#### DRUG REGULATORY AUTHORITY OF PAKISTAN

MINISTRY OF NATIONAL HEALTH SERVICES, REGULATIONS & COORDINATION



# DRAP'S CTC JUN-25 VOLUME-4 ISSUE-1







Dr Obaidullah, CEO of DRAP at the 78th World Health Assembly.

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## INSIGHTS FROM 78TH WORLD HEALTH ASSEMBLY! PAKISTAN'S PRESENCE IN ADVANCING REGULATORY EXCELLENCE

Federal Minister for National Health Services, Regulations & Coordination, Syed Mustafa Kamal, led Pakistan's delegation to the 78th World Health Assembly in Geneva, reaffirming the country's commitment to global health collaboration and resilient regulatory systems. Accompanied by Dr. Obaidullah, Chief Executive Officer of DRAP, the delegation engaged in high-level discussions aimed at strengthening Pakistan's regulatory infrastructure for therapeutic goods and public advancing health emergency preparedness.

#### **Key Engagements and Focus Areas:**

- Bilateral meetings with Health Ministers from China, Turkey, Saudi Arabia, Cuba, Maldives, Somalia, Palestine and Syria.
- Collaboration on resilient health systems, regulatory harmonization, and indigenous vaccine and medical device manufacturing;
- Strategic dialogue with the UK Health Security Agency on disease surveillance system development

 Engagement with the Stop TB Partnership to improve supply chain systems for essential health products

#### **Global Collaborations and Leadership:**

- High-level discussions with Dr. Tedros Adhanom Ghebreyesus (DG, WHO), Dr. Sania Nishtar (CEO, Gavi), and Dr. Hanan Balkhy (WHO EMRO)
- Technical consultations with Prof. Rogério Gaspar (WHO Regulation & Prequalification);
- Industry interactions with USP leadership and International Trade Centre officials

Dr. Obaidullah also represented Pakistan as a panelist in WHO's live global social media dialogue on substandard and falsified medicines—demonstrating Pakistan's proactive stance in safeguarding global public health.

These impactful engagements reinforced Pakistan's leadership role in health diplomacy and regulatory excellence, contributing to a safer, stronger, and more self-reliant health system.





In Geneva, Federal Minister for Health Mustafa Kamal met with WHO Regional Director for the Eastern Mediterranean Dr. Hanan Balkhi.



Dr. Obaidullah meeting with WHO Director General Dr. Tedros Adhanom Ghebreyesus.



Federal Minister of Health Syed Mustafa Kamal met with Palestine's Minister of Health Dr. Majid Abu Ramadan on the occasion of the 78th meeting of the World Health Organization. He conveyed the message of Prime Minister Mian Shahbaz Sharif and reiterated Pakistan's unwavering support for the Palestinian cause.



Federal Health Minister Mustafa Kamal's important meeting with Saudi Federal Health Minister Fahad bin Abdul Rahman Al-Jalajal in Geneva.

The two health ministries agreed on technical cooperation, vaccine preparation, telemedicine and mutual partnership to eradicate polio in the health sector.

Federal Health Minister Mustafa Kamal appreciated Saudi Arabia's continuous support for Pakistan and emphasized on continuing contact for public welfare.



On the sidelines of the World Health Assembly, Federal Health Minister Syed Mustafa Kamal held a pivotal meeting with China's Minister of Health. The Federal Minister emphasized on local production of vaccines and essential medicines and exchange of traditional healing and modern medical innovations.

"The bond between Pakistan and China lives in the hearts of our people."

Syed Mustafa Kamal

There are immense opportunities for Chinese investment in Pakistan's health sector, especially in pharmaceutical manufacturing and telemedicine. Most pharmaceutical companies in Pakistan rely on raw material imports from China. We are keen to develop local production capacity, particularly for Active Pharmaceutical Ingredients (APIs), through joint ventures and public-private partnerships.

Syed Mustafa Kamal



Federal Health Minister Syed Mustafa Kamal met with Dr Chris Elias, President of Global Development at the Bill & Melinda Gates Foundation, to discuss ongoing and future collaboration in Pakistan's polio eradication campaign.



#### Federal Health Minister Mustafa Kamal's meeting with Chief Medical Advisor UKHSA in Geneva.

The Federal Health Minister informed about the ongoing reforms in the health sector, telemedicine, and innovative measures like "One Patient, One ID". Training of 15,000 doctors under the IDSR system, and establishing a strong system for timely disease detection with UK cooperation. UKHSA agrees to cooperate on digital health and international health regulations (IHR) in Pakistan. The Chief Medical Advisor was also invited to visit Pakistan to observe the ongoing projects.



Federal Minister of Health Syed Mustafa Kamal's meeting with CEO of GAVI, the Vaccine Alliance Dr. Sania Nishtar.

## EGYPTIAN AMBASSADOR VISITS DRAP TO STRENGTHEN BILATERAL TIES IN PHARMACEUTICAL SECTOR

His Excellency Dr. Ihab Mohamed Abdelhamid Hassan, Ambassador of the Arab Republic of Egypt to Pakistan, paid a visit to the Drug Regulatory Authority of Pakistan (DRAP), where he held a productive meeting with Dr. Obaidullah, CEO DRAP, along with senior officials from the Authority and representatives of the Pakistan Pharmaceutical Manufacturers' Association (PPMA).

The Ambassador was accompanied by Mr. Amr Abdallah Morsy, Counsellor, and Dr. Hager Mahmoud, Third Secretary (Political) at the Embassy. The visit aimed to enhance bilateral cooperation in the pharmaceutical sector and foster strategic partnerships between the two nations.

During the meeting, both sides engaged in in-depth discussions on regulatory harmonization, technical collaboration, and opportunities for joint initiatives in pharmaceutical research, development, and trade. Topics included collaboration in the areas of raw

materials, biologics (including vaccines), and surgical products.

It was mutually agreed that pharmaceutical manufacturers from both countries should be encouraged to interact and explore avenues for mutually beneficial cooperation.

This visit marks a significant step toward advancing shared public health objectives and deepening Pakistan-Egypt relations through sustained engagement and partnership in the health and pharmaceutical domains.

From DRAP, Dr. Akhtar Abbas, Additional Director; Mr. Muneeb Ahmad, Deputy Director; and Dr. Hasan Afzal, Deputy Director, also attended the meeting. The PPMA delegation included Mr. Tauqeer Ul Haq, Chairman; Mr. Shafique Abbasi; Mr. Aman Shaikh; Mr. Amjad Saeed; Mr. Nawaz Ahmed; and Col. Nayyer Ali Abbas.





## DRAP CEO REPRESENTS PAKISTAN AT "HEALTHCARE SOLUTIONS CONFERENCE" IN DOHA

Dr. Obaidullah, Chief Executive Officer of the Drug Regulatory Authority of Pakistan (DRAP), participated in the prestigious Pakistan Healthcare Solutions Conference held in Doha, Qatar. His participation underscored DRAP's commitment to fostering international regulatory cooperation and strengthening pharmaceutical governance through global partnerships.

The conference, organized by the Embassy of Pakistan in Qatar, served as a dynamic platform to showcase Pakistan's expanding healthcare potential. It brought together leading medical institutions, pharmaceutical manufacturers, health technology companies, and medical professionals from Pakistan to engage with prominent stakeholders in Qatar's healthcare sector.

As a keynote speaker, Dr. Obaidullah addressed the conference on the theme "Advancing Regulatory Excellence", emphasizing Pakistan's regulatory strengths, evolving pharmaceutical landscape, and the opportunities for international collaboration in health product regulation.

On the sidelines of the conference, Dr. Obaidullah held a constructive meeting with Dr. Aisha Ibrahim Al Ansari, Director of the Pharmacy and Drug Control Department, Ministry of Public Health, Qatar. Both sides agreed to enhance collaboration in areas of mutual interest, particularly in streamlining registration processes, strengthening Good Manufacturing Practices (GMP) oversight, and reinforcing regulatory systems between the two National Regulatory Authorities (NRAs).

This engagement signifies a strong step toward deepening Pakistan-Qatar cooperation in the healthcare and pharmaceutical sectors, with shared aspirations to advance public health outcomes through regulatory excellence and strategic alignment.





#### NATIONAL ROLLOUT OF QUALITY MANAGEMENT SYSTEMS: DRAP COMPLETING STRATEGIC TRAINING ACROSS PAKISTAN'S REGULATORY LANDSCAPE

The Drug Regulatory Authority of Pakistan (DRAP) has successfully concluded a nationwide series of Quality Management System (QMS) training workshops, conducted across all provinces and administrative territories of Pakistan, with Gilgit-Baltistan scheduled in early July 2025. This initiative marks a significant advancement in the national effort to strengthen regulatory capacity, institutionalize quality practices, and align with international standards for the regulation of therapeutic goods.

Launched on April 10, 2025, in Islamabad, the QMS workshops were part of DRAP's strategic response to the findings of the 2023 World Health Organization (WHO) Global Benchmarking Tool (GBT) assessment. The WHO review identified over 78 province-specific recommendations, emphasizing the urgent need for regulatory reform in areas including licensing, inspection systems, post-marketing surveillance, drug testing laboratories, pharmacovigilance, and the institutionalization of quality management principles.

Comprehensive two-day training workshops were conducted in Islamabad Capital Territory (ICT), Peshawar (Khyber Pakhtunkhwa), Lahore (Punjab), Quetta (Balochistan), Karachi (Sindh), Muzaffarabad (Azad Jammu & Kashmir). Each session was meticulously designed and delivered by DRAP's QMS experts: Mr. Ajmal Sohail Asif, Mrs. Muneeza Khan, Mr. Abdul Mughees Muddassir, Dr. Hasan Afzaal, and Mr. Muhammad Ayub Naveed, with technical support

from Mr. Asadullah, Technical Officer at WHO Pakistan. These facilitators guided participants through ISO 9001:2015-based methodologies, WHO guidelines, and the practical steps necessary to establish and sustain institutional QMS frameworks. Key outcomes of the trainings included the development and customization of Quality Manuals, Standard Operating Procedures (SOPs), Quality Policies, Objectives & Vision Statements, Process Maps, Organizational Charts, and other Strategic Documents.

The initiative represents a critical component of Pakistan's national regulatory strengthening roadmap, endorsed by the Special Investment Facilitation Council (SIFC) and the Prime Minister's Office, and aimed at progressing toward WHO Maturity Level 3 (ML-3).

The enthusiastic participation of provincial and regional regulatory authorities reflected a collective commitment to excellence, transparency, and harmonization. These efforts will not only uplift institutional performance but also contribute to safer, more effective, and quality-assured access to therapeutic goods for all citizens.

Through this unified national effort, DRAP reaffirms its vision to build a responsive, robust, and internationally benchmarked regulatory system—anchored in quality, accountability, and public health protection.





 DRAP, in collaboration with the Directorate of Drug Control and Pharmacy Services, Government of Khyber Pakhtunkhwa, conducted a comprehensive Provincial QMS Workshop in Peshawar.

Two days capacity-building workshop was held in collaboration with the Directorate of Drug Control and Pharmacy Services / Drug Control Administration, Government of Sindh, Karachi.



DRAP conducted two days training workshop on the implementation of a Quality Management System (QMS) for the drug control administration of Azad Jammu and Kashmir (AJK).

Two days training workshop on Quality Management System (QMS) implementation for the Directorate of Drug Control, Punjab, was held in Lahore.



### Picture Gallary



CEO DRAP, Dr. Obaidullah participated in a plenary session at the International Conference on Science, Technology & Innovation (STI): Catalysts for Regional Connectivity and Sustainable Development in the ECO Region



chaired an online high-level meeting of Health Ministers.



Medication Safety at the 8th International Conference of Patient Safety.



PSW and the Drug Regulatory Authority of Pakistan (DRAP) have officially launched the DRAP Clearance Gateway



DRAP had the honour of hosting Prof. Dr. Atta-ur-Rahman,



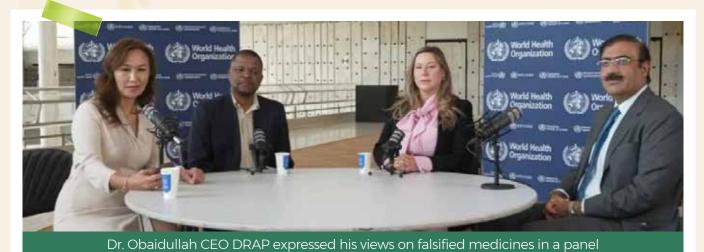
DRAP Engages with NIPA Delegation for discussion on Key Regulatory Issues



Mr. Trouble Chikoko, UNAIDS Country Director for Pakistan and Afghanistan, called on CEO DRAP Dr. Obaidullah.







discussion at 78th World Health Assembly on 24-May-2025

## ڈرگ ریگولیٹری اتھارٹی آف پاکستان منسٹری آف نیشنل ہمیاتھ سروسزر یگولیشنز اینڈ کو آرڈینیشن



جون: ۲۰۲۵ واليم: تهم شاره: ا

## برديپور ليار

#### ادویات کی قلت: ایک قومی مسئله اور اس کامؤثر حل

دنیا بھر کی طرح پاکستان میں بھی ادویات کی قلت ایک مسئلے کے طور پر نمودار ہوتی ہے۔ جس کے اثرات براہ راست مریضوں کی صحت اور نظامِ صحت کی کار کر دگی پر مرتب ہوتے ہیں۔جب نسی دوا کی فراہمی ،اس کی مانگ کو بورانہ کر سکے سچاہے وہ اسپتال ہوں ، فار میسیاں ، ہوں یادیگر صحت کے مر اکز —تواہے دوا کی قلت کہاجا تا ہے۔اس قلت کی کئی وجوہات ہو سكتى بين جيسے كه خام مال كى عدم دستيابى، مينوفيكچرنگ مين تاخير، ترسيل مين خلل، يا بعض مصنوعات کی تیاری کا بند ہونا۔

اس نازک صور تحال کے پیشِ نظر، ڈرگ ریگولیٹری اتھارٹی آف پاکستان نے ایک فعال اور پیش قدمی پر مبنی حکمتِ عملی اینائی ہے۔

ڈریپ نے نہ صرف انڈسٹری سے قریبی روابط کو فروغ دیاہے بلکہ بروقت پالیسی اقدامات اور حقیقی وقت میں رپورٹنگ کے نظام کو بھی تقویت دی ہے تاکہ زندگی بحانے والی اور ضروری ادویات کی مسلسل فراہمی کویقینی بنایاجا سکے۔

ا پنی ویپ سائٹ پر ڈریپ نے حال ہی میں دوا کی قلت کی مؤثر رپورٹنگ کے لیے ایک با قاعدہ ویب صفحہ متعارف کروایا ہے، جس کا مقصد ملک بھر میں ادویات کی دستیانی سے متعلق معلومات کا فوری تبإدله ممکن بنانا ہے۔ اس نظام کے ذریعے عام عوام، فار ماسٹ، اسپتال، اور صحت کے ادارے کسی بھی دوا کی عدم دستیابی کی اطلاع آسانی ہے دے سکتے ہیں۔

#### ڈریپ نے اس سلسلے میں درج ذیل ذرائع فراہم کیے ہیں:

• ای میل کے ذریعے ربور ٹنگ:

ہر فرد، اسپتال یا ادارہ دوا کی موجودہ یا متوقع قلت کی اطلاع درج ذیل ای میل پر جھیج سکتا drugshortage@dra.gov.pk : 4

• 🌐 آن لا ئن ريور ٹنگ فارم: ايک معياري ڏيجيڻل فارم ڈريپ کي ويب سائٹ پر موجو د ہے، جسے عام افراد اور ادارے دونوں بھر سکتے ہیں۔ بیہ فارم QR کوڈیا براہِ راست لنک کے نریع دستیاب ہے: www.dra.gov.pk

ڈریپ نے ادارے کی بہتر ہم آ ہنگی کے لیے تمام اسپتالوں اور صحت کے اداروں سے درخواست کی ہے کہ وہ دوا کی دستیابی سے متعلق اپنے نما ئندے نامز د کریں، جوڈریپ سے براہ راست رابطے میں رہیں گے۔

فوکل پر سنز کی نامز د گیاں ڈریپ کی ویب سائٹ پر دستیاب فارم یا کیو آر کوڈ کے ذریعے جمع کروائی جاسکتی ہیں۔ یہ بات قابلِ توجہ ہے کہ خواہ کوئی مریض کشی دوا کی تلاش میں فارمیسی ہے مایوس لوٹے یا کوئی اسپتال دوا کی فراہنی میں تعطل کا شکار ہو ہم فرد اور ادارہ اس نظام کا حصہ بن کر بروقت ریگولیٹری اقدام کو ممکن بناسکتاہے۔

ڈریپ نے تمام شہریوں، فار ماسٹ، صحت کے ماہرین اور ادارہ جاتی منتظمین سے اپیل کی ہے کہ وہ دواکی قلت سے متعلق رپورٹنگ میں فعال کر دار ادا کریں۔

جبیاکہ چیف ایکزیٹو آفیسر، ڈریپ نے کہا:

" دوا کی قلت سے متعلق رپورٹس کا بروقت اندراج اتھارٹی کو فوری اور مؤثر اقدام کا اختیار دے گا، تاکہ ضروری ادویات وہاں دستیاب رہیں جہاں ان کی سب سے زیادہ ضرورت

ادویات کی بروفت فراہمی نہ صرف مریض کی جان بحاتی ہے بلکہ نظام صحت پر عوام کے اعتاد کو بھی بحال کرتی ہے۔اس قومی مہم میں ہمارا کر دار ذمہ داری اور تعاون پر مبنی ہوناچاہیے۔



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