DRUG REGULATORY AUTHORITY OF PAKISTAN
MINISTRY OF NATIONAL HEALTH SERVICES, REGULATIONS & COORDINATION

DRAP's NewsLetter

MAY-24
VOLUME-3
ISSUE-1

MESSAGE

Dr.Malik Mukhtar Ahmad Bharath
Coordinator to PM on Health

I strongly believe in the power of harmonization, as it fosters international collaboration and strengthens health systems. As diseases have no borders, it is crucial to partner with global health organizations, which contributes to the ongoing global health dialogue. We are dedicated to building strong relationships with regulatory bodies and networks, learning from mutual experiences and encouraging the active participation of our regulators at international forums.

We are working tirelessly to enhance our regulatory capacities by adopting international best practices, enabling an environment that promotes and facilitates the timely availability of new treatment opportunities to the people of Pakistan.

Together, we can build a healthier Pakistan".

MESSAGE

Nadeem Mahbub
Federal Secretary

In the face of global health challenges, we focus on strengthening our healthcare system's resilience. We are dedicated to ensuring that everyone has access to the necessary medical resources, regardless of their location or economic status. Our commitment extends to improving our regulatory systems. We understand that a robust and resilient regulatory system is crucial for maintaining medicines and vaccines' quality, safety, and efficacy.

Patron in Chief:
Mr. Nadeem Mahbub
Secretary MONHS&R

Editor in Chief:
Mr. Asim Rauf
CEO DRAP

Editor:
Dr Akhtar Abbas Khan
Director Licensing

USPTO/FDA COMBATTING COUNTERFEIT PHARMACEUTICALS PROGRAM (PAKISTAN) APRIL 15-18, 2024.

The US Embassy in Pakistan organized a four-day training program titled "USPTO/FDA Combatting Counterfeit Pharmaceuticals Program (Pakistan)" from April 15-18, 2024. This program was held at the Global Intellectual Property Academy, located in the USPTO Headquarters in Alexandria, VA, and the Food and Drug Administration Headquarters at the White Oak Campus in Silver Spring, MD, USA.

During the program, the participants gained valuable insights into legal and practical strategies to combat counterfeit pharmaceuticals and related IP enforcement matters. They learned about best practices in counterfeit detection, investigative and prosecutorial methods, and other relevant topics.

A cohort of nine individuals, including two senior judges from high court, officers from the Drug Regulatory Authority of Pakistan (DRAP), and officers from Pakistan Customs, attended the program. The delegation from DRAP, led by CEO Mr Asim Rauf, played an active role, presenting a comprehensive overview of the current state of counterfeit products in Pakistan and addressing the myths and realities of the presence of counterfeit medicines in the country. CEO DRAP, Mr. Asim Rauf, shared the impressive statistics that only 0.166% spurious drugs were identified during 2023 in Pakistan. He informed the audience about the measures being taken by Pakistan's government to combat counterfeit pharmaceuticals.

The participants also visited JFK-IMF (International Mail Facility) where the US Customs and Border Protection (CBP) officers briefed them. During the briefing, the CBP officer informed the group that they had not seized any parcels from Pakistan containing medications. This information came as a surprise to the other participants, who had been concerned about the possibility of illegal shipments of medicines entering the US from Pakistan.

The CEO DRAP (Drug Regulatory Authority of Pakistan) explained the reason behind this surprising fact. The CEO stated that DRAP's strict enforcement policies had played a significant role in preventing any unauthorized shipments of medicines from Pakistan. He explained that in order to export or ship any quantity of medications from Pakistan, it was necessary to obtain DRAP's No Objection Certificate (NOC).

The CEO's explanation highlighted the importance of strict regulations in safeguarding the quality and safety of medications. By requiring DRAP's NOC for every small quantity, Pakistan ensures that only authorized and regulated medicines leave the country. This proactive measure helps to prevent the potential importation and distribution of counterfeit or substandard medications, protecting consumers both in Pakistan and abroad.

This training program provided an excellent opportunity for participants to exchange knowledge, share best practices, and collaborate on strategies to combat counterfeit pharmaceuticals. It reinforced the importance of international cooperation and collaboration in ensuring the availability of safe and effective medicines for consumers around the world.

27TH TECHNICAL MEETING OF THE G5 FORUM ON HEALTH DIPLOMACY, PHARMACEUTICAL AND MEDICAL DEVICES REGULATORY SYSTEMS, IRAN

For the promotion and development of the health of these countries, the 27th Technical Meeting of the G5 Forum was held in Tehran in September with the participation of food and drug agencies from the member countries, Pakistan, Iran, Afghanistan, Tajikistan, Iraq, and the World Health Organization. Mr Asim Rauf CEO DRAP represented Pakistan in the forum.

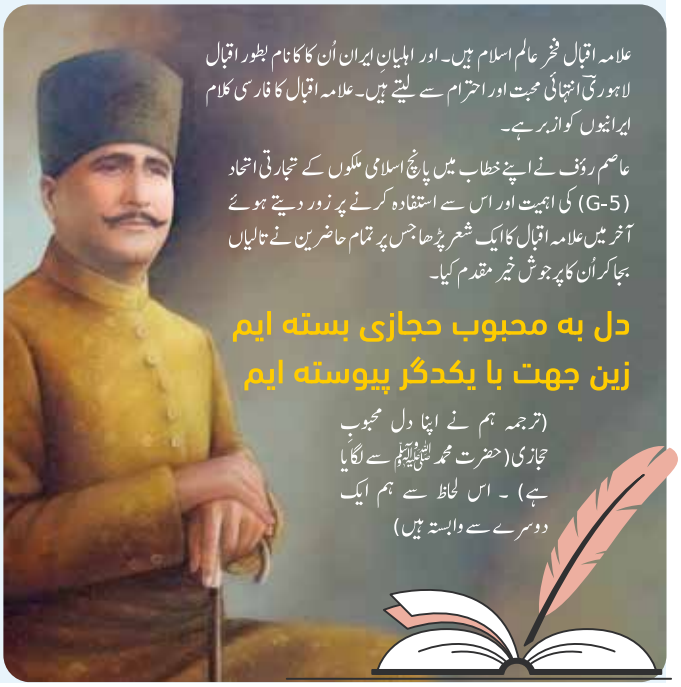
CEO DRAP in his opening remarks said that Pakistan welcomes opportunities for Health diplomacy among our countries. It is a concept that transcends borders, cultures, and ideologies. This collaborative effort empowers regulatory bodies to make informed decisions and effectively regulate the pharmaceutical and medical device industries. Another significant aspect of health diplomacy in the G5 countries is the promotion of research and development in healthcare & especially in alternative medicine. This area is rich in plants of medicinal value which have been used for centuries for curing various ailments. Combined with innovation, these alternative medicines can be manufactured and exported worldwide.

CEO DRAP met with the H.E. Dr Syed Jaffar Hussain WR Iran, various delegations from brethren regulatory authorities, and pharmaceutical firms of Iran and visited the Center of Progress and Development of Iran.

At the end of the 27th technical meeting of the G5 forum on Health Diplomacy, Pharmaceutical and Medical devices regulatory systems, all members, while acknowledging the secretariat of the meeting, emphasized the necessity of cooperation between the member countries in the field of medicine and medical devices to improve access.

The members also wish to complete and expand cooperation in the fields of regulation, supervision and production of pharmaceutical products, including chemical drugs, biological drugs, radiopharmaceuticals, herbal medicine, vaccines and their raw materials, as well as medical supplies and equipment, based on the interests of the countries.

The participating members approved the formation of the "Technical Working Group on Pharmaceutical and Medical Devices " with the membership of the representatives of each country and the World Health Organization in order to implement the resolutions of the meeting. Also, they agreed to report the progress to the secretariat on a quarterly basis.



CONFERENCE ON THE INDIGENOUS VACCINE DEVELOPMENT FOR LIVESTOCK

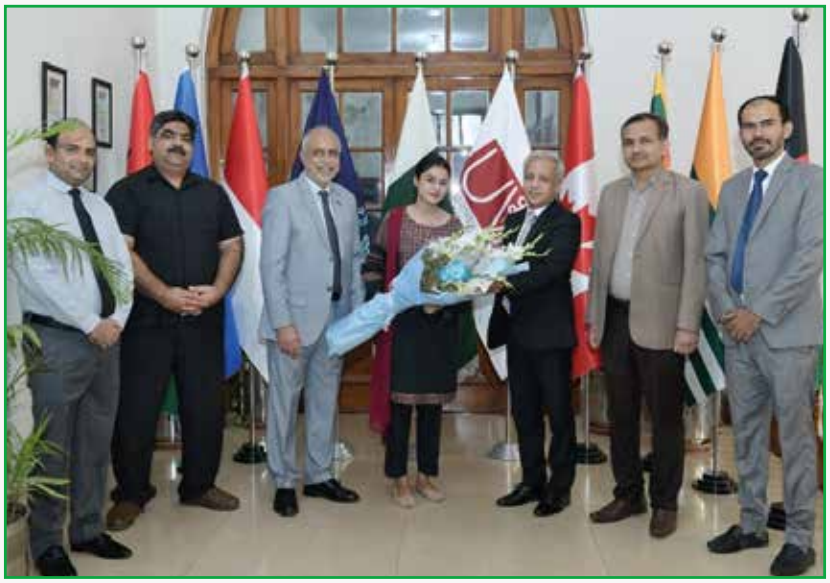
The University of Veterinary and Animal Sciences (UVAS) organized a conference on biological production on Monday, Oct 09, 2023, to encourage the indigenous vaccine development for livestock. The conference aimed to address the challenges and opportunities in Pakistan's production, licensing, and registration of veterinary biologics. It also sought to foster scientific collaboration and promote intellectual property rights among the participants. Secretary Live Stocks and Dairy Development Punjab, Vice Chancellor UVAS and DG (Research) VRIs Punjab and KPK were present at the conference.

Mr Asim Rauf Chief Executive Officer of the Drug Regulatory Authority of Pakistan (DRAP) was the chief guest at the conference, who stated that DRAP is committed to extending support and cooperation in achieving these goals. CEO DRAP emphasized that local production of veterinary vaccines shall be ensured under the law to minimize imports and enhance exports

Dr. Syed Zia Husnain Additional Director / Chairman Gap Analysis Committee on VRIs DRAP gave detailed presentations to all respective VRIs and respective participants on the complete procedure of obtaining the drug manufacturing license and subsequent registration of veterinary vaccines.

The participants appreciated the efforts of DRAP, particularly the establishment of the technical working group, for collaborating with Veterinary Research Institutes (VRI) considering the importance of the livestock sector for the economy and food security of the country.

The University of Education VC Prof. Dr Talat Naseer Pash suggested a joint venture approach with friendly countries to set up training centres.

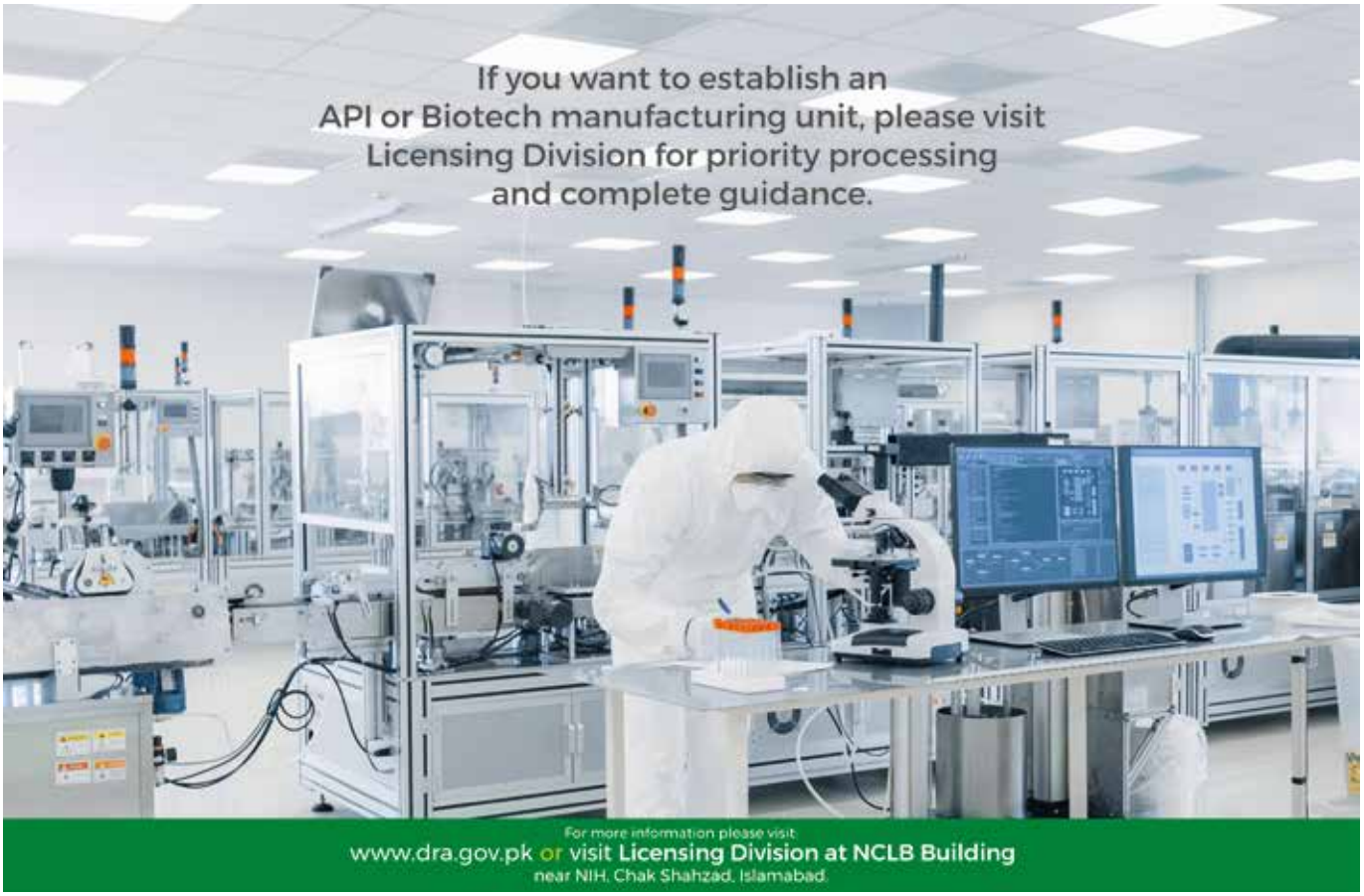


E-APPLICATION SYSTEM FOR LICENSING OF PHARMACEUTICAL FIRMS

MIS division of DRAP has established an online application system for the Division of Licensing, DRAP's accessible at www.eapp.dra.gov.pk. This innovative platform offers a one-stop solution for a wide range of pharmaceutical unit-related functions, including the verification and approval of sites for establishment, building layout plans, technical staff information (or approvals). In addition, it provides a seamless process for grant and renewal of drug manufacturing licenses, panel inspections, and other matters related to licensing of pharma manufacturing. The primary focus of this system is to enhance the ease of doing business in the pharmaceutical sector, enabling prompt and efficient processing of applications, ensuring timely disposal, and significantly reducing hurdles. CEO DRAP Mr Asim Rauf said while inaugurating the pilot project.

“We are confident that this user-friendly interface will foster greater efficiency, transparency, and convenience in our regulatory processes”.

Dr. Akhtar Abbas Khan, Director Licensing Division informed that the Licensing division is developing a database to improve transparency, and access to information and to enhance proficiency. The Drug Licensing Division of DRAP has initiated a "One Window Operation" for the expedited approval of technical personnel working in the drug manufacturing facilities and streamlined the process for pharmaceutical professionals. Additionally, DRAP has established a dedicated Cell for the priority handling of matters about indigenous Active Pharmaceutical Ingredient (API) manufacturers. This cell will actively collaborate with relevant ministries to ensure the swift completion of requirements for the issuance of licenses on a fast-track basis. These measures underscore our commitment to fostering efficiency and innovation in the pharmaceutical sector which will minimize the APIs import dependencies.



Drug Licensing Division-DRAP has recently conducted an online workshop for step by step guide to E-App. This online workshop brought together a diverse group of participants, including pharmaceutical regulatory affairs officers and pharmacists. This learning activity was a testament to our commitment to knowledge sharing and excellence in the pharmaceutical industry.

ENSURING QUALITY AND SAFETY: AN OVERVIEW OF DRAP'S DRUG RECALL SYSTEM

A drug recall is the most effective means of protecting the public from a defective or potentially harmful product. Drugs may be recalled for many reasons including safety issues, quality defects; mislabeling, contamination, deviations in strength or potency, etc. Recalls may be conducted as a voluntary action by the manufacturer or supplier; or statutory upon direction of the regulatory authority.

Recalls occur routinely every year globally. DRAP has also implemented measures to ensure effective recall which include classifying the type of drug recall, alerting the public, and safely removing the affected product from the market.

Recall system

The process of implementing an effective recall system is suggestive of DRAP's steady commitment to quality, safety, and consumer trust. The following are its key components: -

- **Recall Guidelines:** In consultation with the stakeholders, the DRAP has published clear and concise guidelines outlining criteria for classifying the severity of recalls including protocol of recall and when and how recalls should occur and executed.
- **Comprehensive Training:** DRAP invested in training and upskilling the personnel responsible to ensure recall oversight.
- **Cross-Functional National Task Force:** A national force comprising members from various departments including federal and provincial field forces, quality control laboratories and legal team members support the implementation of the recall.
- **Communication Strategy:** Effective communication is the heart of any successful recall system. DRAP's communication strategy includes both internal as well as external communication to ensure that all stakeholders are well informed promptly and accurately.
- **Technology Integration:** Leveraging technology was pivotal to ensure the uninterrupted flow of information in order to meet recall timelines. We are working on integrated recall management software enabling us to track and manage recalls efficiently. This system will also facilitate data analysis, helping us to make data-driven decisions.

Challenges and Lessons Learned

Implementing an effective recall system was not without its challenges. Some key lessons we learned along the way include:

- **Preparedness is Key:** Being proactive and well-prepared for recalls is essential. The more prepared we are, the faster and more efficiently we can respond.
- **Communication and stakeholder engagement is Non-Negotiable:** Clear and timely communication with all stakeholders is vital. Responsiveness of Product Registration holders has remained the greatest challenge for the reconciliation of recalled products to ensure the effectiveness of the recall system.
- **Continuous Improvement:** A recall system is not static. It requires constant evaluation and improvement. Regularly revisiting and updating Guidelines/SOPs/protocols is essential.

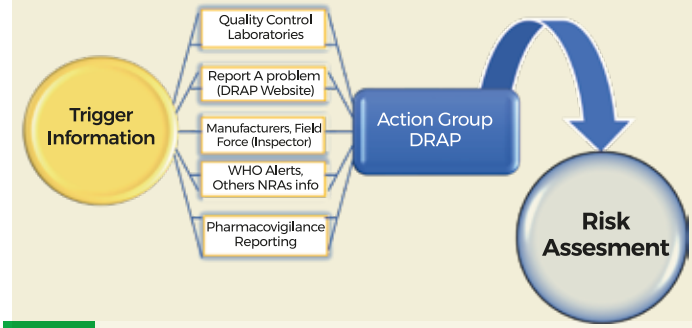
Results and Impact

Our efforts in implementing an effective recall system bore fruit. We observed:

- **Faster Response Times:** Our response time to recall situations improved significantly, reducing potential risks to consumers.
- **Enhanced Public Trust:** Our transparent and efficient recall system bolstered public trust. Consumers appreciated our commitment to safety.

Conclusion

DRAP in line with its vision has been putting continuous efforts into protecting the people of Pakistan from defective potentially harmful products and taking every possible step for continuous improvement. Implementation of an effective recall system requires sustained collaborative efforts of all stakeholders and with combined and targeted efforts we can successfully achieve this goal.



Stages of Effective Recall Process

Stage 01	Trigger Information
Stage 02	Information for Assessment
Stage 03	Risk Assessment
Stage 04	Risk Communication
Stage 05	Monitoring and Progress of Recall
Stage 06	Evaluation of the Recall

Picture Gallary

Mr Asim Rauf CEO of DRAP represented Pakistan in the Shanghai Cooperation Organization Pharmaceutical Cooperation Development Conference held in Shanghai.

Meeting with the CEO of Pakistan Single Window (PSW), Mr. Aftab Haider. We discussed digital transformation and process integration between DRAP and PSW in order to facilitate the pharmaceutical industry and the general public.

CEO DRAP Mr Asim Rauf while delivering a presentation in USPTO

Professor Zaheer-Ud-Din Babar presenting his book to Mr Asim Rauf

Abdul Mughees Assistant Director DRAP represented DRAP attended the ASEAN Regional Regulators Roundtable Conference at ISPE at Suntec, Singapore

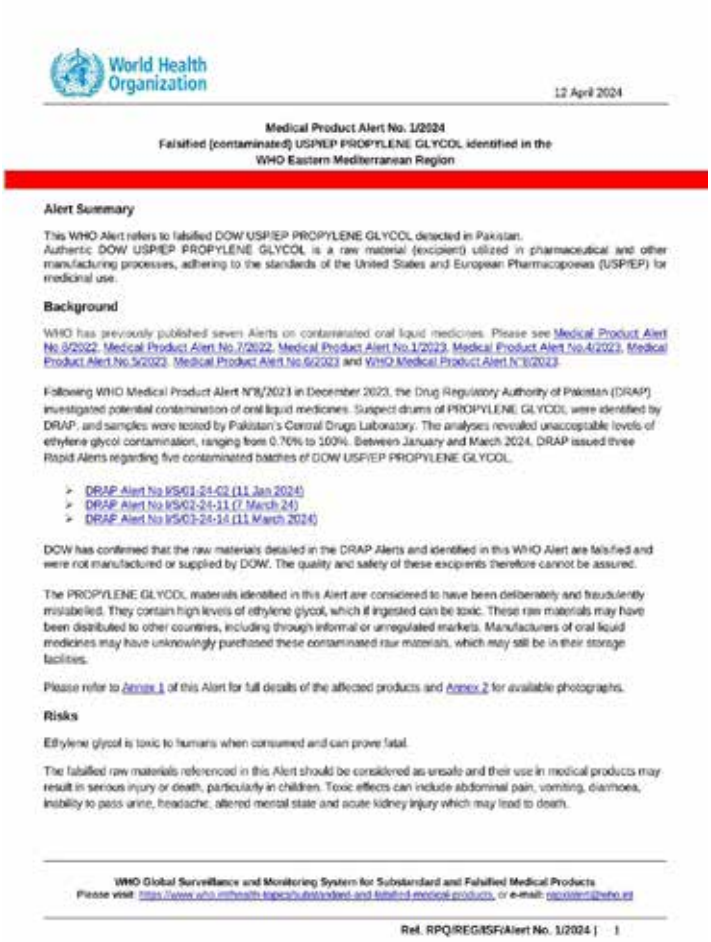
CEO DRAP speaking at a seminar on "Identifying the gaps and charting possible solutions in the pharmaceutical sector: Building a National University of Pharmaceutical Sciences in Pakistan".

ڈرگ ریگولیٹری اتھارٹی آف پاکستان
منسٹری آف نیشنل ہیلتھ سروسز ریگولیشنز اینڈ کوآرڈینیشن

ڈریپ نیوز لیٹر

مئی ۲۰۲۴
والیم ۳
شمارہ ۱

ڈریپ کا ادویات کے معیار کو بہتر بنانے میں فعال کردار



World Health Organization

12 April 2024

Medical Product Alert No. 1/2024
Falsified [contaminated] USP/EP PROPYLENE GLYCOL identified in the WHO Eastern Mediterranean Region

Alert Summary

This WHO Alert refers to falsified DOW USP/EP PROPYLENE GLYCOL detected in Pakistan.
Authentic DOW USP/EP PROPYLENE GLYCOL is a raw material (excipient) utilized in pharmaceutical and other manufacturing processes, adhering to the standards of the United States and European Pharmacopoeias (USP/EP) for medicinal use.

Background

WHO has previously published seven Alerts on contaminated oral liquid medicines. Please see Medical Product Alert No 3/2022, Medical Product Alert No 7/2022, Medical Product Alert No.1/2023, Medical Product Alert No.4/2023, Medical Product Alert No.5/2023, Medical Product Alert No 6/2023 and WHO Medical Product Alert N°8/2023.

Following WHO Medical Product Alert N°8/2023 in December 2023, the Drug Regulatory Authority of Pakistan (DRAP) investigated potential contamination of oral liquid medicines. Suspect drums of PROPYLENE GLYCOL were identified by DRAP, and samples were tested by Pakistan's Central Drugs Laboratory. The analyses revealed unacceptable levels of ethylene glycol contamination, ranging from 0.76% to 100%. Between January and March 2024, DRAP issued three Rapid Alerts regarding five contaminated batches of DOW USP/EP PROPYLENE GLYCOL.

- DRAP Alert No IHS/01-24-02 (11 Jan 2024)
- DRAP Alert No IHS/02-24-11 (7 March 24)
- DRAP Alert No IHS/03-24-14 (11 March 2024)

DOW has confirmed that the raw materials detailed in the DRAP Alerts and identified in this WHO Alert are falsified and were not manufactured or supplied by DOW. The quality and safety of these excipients therefore cannot be assured.

The PROPYLENE GLYCOL materials identified in this Alert are considered to have been deliberately and fraudulently mislabelled. They contain high levels of ethylene glycol, which if ingested can be toxic. These raw materials may have been distributed to other countries, including through informal or unregulated markets. Manufacturers of oral liquid medicines may have unknowingly purchased these contaminated raw materials, which may still be in their storage facilities.

Please refer to Annex 1 of this Alert for full details of the affected products and Annex 2 for available photographs.

Risks

Ethylene glycol is toxic to humans when consumed and can prove fatal.

The falsified raw materials referenced in this Alert should be considered as unsafe and their use in medical products may result in serious injury or death, particularly in children. Toxic effects can include abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state and acute kidney injury which may lead to death.

WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products
Please visit: https://www.who.int/health-topics/substandard-and-falsified-medical-products, or e-mail: ssfdalert@who.int

Ref. RPQ/REG/SSF/Alert No. 1/2024 | 1

گزشتہ برس ورلڈ ہیلتھ آرگنائزیشن نے Gambia اور Indonesia میں DEG/EG کی ملاوٹ سے ہونے والے نقصان کے پیش نظر تمام رکن ممالک کو سیرپس میں موجود زہریلے اجزاء کی موجودگی کے معاملے پر نگرانی کی اپیل کی، جس کے مدنظر ڈرگ ریگولیٹری اتھارٹی آف پاکستان (ڈریپ) نے سیرپ بنانے والے فارماسیوٹیکل اور نیوٹراسیوٹیکل مینوفیکچررز پر کڑی نگرانی کا آغاز کیا۔ ابتدائی تحقیقات کے مطابق مقامی کیمیکل سپلائرز اس ملاوٹ میں ملوث پائے گئے۔ ڈریپ نے قانون نافذ کرنے والے اداروں کی مدد سے ایسے عناصر کیخلاف سخت کارروائی کی۔ مزید برآں، ڈریپ کی جانب سے فارماسیوٹیکل مینوفیکچررز کو پابند کیا گیا ہے کہ وہ Sorbitol, Glycerine اور Polyethylene Glycol اور ان سے بننے والے سیرپس کی جانچ کروائیں۔

دسمبر 2023 میں WHO میڈیکل پروڈکٹ الرٹ N°8/2023 کے بعد، ڈرگ ریگولیٹری اتھارٹی آف پاکستان (DRAP) نے سیرپس کی ممکنہ آلودگی کی تحقیقات کی۔ PROPYLENE GLYCOL کے مشتبہ ڈرموں کی شناخت ڈریپ کی تحقیقات کے نتیجے میں ہوئی۔ اور پاکستان کی سنٹرل ڈرگز لیبارٹری سے نمونوں کی جانچ کی گئی تھی۔ تجزیوں سے 0.76% سے 100% تک ایتھیلین گلائکول آلودگی کی آمیزش کا انکشاف ہوا۔ جنوری اور مارچ 2024 کے درمیان ڈریپ نے تین الرٹ جاری کیے۔

کھانسی کے شربت کی تیاری میں استعمال ہونے والے آلودہ پروپیلین گلائکول کے بارے میں ڈریپ کی ملک گیر تحقیقات عوامی تحفظ کو یقینی بنانے کی جانب ایک قابل ستائش کوشش ہے۔ ڈبلیو ایچ او کا الرٹ جعلی خام مال کی تقسیم کو روکنے کے لیے مینوفیکچرنگ کے اچھے طریقوں پر عمل کرنے کی اہمیت کو اجاگر کرتا ہے جو صحت عامہ کو شدید نقصان پہنچا سکتے ہیں۔

کسی بھی سوال، تبصرے یا اپنی قیمتی رائے سے نوازنے کے لیے رابطہ کریں۔
akhtar.abbas@dra.gov.pk
or
Call at: 051 92 55 974