be required for these patients.

Special Warnings and Contraindications:

- Contraindicated in patients with hypersensitivity to warfarin and any other excipients, pregnancy, hemorrhagic stroke, clinically significant bleeding, within 72 hours of major surgery with risk of severe bleeding, within 48 hours postpartum, within 48 hours postpartum.
- Warfarin needs regular monitoring of INR, to avoid over coagulation.
- INR should be monitored more frequently in patients at an increased risk of over coagulation e.g. patients with severe hypertension, liver or renal disease.

Local Case Safety Report: Hidden Risk on the Plate: Food–Drug Interaction between Warfarin and leafy greens followed by Ischemic Stroke

- In patients with protein C deficiency, therapy should be introduced without a loading dose of warfarin even if heparin is given. Patients with protein S deficiency may also be at risk and it is advisable to introduce warfarin therapy slowly in these circumstances.
- **Note**: Protein C is a natural anticoagulant (blood thinner) that prevents excessive clotting.
  When Protein C levels are low or the protein does not work properly (Protein C deficiency), the body becomes more prone to forming dangerous blood clots, such as:
- Deep vein thrombosis (DVT) – clots in deep veins, usually in the legs. Pulmonary embolism (PE) – clots that travel to the lungs
- All patients treated with warfarin should have INR monitored regularly. Those at high risk of bleeding may benefit from more frequent INR monitoring, careful dose adjustment to desired INR, and a shorter duration of therapy. Patients should be instructed on measures to minimize risk of bleeding and to report immediately to physicians signs and symptoms of bleeding.
- Warn about any concomitant anti-platelet drugs as they should be used with caution due to an increased risk of bleeding.
- Use with caution in patients with peptic ulcer.
- Patients should keep their overall diet stable and avoid sudden big changes in what they eat, because this can change how warfarin works and affect INR control.
- Green leafy vegetables (such as spinach, broccoli, cabbage, kale, and lettuce) and liver are rich in vitamin K, which has an antagonistic effect on warfarin and can reduce its anticoagulant effect if intake is suddenly increased.

Side note: According to the above case, Excessive consumption of green leafy vegetables rich in vitamin K may have clinically significant implications in patients receiving warfarin therapy. Vitamin K is an essential cofactor for the hepatic synthesis of vitamin K–dependent clotting factors (II, VII, IX, and X), and high dietary intake can antagonize the anticoagulant effect of warfarin by reducing its ability to inhibit vitamin K epoxide reductase. This antagonism may lead to subtherapeutic anticoagulation, reflected by a reduced international normalized ratio (INR), thereby increasing the risk of thromboembolic events. In patients with underlying cardiovascular or cerebrovascular risk factors, inadequate anticoagulation may predispose to ischemic stroke. Consistent and excessive fluctuations in vitamin K intake have been associated with poor warfarin control and increased variability in anticoagulant response.

Therefore, careful dietary counseling and regular INR monitoring are essential to minimize the risk of ischemic complications in patients treated with warfarin.

Recommendations for Healthcare Professionals:

- Educate patients on the importance of regular INR monitoring and maintaining therapeutic range to prevent complications.
- Maintaining therapeutic range to prevent complications.
- Advise maintaining a consistent diet, especially regarding vitamin K intake, to avoid fluctuations in anticoagulant effect.
- Warn patients to consume green leafy vegetables and liver with caution due to their high vitamin K content, which can antagonize warfarin.
- Screen for potential drug interactions before prescribing warfarin, including OTC medications, herbal supplements, and other anticoagulants.
- Counsel patients to avoid aspirin, NSAIDs, and other blood-thinning agents unless specifically prescribed, to reduce bleeding risk.
- Recommend limiting alcohol intake and avoiding binge drinking to maintain stable warfarin metabolism and INR control.
- Encourage patients to inform all healthcare providers about their warfarin therapy before any surgical or dental procedures.
- Instruct patients on lifestyle precautions to minimize bleeding risk, such as using soft toothbrushes and avoiding contact sports.
- Monitor for and immediately address signs of bleeding or thrombosis, such as unusual bruising, hematuria, or symptoms of ischemic stroke.
- Document all dose adjustments, dietary changes, and adverse events carefully, with timely follow-up especially after dose changes or illness.
- Consider personalized warfarin dosing based on patient age, comorbidities, genetic factors, and concomitant medications.
- Coordinate with specialist services (e.g., hematology, cardiology) in complex cases or if anticoagulation control proves difficult.

References

1. ***Warfarin FDA SMPC*** Click here
2. ***Marevan SMPC***:Click here
3. ***EMC SMPC:*** Click here
4. ***MHRA SMPC:*** Click here
5. ***Literature screening link:*** Click here

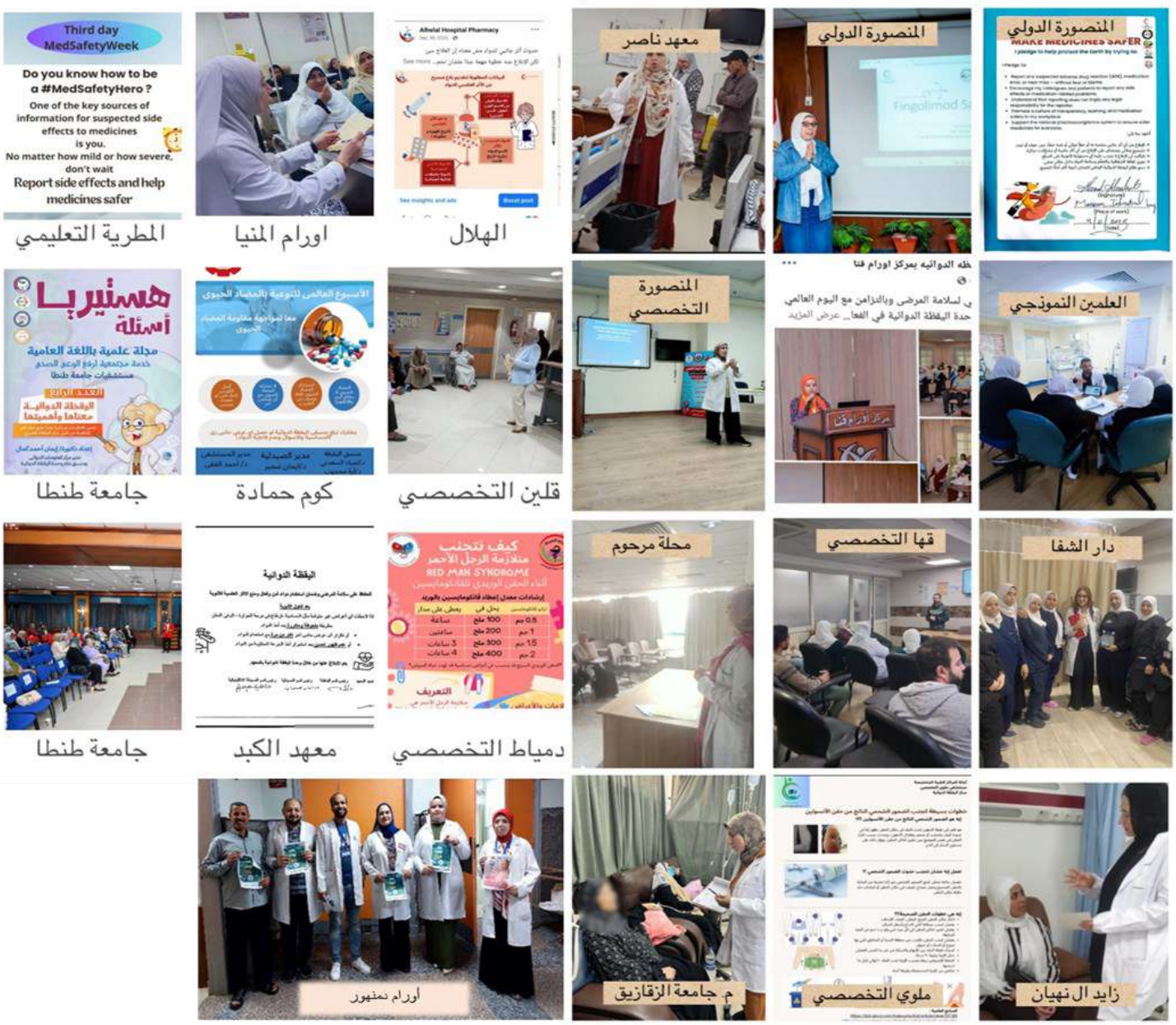
“EPVC 2025 Highlights: A Year Worth Celebrating

PV remains a cornerstone of patient safety and public health, ensuring that medicines continue to deliver more benefit throughout their lifecycle. In line with this mission, we have delivered a year marked by innovation, capacity building, and measurable impact, translating PV principles into tangible outcomes.

1.**Strategic Initiatives**

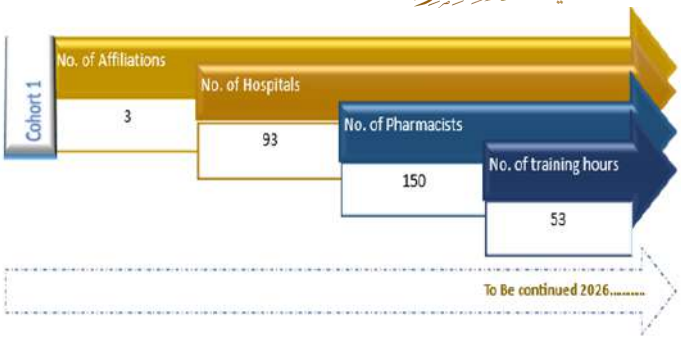
A. Be Vigilant Initiative for central focal points inside hospitals

Launched in June 2025, Be Vigilant initiative was designed Under the slogan Expand the Learning More to increase adverse drug reaction reporting while maximizing the capacity of central pharmacovigilance focal points within hospitals across diverse affiliations, including SMC, GOTHI, and SCOUH as 1st cohort for both beginner and intermediate levels that was successfully



B. Together for Safe Medicines Initiative for Community Pharmacists

The seventh cohort was completed in 2025 reflecting the growing role of community pharmacists as frontline contributors to patient safe.



Statistics: with the participation of 96 pharmacists. During this cohort alone, 175 adverse drug reaction reports were identified and documented.

2. International Representation and Global Engagement

Actively represented in 5 major international conferences and training programs. These contributions strengthened international collaboration and positioned Egypt as a leader in global pharmacovigilance.

3. Awareness and Educational Visits

Awareness and educational visits were conducted to promote the importance of pharmacovigilance systems and their integration within the healthcare ecosystem. These visits targeted faculties of pharmacy across Egyptian universities as well as private hospitals.

Statistics: benefiting 200 academic staff members and students, in addition to 247 healthcare professionals within private hospital

.

4. National Scientific Events Participation

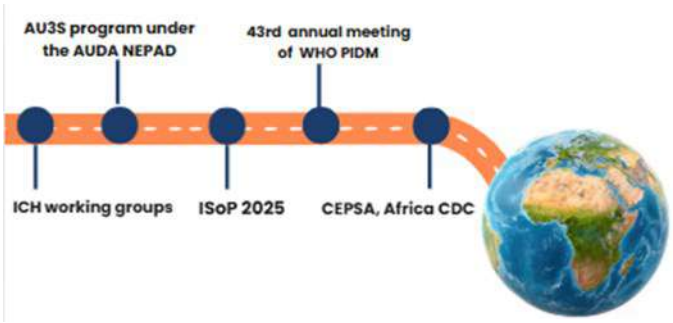
At the national level, participated in two major scientific conferences, also in two career fairs at the Faculties of Pharmacy at Cairo University and Ain Shams.

Statistics: reaching approximately 300 HCG, hospital directors, and health sector decision makers. In parallel, participation University supported professional development for nearly 1100 students across different academic stages.

5. Trainings and Workshops

Capacity building remained a central pillar of our strategy, through online and physical continuous training for HCPs and PV coordinators nationwide, reinforcing standardized practices and fostering a culture of safety monitoring.

Statistics: 71 physical and virtual lectures and webinars. These activities reached 4,189 of HCPs.



6. Impact on reporting of ICSRs

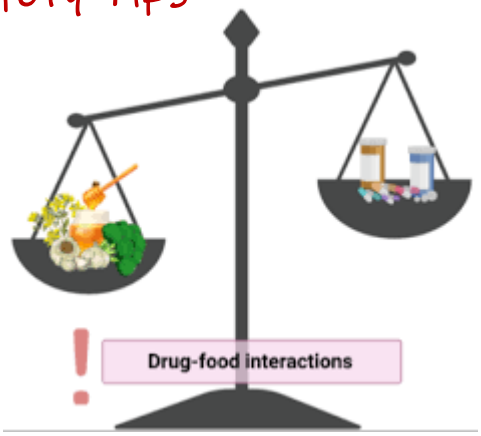
As a direct result of these integrated efforts, this milestone reflects both improved reporting culture and strengthened operational efficiency, underscoring our commitment to signal detection and patient safety.

Together, these achievements illustrate a year of purposeful action where education engagement and collaboration converged to advance pharmacovigilance from policy to practice, reinforcing Egypt's role as a regional leader and international contributor to medicine safety.

EPVC Tips

On Pharmacovigilance

Food and Medicine: Safety Tips



* Some foods can change how your medicine works.
* Avoid grapefruit or grapefruit juice unless your doctor says it is safe.
* Milk and dairy products may reduce the effect of some antibiotics.
* Eat similar amounts of green vegetables if you take blood thinners like warfarin.
* Tell your doctor or pharmacist about herbal products and supplements you use.
* Take your medicine with or without food exactly as instructed.
* Report any unusual symptoms after taking medicine with food or drinks.

You can report any Adverse drug Reactions to the Egyptian Drug Authority (EDA)
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.

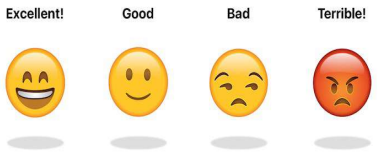
What is the Egyptian Pharmaceutical Vigilance Center?

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)