EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

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EPVC
The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

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.

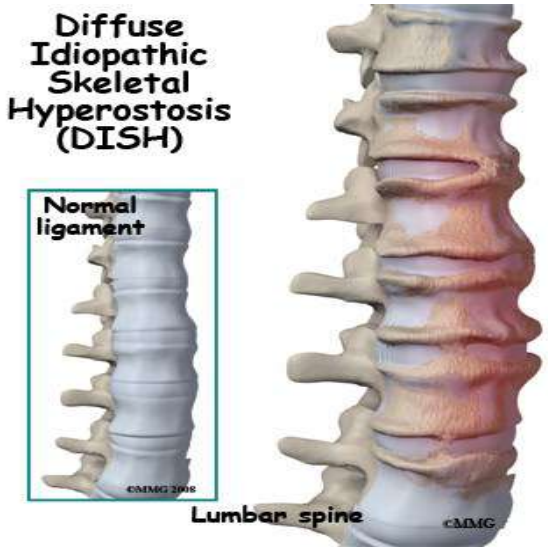
Newsletter

November 2025

Volume 19 Issue 11

Prescriber Guide: Systemic retinoids and diffuse idiopathic skeletal hyperostosis (DISH)

- The regulatory authority in New Zealand published the following prescriber guide whose key message is:
- Diffuse idiopathic skeletal hyperostosis (DISH) is a non-inflammatory, systemic condition characterized by abnormal bone formation, primarily in the spine.
- Most patients with DISH are asymptomatic until the condition progresses and causes musculoskeletal problems, such as pain, morning stiffness and reduced range of motion.
- Cases of DISH have been reported following use of systemic retinoids, usually after prolonged use and/or at high doses.



Diffuse idiopathic skeletal hyperostosis

DISH is a non-inflammatory, systemic condition characterised by the calcification and ossification of ligaments and entheses (the regions where tendons and ligaments attach to bone). It primarily affects the spine, although the pelvis, knee, heels and shoulders may also be affected.
Most patients with DISH are asymptomatic and the condition is generally an incidental find on imaging. However, in advanced disease, new bone formation can cause patients to experience musculoskeletal symptoms such as pain, morning stiffness and reduced range of motion. Rarely, compression of the oesophagus and spinal cord can cause dysphagia and motor and sensory disturbances, respectively.
DISH is more common in men and its prevalence increases with age.
The cause of DISH remains unclear. Genetic, metabolic, mechanical and environmental factors may be associated with its development.

Systemic retinoid exposure and DISH

Cases of DISH have been reported with the use of systemic retinoids, such as isotretinoin and acitretin, usually after long-term use and/or at high doses. Retinoids may cause stem cell proliferation and differentiation, leading to osteoblast formation and ossification.
Abnormal bone formation (hyperostosis) may be detectable on imaging as soon as 6 months after starting retinoid treatment. More extensive hyperostosis can appear 3 to 5 years after continuous long-term therapy. However, patients with hyperostosis usually remain asymptomatic, unless the condition becomes advanced.
Disease progression does not appear to continue after stopping retinoid therapy. Management of DISH is generally symptomatic.

References

1. Med safe: (click here)

Local Case Safety Report: Case series related to Illegally Imported Dietary Supplements Marketed for Weight Reduction

Reason for publishing

In October 2025, the Regional Center of Pharmacovigilance in Cairo received multiple reports from different healthcare professionals and consumers describing serious adverse reactions following the use of illegally imported dietary supplements marketed for weight loss. These products had been purchased through unofficial distribution channels, including social media platforms, fitness centers, and non-licensed online vendors.

Reported serious adverse events included:

- Dilated atrium
- Mitral valve regurgitation
- Severe hypotension
- Shortness of breath
- Tachycardia

Reported non-serious adverse reactions included:

- Dizziness
- Weakness
- Diarrhea
- Constipation
- Decreased blood glucose level
- Increased blood pressure
- Abnormal weight gain following product discontinuation

Notably, several patients continued to experience certain adverse effects even after cessation of the implicated products, indicating possible prolonged pharmacological impact or toxicological effects from undeclared substances.

Background

Illegally imported dietary supplements for weight reduction refer to products not approved by the regulatory authorities; neither on national level {the Egyptian Drug Authority (EDA) and the National Food Safety Authority (NFSA)}, nor on international level {U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA)}.

These products enter the market without undergoing the required evaluation for safety, quality, or efficacy. Their complete ingredient profiles are often unknown, incorrect label, and they may contain undeclared active pharmaceutical ingredients (APIs) that pose significant health risks.

In addition to the growing threat of counterfeit and falsified medications poses a major risk to public health, directly compromising patient safety and undermining the entire pharmacovigilance system due to containing toxic contaminants (e.g., heavy metals, industrial solvents, or rat poison) that can lead to severe organ failure, poisoning, and death.

Among the most frequently identified undeclared substances is sibutramine, previously used as an anti-obesity agent but withdrawn from many international markets due to its association with severe cardiovascular adverse events. Many illegal products containing sibutramine fail to disclose this information on their labels, leading consumers to unknowingly ingest a banned pharmaceutical agent.

Identified Risks

Recent pharmacovigilance reports received from the public and healthcare professionals have highlighted the following safety concerns:

1. Presence of Undeclared Active Pharmaceutical Ingredients

Several confiscated products were found to contain sibutramine, potent stimulants, and high-dose laxative agents without any mention on product labeling. Such APIs may interact with prescribed medications or exacerbate underlying health conditions.

2. Cardiovascular Adverse Effects

- Tachycardia
- Elevated blood pressure
- Palpitations
- Arrhythmias

These reactions may progress to myocardial ischemia or stroke in susceptible individuals. Cardiovascular toxicity remains one of the most significant safety concerns related to sibutramine-containing products.

3. Neuropsychiatric Reactions

- Anxiety and agitation
- Sleep disturbances
- Severe headaches
- Mood alterations

Such reactions are often associated with excessive stimulant content or undeclared psychoactive components.

4. Gastrointestinal and Metabolic Toxicities

- Reports include:
- Persistent diarrhea
- Severe abdominal pain
- Nausea and vomiting
- Electrolyte imbalance

These events may result from unregulated high-dose laxatives, poorly standardized herbal components, or adulterated formulations.

5. Counterfeit and falsified medications

Counterfeit and falsified medications cause adverse effects/ outcomes because they lack the quality, identity, and composition of the genuine product which can result in either direct toxicity from undeclared, harmful substances, or failure to treat the underlying condition from none/incorrect/ insufficient active ingredient.

Recommendations for Healthcare Professionals:

- Maintain a high index of suspicion when assessing patients presenting with unexplained cardiovascular, hepatic, neuropsychiatric, or gastrointestinal symptoms.
- Actively inquire about the use of dietary supplements or weight-loss products purchased through non-official channels.
- Report all suspected adverse reactions promptly to the Pharmacovigilance Center, EDA, using standard reporting tools to support ongoing safety monitoring.
- Counsel patients on the importance of verifying product registration and approval status through official EDA platforms before using any supplement.
- Encourage consumers and other health workers to inspect the packaging for any signs of tampering, spelling mistakes, poor print quality, or unusual appearance (color, smell, consistency) of the medicine itself.
- Verify the Source of buying as the only licensed pharmacies and healthcare institutions are legitimate sources. And patients should avoid buying medicines from unverified online sellers, street vendors, or informal markets.
- Advise patients to consult qualified healthcare professionals prior to initiating any weight-loss supplement or regimen.
- Ensure using authorized medications and avoid promoting unlicensed products that could lead to loss of trust in healthcare as a result of experiencing severe adverse effects or treatment failure.

References

1. Sibutramine Monograph : (Click here)

2. FDA: (Click here)

3. Drug Therapy of Obesity : (Click here)

Potential Signal : Potential Signal of Angina Pectoris Associated with the Administration of Ocreli-

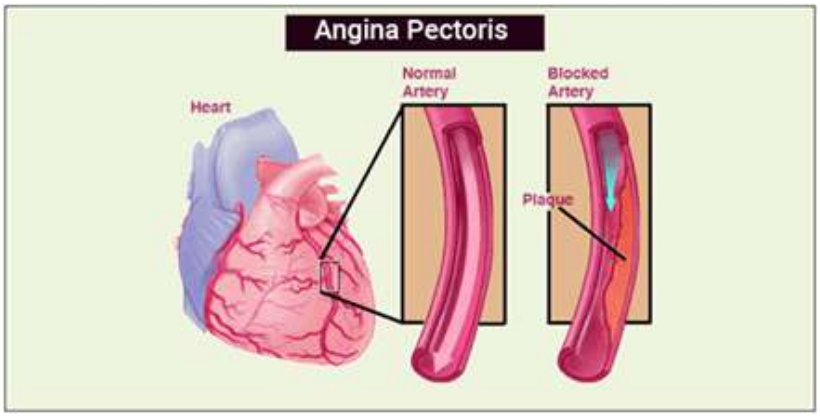
The Safety Signals Management Unit, in the Pharmaceutical Vigilance General Administration (PVGA), identified cases of angina pectoris in patients receiving ocrelizumab, with an emphasis on assessing causality and potential risk factors.

Background

Ocrelizumab is a CD20-humanized monoclonal antibody used to treat patients with primary progressive or relapsing forms of multiple sclerosis (MS) [1]. Angina, or chest pain, is the most common symptom of ischemic heart disease, a major cause of morbidity and mortality worldwide. Chest pain can be due to non-cardiac or cardiac causes. Angina is one of the signs of acute coronary syndrome (ACS) and can be further subdivided into stable and unstable angina [2].

Methodology

A quantitative signal of disproportionate reporting (SDR) using the information component measure (IC) between ocrelizumab and angina pectoris, a total of 54 case reports (49 serious cases and 5 non-serious cases) from the WHO global database of adverse event reports for medicines and vaccines (VigiBase) retrieved till 28/10/2025. The systematic application of the Bradford Hill criteria, along with a supporting literature review, strengthened the evidence of a potential causal relationship for this risk. Additionally, tachycardia associated with infusion-related reactions is labeled in the ocrelizumab SmPC. Likewise, angina is labeled in the rituximab SmPC, which is an anti-CD20 monoclonal antibody.



Results

The review of global cases involved 31 females and 22 males, while gender was unknown in one case report. Ages ranged from 20 to 73 years, with a mean of 46.5 years. Sixteen cases (29.6%) were medically confirmed by physicians. Case reports were received from ten countries between May 6, 2018, and October 28, 2025, indicating consistent reporting across different locations. Additionally, reviewing the cases revealed that 44.4% of cases reported drug-related reactions, including infusion-related reactions, palpitations, increased heart rate, anaphylactic reactions, arrhythmia, cardiac and cardiovascular disorders, chest pain, coronary artery disease, myocardial infarction, ECG abnormalities, transient ischemic attack, and product administration errors. These findings support the safety concerns regarding cardiovascular events associated with ocrelizumab, as highlighted on the Health Canada website [3].

Conclusion and recommendation for actions

The weighted available evidence identified from the case series analysis, the literature review, and the reference regulatory authority's websites suggests a potential signal of angina pectoris associated with ocrelizumab administration. The PVGA imposes risk minimization activities to better inform healthcare professionals about potential cardiac-related risks, including angina pectoris associated with the administration of ocrelizumab, and to collect more data in related case reports to better characterize potential cardiac risks.

References

1. Ocrelizumab SmPC: (Click here)

2. NCBI : (Click here)

3. Health Canada : (Click here)

Safety Signal : A Safety signal of Seizures Associated with the overdose administration of Pipazetate.

The Safety signals management unit, in the Pharmaceutical Vigilance General Administration (PVGA), identified three cases of patients who experienced seizures following overdose administration of pipazetate.

Background:

Pipazetate: is an antitussive agent that acts centrally on the medullary cough center. [1]

Seizures: is a condition where brain cells malfunction and send electrical signals uncontrollably. That causes symptoms affecting other parts of your brain and body. Everyone can have seizures, but some people can have them more easily for various reasons. Seizures are often treatable, especially depending on the underlying cause. [2]

A safety signal for the risk of seizure associated with the administration of Pipazetate (Pipazethate) hydrochloride was identified by PVGA, based on reported cases in the national database, literature screening [3], and cumulative review submitted by the MAH. A case series analysis applying the Bradford-Hill criteria and disproportionality analyses information component (IC) was conducted.

The weighted available evidence confirms a signal of seizure associated with pipazetate administration. The results revealed that the majority of reported cases involved patients aged 6 months to 3 years, and seizures were linked to overdose in 71% of the cases. In addition to the temporal relationship, as the reaction happened within 25 mins to 1 hour from the drug administration, positive de-challenges and medically confirmed outcomes in (100%) of the cases, support a positive causal association. Different formulations' concentrations could lead to a medication error.

In line with FDA recommendations advising against the use of OTC cough and cold medicines in children under 4 years due to the risk of serious and potentially life-threatening side effects [4], and the literature on "Use of antitussive medications in acute cough in young children," which advises that OTC antitussives should not be routinely used in children under 2 years. [5]

Actions

Accordingly, the Egyptian Drug Authority has imposed regulatory measures, including restricting the use of the drug in patients under four years old and updating the product leaflet to emphasize the potential risk of seizures associated with overdose.

References

1. ***What is Pipazetate:*** (Click here)
2. ***What is Seizure :*** (Click here)
3. ***Cases from literatures:*** (Click here) (Click here) , (Click here) , (Click here)
4. ***FDA publication :*** (Click here)
5. ***Literature of antitussive use :*** (Click here)

Egyptian Drug Authority Participation in the ISoP Cairo 2025 Annual Conference from 24-27 October 2025

Representatives from the Egyptian Drug Authority (EDA), Pharmaceutical Vigilance General Administration (PVGA), actively participated in the Annual Conference of the International Society of Pharmacovigilance (ISoP Cairo 2025), held in Cairo from 24–27 October 2025.

The Director of the Pharmaceutical Vigilance General Administration (PVGA) participated as a panel speaker and delivered an oral presentation highlighting the administration's role in monitoring and assessing post-marketing drug safety, promoting a culture of adverse drug reaction reporting, and showcasing recent developments in pharmacovigilance activities in Egypt.

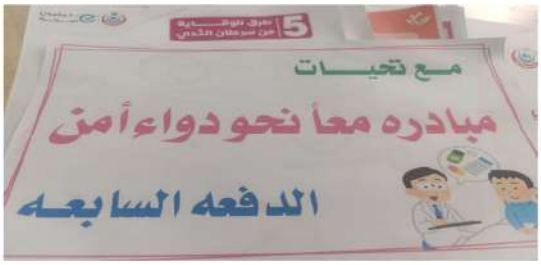
The EDA team also presented four scientific posters, three of which resulted from potential safety signal evaluations conducted by the Safety Signals Management Unit at PVGA. The poster topics included:

- A Potential Signal of Seizure Associated with the Administration of Pipazetate
- A Potential Signal of Osteonecrosis Associated with the Administration of Fingolimod
- Evaluating Liver-Related Risks of Nitazoxanide: Findings from Egyptian Post-marketing Pharmacovigilance Case Reports

The fourth poster explored the role of artificial intelligence in pharmacovigilance, developed through a collaboration between an EDA representative and the ISoP Artificial Intelligence Special Interest Group.

Together for Safer Medicine Initiative News:

EPVC is extremely proud for ending the activities of 7th wave of initiative "together for safe medicine" on 1 November 2025 where 47 participants from governmental and community pharmacies from 16 governorate all over Egypt had entered 158 ADRs reports on vigiflow data base where participants made a 142 different activities for spreading pharmacovigilance science either through social media , awareness lectures for HCPs and public and through sharing in national and international pharmacovigilance events as the annual #MedSafetyWeek 2025, patient safety day, world pharmacist day that helped in increasing awareness and practicing of pharmacovigilance between HCPs and public in all governmental and community pharmacies all over Egypt.



BE-Vigilant Initiative

The Egyptian PV Center (EPVC) has officially ended up the first phase of BE-Vigilant Initiative, under the theme "Expand the Learning More…" for Cohort 1 from Specialized Medical Centers SMC that passed the Mentorship based approach (Beginner and Intermediate levels). This phase is reached out **76 of PV focal points across SMC facilities with total number of 11 lecture and workshops over 45 hours of training through 5 months journey**. The next phase to evaluate the candidates' activities to move for the next level from beginner to intermediate, and from Intermediate level to Case Based learning phase. In addition to starting Cohort 2 from Beginner level.

Agile Mindset for Growth 2025–2026.

The Egyptian Drug Authority (EDA) is pleased to announce the official launch of the initiative **Agile Mindset for Growth 2025–2026**. This initiative is designed to engage medical students at universities to the pharmacovigilance scene with the suitable skills to help achieve medication safety and the ultimate goal of PV: patient safety.

The objectives of this national initiative are to:

Build generation of PV-conscious medical graduates, the new generation.
Provide the opportunity to make the new generation able to participate in raising awareness about the importance of PV and how to monitor and report adverse effects.
Achieve community integration and society engagement.

EPVC celebrates MedSafety Week 2025

First; EDA provided 1 session at BUE about the role of EPVC in PV activities on national level and encouraging participation in ADR reporting through using available channels, this session has approached no. 70 of students and faculty staff.

Second; EDA participated in panel discussion in conference that approached no. of 200 nutritionist/dietician/HCP and public audience which focused on nutrition and herbal medicines and how it is important to embed PV activities among society members and the role of ADR reporting in achieving ultimate goal of patient safety.

Third; EPVC would like to extend sincere appreciation to hospitals for their efforts in MedSafety Week under theme of "We can all help make medicines safer" through 3-9 November to enhance pharmacovigilance practices through various tools of patient education and awareness about the importance of Adverse drug reaction reporting.

⇒19 hospital, affiliated to SMC, in different Governorates:
The PV coordinators with pharmacy department have published 18 flyers/posters and provided 20 workshops/lectures for 773 of HCGs (physician, nurse and pharmacist). In addition to conducted 22 awareness sessions for 401 patients and launched 9 awareness videos.

⇒Big thanks for (Mansoura international & Mansoura specialized & Meet ghamr oncology -Mansoura – Dakahlia) (Mallawi Specialized & Minia oncology – Minya) (El helal & New cairo specialized & Dar elshefa & El salam specialized & Haram specialized & National institution of chest disease – Cairo) (Day case surgery raselbarr & Damietta specialized – Damietta) (Sharq Elmadina -Alexandria) (Damanhour Oncology & Kom Hamada Specialized - El Beheira) (Qallin Specialized - kafrElshiek) (Mahalet marhoum specialized - Tanta - Gharbeya) (Sohag Oncology – Sohag) (Benha children – Qalyubiyya) (Qena oncology - Qena)

⇒7 hospitals, affiliated to SCOUH, in different Governorates:

⇒The PV coordinators have approached 310 of HCGs (physician, nurse and pharmacist) through publishing newsletter/posters, providing training lectures and conducting awareness sessions and videos. Special thanks for Monufia university hospital, Alexandria university, Tanta university, Zagazig university, National cancer institute, Cairo University and Mansoura University hospital.

⇒63 hospitals, affiliated to EHA, in 4 Governorates:
The PV coordinators have published flyers/posters and provided 12 workshops/lectures for 1297 of HCGs (physician, nurse and pharmacist). In addition to conducted 50 awareness sessions for 3106 patients and videos.

⇒4 hospitals, affiliated to GOTHI, in different Governorates:
The PV coordinators with pharmacy department have published flyers/posters and provided 12 workshops/lectures for 240 of HCGs (physician, nurse and pharmacist). In addition to conducted awareness sessions for 195 patients.

⇒ Big thanks for National heart institute, Liver Institute Kasr Al Ainy, National institute of diabetes and Matarya teaching hospital.

VigiTest Competition: The 2025 Challenge is Nearing the Finish Line!

As the VigiTest 2025 Challenge draws to a close, we extend our most sincere gratitude for your dedicated participation. Your commitment, effort, and valuable contributions are highly commendable and profoundly appreciated.

We received responses from participants across various facilities, which resulted in a **remarkable overall score** and a collective outstanding achievement that we are delighted to recognize.

Heartfelt congratulations to the participants whose exceptional scores contributed significantly to the success of this journey.

The participants who got an impressive score for round 4 of VigiTest Competition:

Name	Affiliation	Title
Reem Khalil Mohammed	**Qena Oncology Center, SMC**	**PV specialist**
Alaa Awad-Allah Elgnainy	**Qualified Person Responsible for Pharmacovigilance**	**QPPV**

Thank you once more for your professionalism.

The answers of R4 are:

Round 4:

The time window of reporting serious ICSRs and AEFIs is …… days, respectively.

The Answer is: **15,1**. The time window of reporting serious ICSRs is within 15 days and AEFIs is within 24 hours.

Which of the following scenarios most likely represents a 'Type B' adverse drug reaction?

The Answer is: **Anaphylaxis following penicillin administration**.

In the WHO-UMC causality categories, which of these is required for a reaction to be classified as "Certain"?

The Answer is: **Re-challenge, if necessary, plus de challenge**.

Which of the following(s) would increase the VigiGrade completeness score of an ICSR report?

The Answer is: **Precise time-to-onset specified with correct units and Indication.**

Which of the following is correct about de-challenge and re-challenge in causality assessment?

The Answer is: **Re-challenge refers to reintroducing the drug to see if reaction recurs and De-challenge means stopping the suspected drug.**

Validation process answers the question of: How detailed and useful is the case for signal detection and regulatory assessment?

The Answer is: **False**

Vigiflow is a measuring tool to identify well-documented ICSRs and highlight systematic data quality issues in collections of ICSRs.

The Answer is: **False**

WHO-UMC scale has 4 dependent steps for causality assessment of ICSRs

The Answer is: **False**

Cluster analysis in PV refers to either spatial clustering (geographical); or temporal clustering?

The Answer is: **True.**

Case definitions like Brighton Levels are used to standardize identification of AEFI.

The Answer is: **True.**

EPVC Tips

On Pharmacovigilance
Be a Med Safety Hero

Every patient or patient carer has the power to make medicines safer for all. Here are 4 ways that you can be more vigilant in the use of medicines and help raise awareness of #pharmacovigilance:

- ✔ Talk to your healthcare professional about the potential side effects of a medicine
- ✔ Ask your healthcare professional how and where you can report suspected side effects
- ✔ Read the patient information leaflet supplied with the medicine and follow the dosage instructions
- ✔ Tell your healthcare professional about suspected side effects and report them to us

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*

The Egyptian Pharmaceutical Vigilance center
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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.

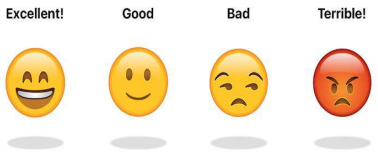
What is the Egyptian Pharmaceutical Vigilance Center?

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

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هيئة الدواء المصرية (الرعاية الصيدلية)