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

QUARTERLY DRAP's NewsLetter

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My New Year's Resolutions

I shall not take any medicine without a prescription from doctor.

I shall not take Antibiotics as self-medication.

I shall clean out my medicine cabinet and discard expired medicines properly.

I shall report any adverse drug reaction to DRAP / Provincial PV center / HCPs.

I shall count my blessings every day.

DRAP's Strategic Plan 2022-2025
A New Day is Dawning

Sayyad Hussain, Abdul Mughees Muddassir, Asad Ullah, Urooj Fatima

Strategic Plan 2022-2025 sets ambitions for us to achieve our strategic objectives that contribute towards ensuring availability of quality assured, safe and effective Therapeutic Goods (TGs) in Pakistan. we are committed to maximize opportunities of treatment for patients for the people of Pakistan.

The goal of developing a strategic plan is to ensure the consistency of work on priority areas and target set for the organization and align regulators workforce to achieve common objectives.

DRAP will continue to effectively play its vital role in regulations of therapeutic goods and enforcement of drug laws in the country, keeping in view the best public interest for the people of Pakistan and globally.

An Overview of Strategic Plan 2022-2025

"It is the first time that DRAP has outlined its strategic plan based on the necessary improvements that regulatory framework requires at this time. This document will allow us to move quickly towards establishing an agile regulatory system to protect the citizens of Pakistan from spurious and sub-standard therapeutic goods"

Asim Rauf, CEO DRAP

PICTURE GALLARY

CEO DRAP Mr Asim Rauf presenting the first copy of the Newsletter to Minister for NHSR&C

Director Licensing Mr. Akhtar Abbas Khan presenting the DRAP's Newsletter to Dr Fakhre Alam Secretary MNHS&R

Secretary MNHSR&C chaired the 44th meeting of the Policy Board DRAP. The Secretary being chairman Policy Board welcomed the new members of the Board.

DRAP has entered into a MoU with Pakistan Single Window (PSW) to reduce the time and cost of doing Pakistan's pharmaceutical business by digitizing cross border trade & eliminating paper based manual processes.

Participants of the Mid-Career Management course (MCMC) visited DRAP. Dr Obaidullah Director PE&R briefed the guests about DRAP's working and current initiatives

A delegation led by Jamie Forrest, PhD, Chief Partnerships Officer, Platform Life Sciences Canada, and Dr. Syed Uzair Irfan, Consultant, Faculty, North American College, Director, Canada-Pakistan R & D Council, visited CEO DRAP Mr. Asim Rauf.

Pakistan's Pharma Industry is Contributing to the Country's Progress

Dynatis Pakistan (Pvt.) Ltd.

Dynatis Pakistan (Pvt.) Limited is the national pharmaceutical company to achieve international certification viz. Pharmaceutical Inspection Co-operation Scheme (PIC/s) for Good Manufacturing Practice. PIC/s certified companies can obtain GMP inspection waivers from many regulatory authorities including PIC/s participating authorities due to their harmonized systems. This certification helps the industry for fast-track regulatory approval by regulatory authorities and the launching of products in these markets due to mutually accepted quality standards.

Remington

Your Health - Our Commitment

Remington Pharmaceuticals is the first and only Pakistani pharmaceutical company to receive global licenses to develop, manufacture, and supply generic versions of the world's first two oral treatments for COVID-19 by the Medicines Patent Pool (MPP). Under the said licensing from MPP, Remington Pharma will manufacture generic versions of the molnupiravir 200mg Capsules (RLD: Lagevrio, Merck & Co.) and Nirmatrelvir/Ritonavir (RLD: PAXLOVID™, Pfizer) with the approval and authorization from MPP to supply in Pakistan and export to and 105 countries and 95 countries respectively. The firm has also received WHO prequalification for one of its products.

PACIFIC PHARMACEUTICALS LTD.

Pacific Pharmaceuticals Ltd. is the first and only EU GMP and MHRA Certified pharmaceutical company in Pakistan. The facility is equipped with sophisticated and state-of-the-art machinery and equipment, meeting international standards of excellence. Because of quality and proactive strategies, the firm takes pride in providing the same quality products to Pakistan as do to International markets like the UK, Germany, EU, Latin America, South America and more. The company has also targeted to achieve WHO prequalification of their products and USFDA GMP Certification.

Getz pharma

A member of The Getz Group, U.S.A.

Getz Pharma (Private) Limited is the first company in Pakistan to have World Health Organization (WHO) Prequalification of a product and Pharmaceutical Inspection Co-operation Scheme (PIC/s) certification for Good Manufacturing Practice. Getz Pharma is the largest exporter of pharmaceuticals from Pakistan and the only pharmaceutical company in the top 50 exporters of Pakistan as listed by the State Bank of Pakistan. Getz Pharma's new manufacturing facility has LEED (Leadership in Energy and Environmental Design) Platinum Certification by US-Green Building Council (USGBC), which is the most widely used green building rating system in the world.

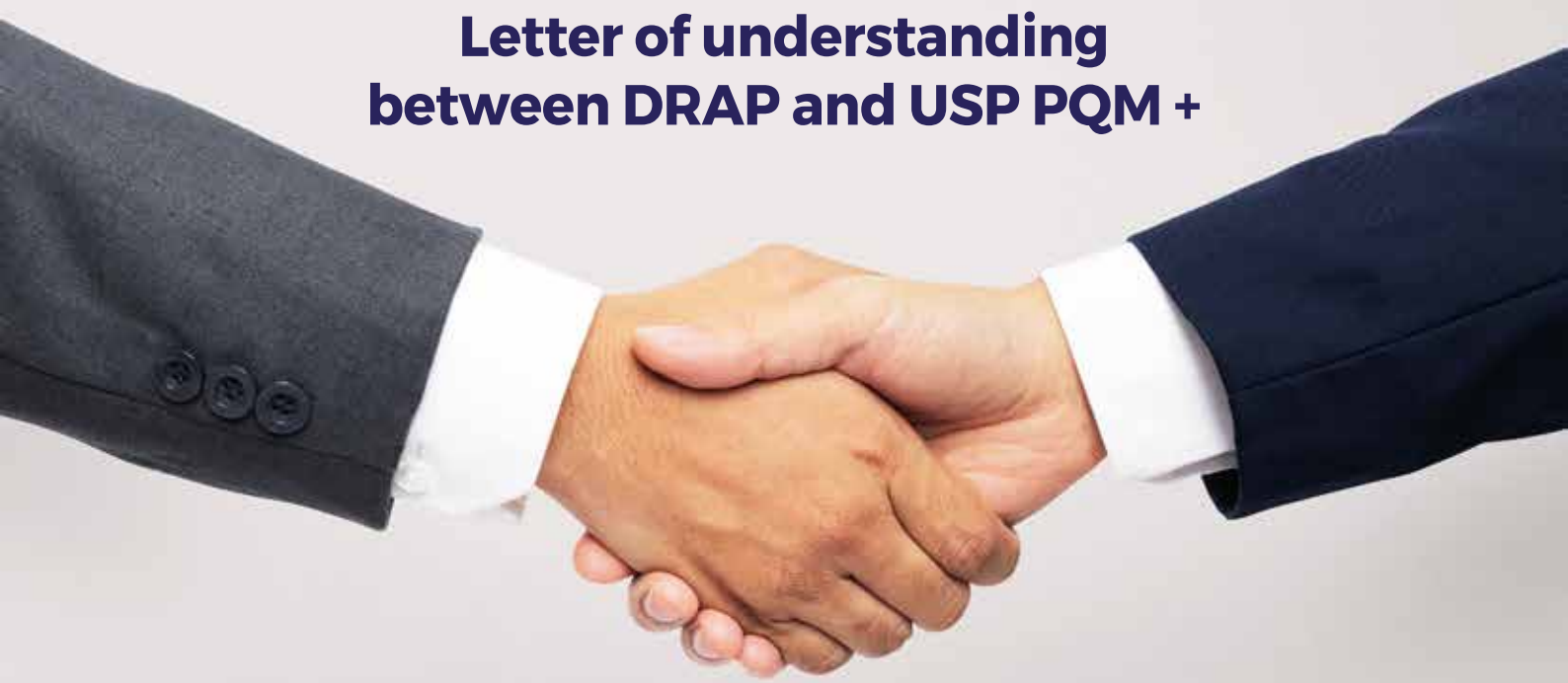
(This page contains the information provided by the above firms)

Risk Based Inspections

Ajmal Sohail Asif

The Quality Assurance & Laboratory Testing Division of DRAP has started Risk-Based Benchmarking of Pharmaceutical Industry of Pakistan against well-defined audit tools based on risk assessment. All the pharmaceutical manufacturers in the country will be assessed on latest quality risk management approach through a pool of proficient team of GMP auditors who have been extensively trained to evaluate cGMP compliance level. The first phase of which has been completed successfully with inspections of 20 pharmaceutical units planned for November to December 2022. Next phase is scheduled from January to June 2023. This will be of great help towards achievement of DRAP's accession of PIC/s and also WHO accreditation. One of the numerous benefits of such a program is enhanced exports of pharmaceuticals as the local industry will be uplifted through adoption of international practices.

Letter of understanding between DRAP and USP PQM +



DRAP is going to sign a formal Letter of Understanding (LoU) with the USAID-funded Promoting Quality of Medicine Plus (PQM+) Program implemented by United States Pharmacopeia (USP) for collaboration and coordination for regulatory reforms as per international best practices to improve the quality of medical products in Pakistan, especially for infectious diseases. DRAP and PQM+ have a long history of productive collaboration on knowledge and capacity building in regulatory system strengthening. Over the years, the partnership has focused on activities related to the harmonization of therapeutic goods regulation with international regulations and best practices through international certifications and accreditations like the World Health Organization Global benchmarking tool maturity level 3 and pharmaceutical inspection and cooperation scheme membership.

This LoU shall formalize and affirm the collaboration of both parties on the implementation of clinical studies to assess the safety of medicines, risk-based post-market surveillance for monitoring the quality of medicine in the market, strengthening of Pharmacovigilance to monitor the safety and prevent the patient medical products adverse events. This Collaboration will improve the overall regulatory system in the country to monitor and control the safety, efficacy, and quality of medicine from its development to its utilization by the public/patients. DRAP and PQM+ will work jointly to implement Global Health Security Agenda (GHSA) in Pakistan, which is an effort by Nations, International Organizations, and Civil society to accelerate progress toward a world safe and secure from infectious disease threats and a platform for multi-sector collaboration stimulating global support and commitments, workforce development, laboratory system strengthening/ networking, and guiding countries to enhance their capacities to prevent, detect and respond to potential outbreaks of infectious diseases and other public health threats.

Mr. Waqas Ahmad Zaibi
Chief of Party USP PQM+

1st meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC)

Abdul Mateen, Aqsa Hashmi

The 1st meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) was held in the Committee Room of the Drug Regulatory Authority of Pakistan (DRAP) on the 12th of October, 2022. The meeting was Chaired by Brigadier Retired Dr Akbar Waheed and Co-Chaired by Dr Noor Muhammad Shah, Director, Division of Pharmacy Services. The committee discussed ten cases of medicines safety, of which two cases of local signals and eight cases of reliance were accordingly decided.

In compliance with the aforementioned decisions of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) of the Drug Regulatory Authority of Pakistan, the National Pharmacovigilance Centre issued the following safety alerts on its website:

1. Safety alert of the risk of anaphylactic reaction / anaphylactic shock with pain treatment medicine Diclofenac Sodium Injection. For further details visit the website:https://www.dra.gov.pk/safety_info/safety_communication/safety_updates/drug-safety-alert-risk-of-anaphylactic-reaction-anaphylactic-shock-with-diclofenac-sodium-injection/

2. Safety alert of the risk of infusion-related hypersensitivity reactions with COVID-19 treatment medicine Remdesivir. For further details visit the website: https://www.dra.gov.pk/safety_info/safety_communication/safety_updates/drug-safety-update-risk-of-infusion-related-hypersensitivity-reactions-with-remdesivir/

3. Risk of constipation and Serious Bowl complications with Schizophrenia treatment medicine Clozapine. For further details visit the website: https://www.dra.gov.pk/wp-content/uploads/2022/11/22-Safety-Alert-of-Risk-of-Serious-Bowel-Complications-with-Clozapine..pdf

4. Safety Alert of risk of reduced vitamin B12 level with sugar medicine Metformin. For further details visit the website:https://www.dra.gov.pk/safety_info/safety_communication/safety_updates/drug-safety-alert-risk-of-reduced-vitamin-b12-level-with-metformin-and-metformin-containing-medicines/

5. Safety alert of the risk of major congenital malformations in infants with Pregabalin which is used as adjuvant therapy in partial seizure, if this medicine is used during pregnancy. For further details visit the website: https://www.dra.gov.pk/news_updates/regulatory_updates/drug-safety-alert-risk-of-major-congenital-malformations-with-pregabalin/

For More Safety Alerts Please Visit DRAP's website:
https://www.dra.gov.pk/category/safety_info/safety_communication/safety_updates/

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

سہ ماہی

ڈریپ نیوز لیٹر

جنوری ۲۰۲۳
والیم ۲
شمارہ ۱

اداریہ

اسٹریٹیجک منصوبہ 2022-2025

ایک نئی صبح کا آغاز

13 نومبر 2022 کو ڈریپ نے اپنے قیام کے دس برس مکمل کرلیے ہیں۔ اس عشرے میں ڈریپ نے بہت سے نشیب و فراز دیکھے ہیں۔ اپنے قیام کے ابتدائی برسوں میں ڈریپ کو بھی اُن چیلنجز کا سامنا کرنا پڑا جن کا سامنا ہر نئے قائم ہونے والے ادارے کو کرنا پڑتا ہے۔ ان چیلنجز میں جعلی ادویات بنانے والے مافیا اور ان کے حواریوں کے جھوٹے الزامات اور ادارے کو درپیش اندرونی اور بیرونی مسائل کے انبار شامل تھے۔ لیکن اب ڈریپ اُن مسائل سے نکل کر آگے بڑھ رہا ہے۔

ڈریپ کے موجودہ سی ای او اور ڈریپ اتھارٹی نے مل کر ایک خواب دیکھا ہے جس کی تعبیر ایک بین الاقوامی معیار کی ادویات کی اتھارٹی میں مضمر ہے۔ ایک ایسا ادارہ جس کی سند سے پاکستانی ادویات ترقی یافتہ ممالک کو برآمد کی جا سکیں گی۔ اسی خواب کی تعبیر کے حصول کے لیے ورلڈ ہیلتھ آرگنائزیشن کی درج اتھارٹیز میں شمولیت (WHO WLA Status) کے حصول کے لیے ایک جامع منصوبہ بنایا گیا ہے۔ مستقبل کے حوالے سے ایسی منصوبہ بندی پہلی بار کی گئی ہے۔اسٹریٹیجک منصوبہ 2022-2025 اپنی نوعیت کی واحد مثال ہے۔ ڈبلیو ایچ او کی ٹیم انشاء اللہ فروری اور مئی 2023 میں ڈریپ کا دورہ کرے گی۔انشاء اللہ یہیں سے ایک نئی صبح کا آغاز ہو گا۔ اور پاکستانی ادویات کی ایکسپورٹ میں اضافہ دیکھنے کو ملے گا۔

پوری دنیا بشمول پاکستان نے کرونا وبا کی شکل میں ایک ایسے عفریت کا سامنا کیا ہے جو ہم سے ہمارے پیاروں کو چھین کر لے گیا ہے۔ پاکستانی عوام نے جس طرح کرونا کے خلاف جنگ جیتنے میں اداروں کا ساتھ دیا ہے وہ قابل ستائش ہے۔ ڈریپ اپنی تمام توانائیاں اس مقصد کے حصول کے لیے صرف کر رہا ہے کہ وطن عزیز میں تمام امراض کی ادویات عوام کی پہنچ میں ہوں۔ نئے برس کی آمد پر ڈریپ دعا گو ہے کہ پاکستانی عوام ہر بیماری اور مصیبت سے دور رہیں۔ ہم محفوظ معیاری اور موثر ادویات کی ہمہ وقت فراہمی کے لیے کوشاں رہیں گے۔

سرپرست اعلیٰ: ڈاکٹر فخر عالم
سیکریٹری منسٹری آف نیشنل ہیلتھ سروسز اینڈ کوآرڈینیشن

مدیر اعلیٰ: عاصم رؤف
چیف ایگزیکیٹو آفیسر ڈریپ

مدیر: اختر عباس خاں
ڈائریکٹر لائسنسنگ

کسی بھی سوال، تبصرے یا اپنی قیمتی رائے سے نوازنے کے لیے رابطہ کریں۔
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