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

QUARTERLY DRAP's NewsLetter

OCTOBER-22
VOLUME-1

MESSAGE

Abdul Qadir Patel
Minster, Ministry of National Health Services Regulation and Coordination

"We are focused on providing better health to people of Pakistan. We are fully committed to provide benefit to the people in form of quality assured, affordable, and safe therapeutics. In this respect, DRAP is an important institution which is directly involved in the protection of public health through regulation of therapeutic goods. To see DRAP prosper as an effective regulator is our vision."

MESSAGE

Dr M. Fakhre Alam
Secretary Ministry of National Health Services Regulation and Coordination

"I am pleased to note that Drug Regulatory Authority of Pakistan (DRAP) has taken the much required step of publishing its activities in the form of a newsletter. Effective regulation requires clear and timely communication. This newsletter will prove instrumental in presenting DRAP's values, aspirations, decisions and commitments to its stakeholders and general public.

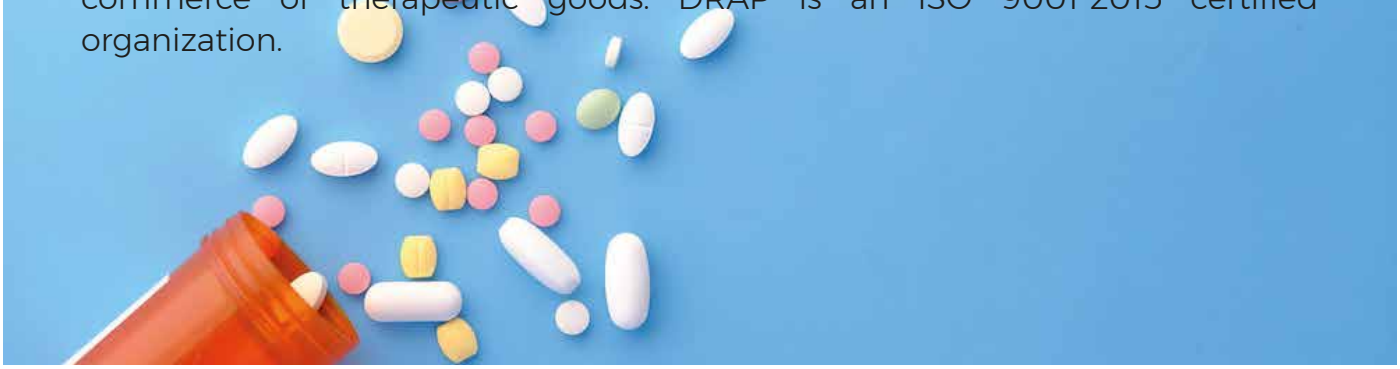
The steps taken by DRAP for enhancing access of citizens to quality assured, safe and effective therapeutic goods will be outlined in this newsletter, inter alia. Enhancing capabilities of regulators, up-lifting pharmaceutical sector of the country, and ensuring early availability of treatment options to the people are priority of the Ministry and DRAP. Launching this newsletter is the first step in sharing such priorities and strategies with you that DRAP is undertaking for ensuring provision of safe effective and quality therapeutic goods in the country."

"Pakistani pharmaceutical firms are exporting pharmaceuticals to 128 countries in the world"

DRAP AT A GLANCE

WHO ARE WE?

Established under DRAP Act 2012, Drug Regulatory Authority of Pakistan (DRAP) is responsible for providing effective coordination and enforcement of The Drugs Act, 1976 (XXXI of 1976) and to bring harmony in inter-provincial trade and commerce of therapeutic goods. DRAP is an ISO 9001-2015 certified organization.



Regulatory Landscape

LOCAL MANUFACTURING BASE

Pharmaceutical Units	H&OTC Units	Medical Device Units
620	465	53

IMPORTERS

Drug Importers	H&OTC Importers	Medical Device Importers
900	465	912

THERAPEUTIC GOODS

Registered Drugs	H&OTC Products	Medical Device
65000	41801	3892

"Pakistan Exported pharmaceuticals of worth approximately 300 million USD during last year"

MAJOR Achievements SINCE INCEPTION

DRAP is on the way to be recognized as internationally accredited body by the prestigious institutions. During this important journey to achieve the said target, extensive transformational steps has been taken in line with the internationally harmonized guidelines. Some of the major steps are entailed below:

Automation:

- Online system for issuance of import and export NOCs.
- Online licensing of Medical Devices' establishment licenses.
- Online Fee Challan generation.
- Online issuance of NOC to patients for import of un-registered/unavailable drugs.
- Online Software for Clinical Trial, Bio-Equivalence study, CRO, Lab or relevant License (Pharmacy Services Division).
- Med Safety mobile application for online reporting of Adverse Events and Adverse Drug Reactions.

International Accreditations:

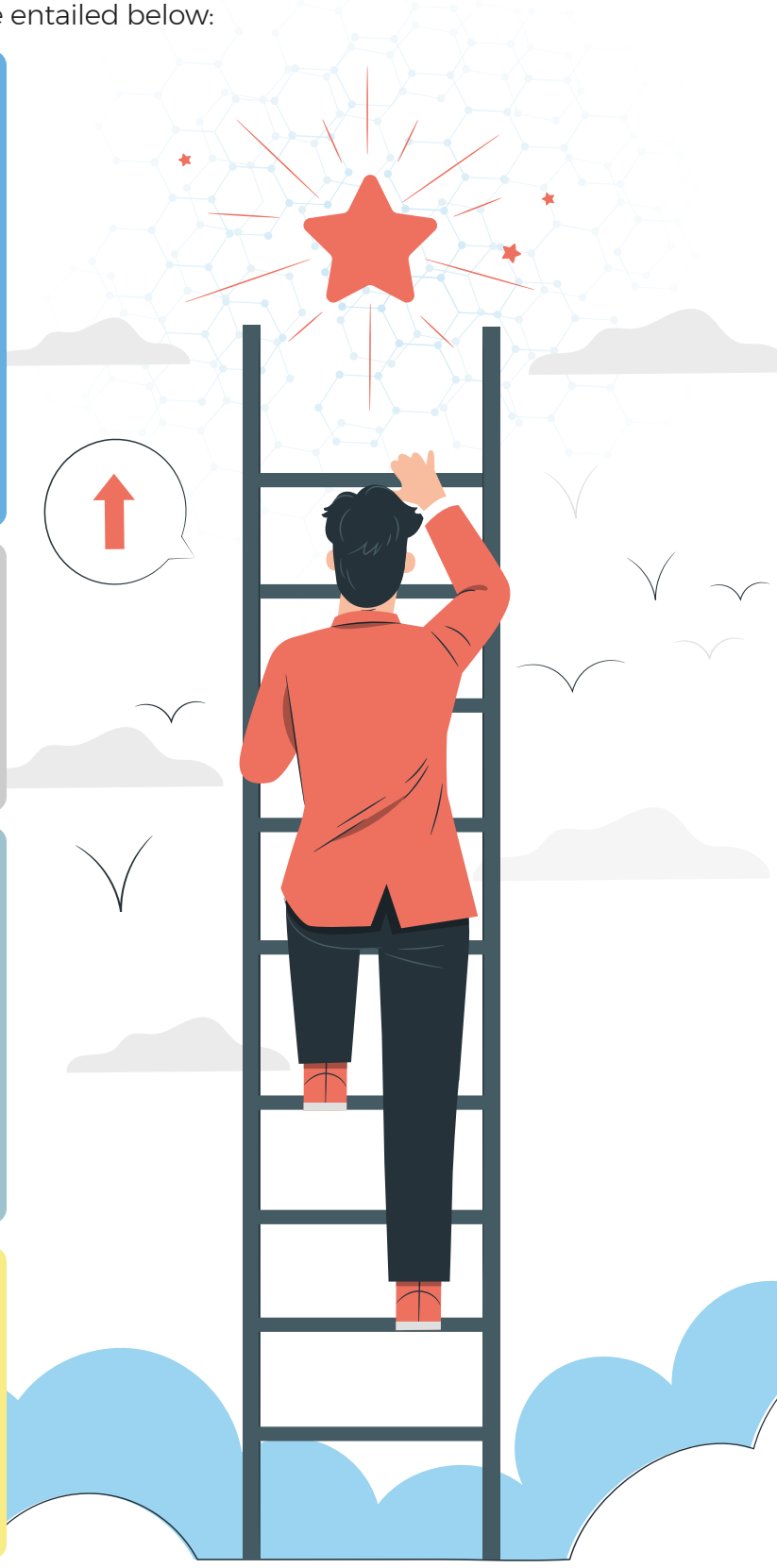
- Attainment of full membership of WHO Uppsala Monitoring Center (UMC), to collect and disseminate the Adverse Drugs reaction reporting system.
- Upgradation of Central Drugs Laboratory Karachi to conform to international standards.

International Harmonization:

- Common Technical Document (CTD) implementation
- ISO Certification
- Signing of an Agreement with World Health Organization (WHO), Geneva for participation in WHO program for Accelerated Registration of Prequalified Finished Pharmaceutical Products (FPPs).
- Prioritized registration handling of COVID-19 related medicines.

Ease of doing business:

- Development and implementation of Active Pharmaceutical Ingredients (API) Policy.
- Development of contract policy to attract foreign investment.
- Development of 5 years strategic plan to transform into modern day regulatory authority.



"DRAP is on way to become a world class regulartory body at par with international best practics. We are committed to achieving our VISION of turning innovative sscience into value for people. *Asim Rauf*"

INVESTING IN

Pharmaceutical API Industry

LUCRATIVE VENTURE, WITH LOTS OF

Incentives Available

Global API market is currently over 180 billion USD and projected over 250 billion by 2024. Owing to its great potential and attaining self-reliance, it is desirable to invest in this sector. For creating self-reliance in the country by encouraging manufacture of pharmaceutical raw materials by way of basic / semi basic manufacture.

Government of Pakistan has announced short term and long-term incentives through **Promotion and growth of API industry in Pakistan policy.** DRAP will establish a cell for guidance to applicants/ investors, and to coordinate with relevant ministries on timely completion of requisites for issuance of licenses and registrations applied to it on a fast-track basis.

The **short-term incentives** included reduction in customs duty and import prices (dumping prices) imposition of regulatory duty and tariff protection against import of materials manufactured in Pakistan and financial incentives like soft loans and keeping 15% export earnings. For the **long term,** the establishment of API mega parks with all the required facilities including but not limited to wastage and effluent treatment plants, power houses, distillation plants and environmental control.

جو عالم ایجاد میں ہے صاحب ایجاد ---- ہر دور میں کرتا ہے طواف اس کا زمانہ (اقبال)

AN ICON OF PHARMACY PROFESSION
Prof. Zaheer-ud-Din Babar
DELIVERED A LECTURE IN DRAP

On invitation of CEO DRAP Prof Zaheer-Ud-Din Babar visited DRAP Islamabad office and delivered a lecture on "Pharmaceutical industry influence in healthcare and research: Does it matter?" to DRAP officers.

Dr Zaheer-Ud-Din Babar is a professor in Medicines and Healthcare and the Director of Centre of Pharmaceutical Policy and Practice Research at the University of Huddersfield.

Bob Tribe,
TGAs Former GMP Chief,
TRAINED DRAP DRUG INSPECTORS

DRAP aims at harmonization of Inspection system and procedures in the field of Good Manufacturing Practices (GMP) for drugs, and quality system for inspectorate, comparable with the best international regulatory practices. In this regard, Mr. Robert Wayne Tribe, TGAs former GMP Chief is providing Consultation to DRAP for progress toward PIC/s membership.

A training session was also organized for DRAP's staff on PIC/s background information for the Applicant Authorities, PIC/s GMP requirements and inspection approach.

Mr. Bob served as Chief GMP at the Australian TGA for 23 years.

It was a real pleasure to visit the drug regulatory authority of Pakistan. I think they are doing a wonderful job to promote the regulation of medicinal products as well as to promote the rational use of medicines in the country. I have the pleasure to interact with a number of colleagues and staff really impressed with the quality of work they are producing. I spoke about the pharmaceutical industry and the impact of industry on the work of medicines regulatory authority and the various facets of medicines regulations including the industry support for research, scientific work, advocacy, patient organization and I hope this interaction will be beneficial. I will be very happy to work and support, I work further with DRAP to support any other aspects.

Thank you
Prof. Zaheer-Ud-Din Babar

جہانِ تازہ کی افکارِ تازہ سے ہے نمود۔۔۔۔کہ سنگ و خشت سے ہوتے نہیں جہاں پیدا۔ (اقبال)

Director General, Department of Drug Administration (DDA), Government of Nepal visited DRAP HQ to foster mutual cooperation

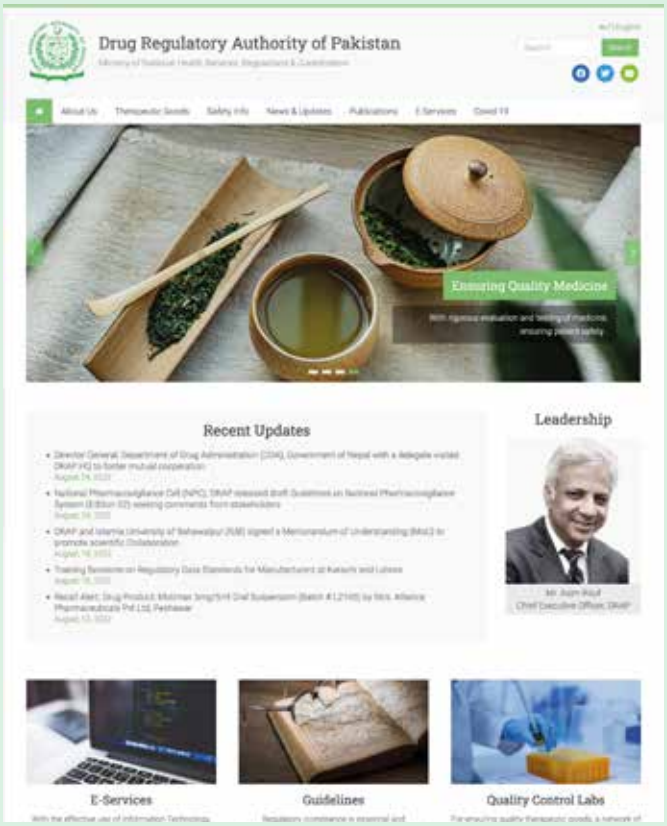
An official delegate from Department of Drug Administration (DDA), Ministry of Health & Population, Government of Nepal under the leadership of Mr. Bharat Bhattarai, Director General, DDA visited DRAP HQ, Islamabad.

Mr. Asim Rauf, CEO DRAP warmly welcomed the Mr. Bhattarai and other senior officials from DDA and MoH, Nepal.

The delegates showed keen interest in the journey of Pakistan toward successful implementation of WHO/ICH Common Technical Document (CTD) format for registration of pharmaceutical and biological drugs in Pakistan, and praised the IT Systems establish by DRAP for integrated regulatory data management in the country.

Explore our New Website

We have got a new look full of features and solution to your regulatory needs



Report a problem

DRAP would like to hear from the consumers about their concerns, if they have experienced any problem with the use of a therapeutic good (e.g. drug, vaccine, medical device or alternative medicine, etc.,) or had any adverse event associated with its use.

Please visit *https://www.dra.gov.pk/safety-information/safety-communication/report-a-problem/ to know how to report a problem*

Open Consultations

DRAP also seek comments from public and relevant stakeholders to identify their needs and expectation, to gather deep insights on proposals, in order to strengthen the regulatory decision making process, and to comply with the international best practices.

You can provide your comments on guidelines available at *https://www.dra.gov.pk/publications/public-consultations/open-consultations/*

PICTURE GALLARY

Federal Minister of Health **Abdul Qadir Patel,**
along with CEO DRAP while addressing a press conference

Federal Secretary, Health
along with a foreign delegate

Mr. Asim Rauf, *CEO DRAP Speeking at the 2nd meeting of the heads of national medicine regulatory authorities of OIC member states. (Istambul Turkiye)*

Mr. Asim Rauf, *CEO DRAP met with*
Dr Palitha Mahipala, *WHO representative in Pakistan to promote bilateral cooperation*

Write to us

If you have any questions, comments or any suggestions please contact us:
akhtar.abbas@dra.gov.pk
or
Call at **051 910 73 06**

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

سہ ماہی

ڈریپ نیوز لیٹر

اکتوبر 2022
شمارہ 1

اداریہ

ڈریپ اپنے پہلے سہ ماہی نیوز لیٹر کے اجرأ کے موقع پر انتہائی مسرت کا اظہار کرتے ہوئے اس عزم کا اعادہ کرتا ہے کہ عوام اور سٹیک ہولڈرز کو اپنی سرگرمیوں سے آگاہ کرتا رہے گا۔ پاکستان میں ادویات کی تیاری، درآمد اور برآمد کے ذمہ دار ادارے کا نام ڈرگ ریگولیٹری اتھارٹی یعنی ڈریپ ہے۔ اس ادارے نے اپنے قیام کے نو برسوں خصوصاً آخری تین برس میں محفوظ، موثر اور معیاری ادویات کی فراہمی کے حوالے سے گراں قدر خدمات سر انجام دی ہیں۔ رواں برس پنتالیس سالوں سے جاری مینول کام کو مکمل طور پر آن لائن کام میں تبدیل کیا گیا ہے اور روائتی کاغذی فائل کو ای-فائل میں بدل کر غیر ضروری رکاوٹوں کا خاتمہ کیا گیا ہے۔

پاکستان میں ادویات کی تیاری میں استعمال ہونے والے خام مال کی امپورٹ کے لیے برس ہا برس سے این او سی کے حصول کے لیے درخواست گذاروں کی قطاروں کا خاتمہ کر کے مکمل آن لائن نظام متعارف کرایا جانا موجودہ سی ای او عاصم رؤف کا ایک سنہرا قدم ہے۔ اس نظام سے شفافیت کو فروغ ملا ہے اور ایک کارآمد ڈیٹا بیس کا قیام عمل میں آیا ہے۔

پاکستان کی کرونا کے خلاف جنگ میں بھی ڈریپ نے کلیدی کردار ادا کیا ہے۔ ملک عزیز میں کرونا ویکسین کی بر وقت فراہمی کے لیے ڈریپ نے آٹھوں پہر کام کیا۔ بات ویکسین کی امپورٹ کی اجازت دینے کی ہو یا پھر ملک میں مقامی سطح پر تیاری کی، ڈریپ کو اداروں نے ہمیشہ پہلی صف میں موجود پایا۔ ڈریپ کی انتھک محنت کا اعتراف ملکی اور غیر ملکی اداروں نے سی ای او عاصم رؤف سے مختلف میٹنگز کے دوران تعریفی کلمات سے کیا۔

ڈریپ کے افسران اور معاون سٹاف نے وبا کے دنوں میں لازمی سروس کے اصول کی پاسداری کرتے ہوئے کرونا کے خلاف جہاد میں بھرپور حصہ لیا اور اس جہاد میں بہت سے افسران اور سٹاف کو کرونا انفیکشن کی سختیوں کا سامنا بھی کرنا پڑا لیکن ڈریپ افسران اور سٹاف کے جذبہ خدمت میں کوئی کمی نہیں آئی۔ ڈریپ کے ایک قابل سٹاف ممبر نور حسین کرونا وبا سے شہادت کے مرتبے پر فائز بھی ہوئے۔

ڈریپ ہر پاکستانی کو کوالٹی ادویات کی فراہمی کے لیے تمام وسائل کو بروئے کار لا رہی ہے. پاکستان اس وقت شدید بارشوں، سیلاب اور اُس کے نتیجے میں پیدا ہونے والی تباہ کاریوں کا شکار ہے۔ ڈریپ اس ہنگامی صورتحال میں دوست ملکوں سے ملنے والی ادویات کی بروقت فراہمی کے لیے اپنا کردار ادا کر رہا ہے۔

کیا آپ جانتے ہیں کہ اگر کوئی جان بچانے والی دوا پاکستان میں ابھی رجسٹر نہیں ہوئی یا پھر کسی وجہ سے مارکیٹ میں دستیاب نہیں ہے تو آپ اُسے اپنے ذاتی استعمال کے لیے امپورٹ کر سکتے ہیں۔ ذاتی استعمال کی ادویات کی امپورٹ کے لیے این او سی مکمل درخواست موصول ہونے پر ایک دن میں جاری کر دیا جاتا ہے۔ مزید تفصیلات کے لیے ہماری ویبسائٹ یا قریبی ڈریپ کے دفتر سے راابطہ کیجیے۔

مدیر اعلیٰ: عاصم رؤف
CEO 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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