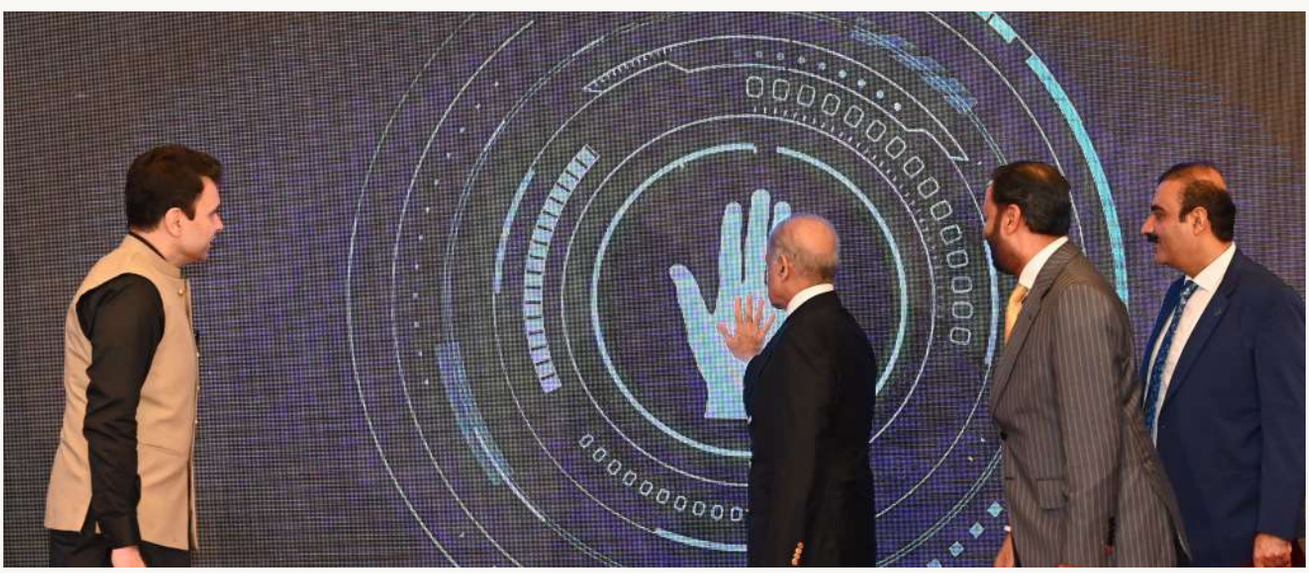
DRUG REGULATORY AUTHORITY OF PAKISTAN
MINISTRY OF NATIONAL HEALTH SERVICES, REGULATIONS & COORDINATION

DRAP's NewsLetter

AUG-25
VOLUME-4
ISSUE-2

FROM VISION TO REALITY



Honorable Prime Minister of Pakistan,
Unveils Digital System for Licensing and Registration of Medical Devices.

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HONORABLE PRIME MINISTER OF PAKISTAN, MIAN MUHAMMAD SHEHBAZ SHARIF

قومی ترانہ

پاک سرزمین شاد باد — کشور حسین شاد باد
تو نشانِ عزمِ عالیشان — ارضِ پاکستان!
مرکزِ یقین شاد باد
پاک سرزمین کا نظام — قوتِ اخوتِ عوام
قوم، ملک، سلطنت — پائندہ تابندہ باد
شاد باد منزلِ مراد
پرچمِ ستارہ و ہلال — رہبر ترقی و کمال
ترجمانِ ماضی، شانِ حال — جانِ استقبال!
سایہ خدائے ذوالجلال

PM and all delegates standing in honor of national anthem

"Today, I extend my heartfelt congratulations to Mustafa Kamal Sahib, the CEO of DRAP, the Secretary of Health, the Minister of State, and the entire team. This remarkable achievement is the result of your collective dedication and tireless efforts."

"Over the past few months, our Minister, Mustafa Kamal Sahib, has been working with unwavering commitment, day and night. I am truly pleased to witness this. The management qualities that once earned him admiration as the Mayor of Karachi are clearly reflected in his current efforts and dedication."

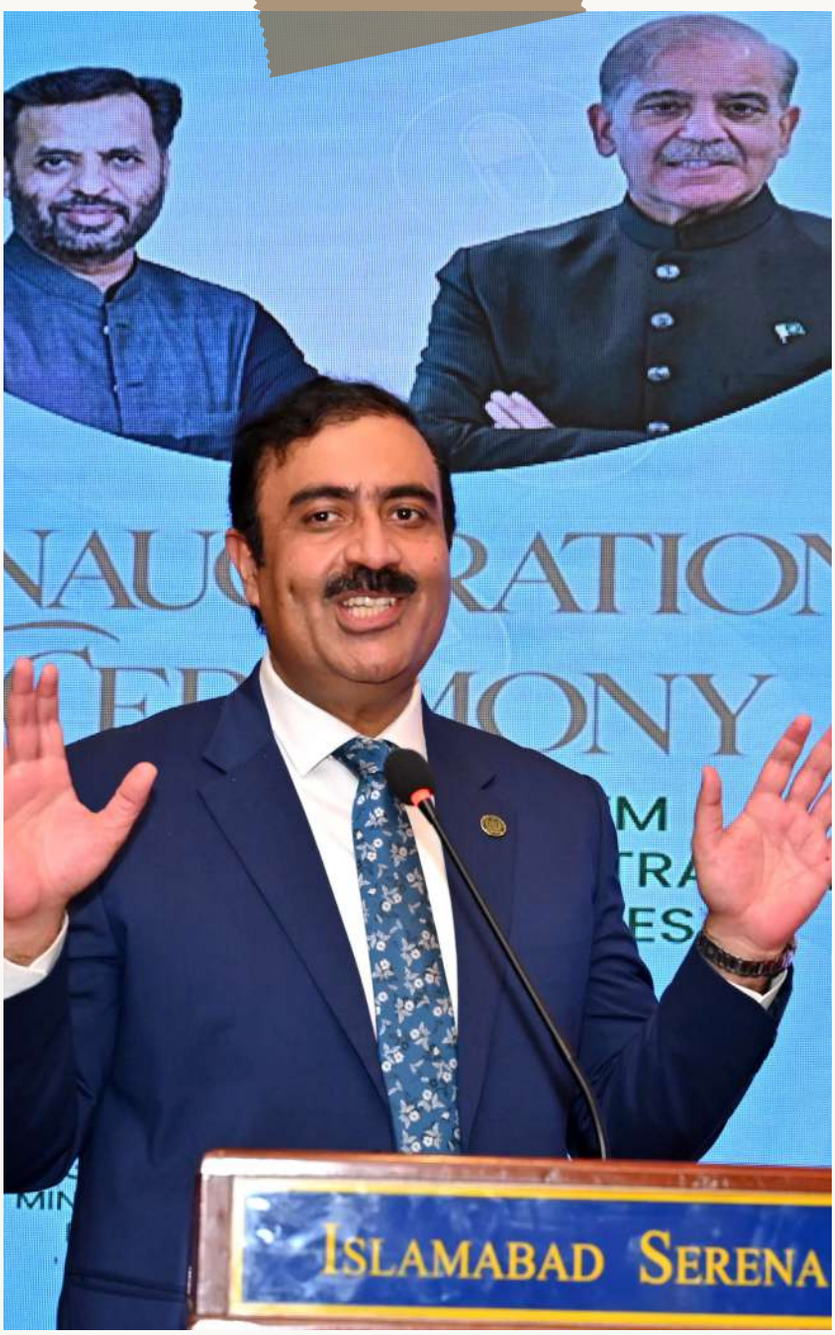
“I am happy that we have appointed a competent CEO DRAP on merit”

IN PICTURES: A DAY TO REMEMBER

SHAPING FUTURE HEALTH OF PAKISTAN: DRAP'S GLOBAL BLUEPRINT FOR REGULATORY EXCELLENCE

BY DR. OBAIDULLAH, CHIEF EXECUTIVE OFFICER, DRUG REGULATORY AUTHORITY OF PAKISTAN

In a world of constant medical breakthroughs, paramount responsibility of any National Regulatory Authority (NRA) mandated with regulation of therapeutic goods is to build and maintain public trust and regulatory credibility, ensuring that every therapeutic innovation genuinely enhances the health and well-being of citizens. This crucial commitment places the Drug Regulatory Authority of Pakistan (DRAP) at a pivotal juncture. A functional NRA is not merely a custodian of therapeutic goods, rather it's a foundation of nation's public health, economic prosperity, and international standing on global health arena. Post pandemic world (COVID-19) is experiencing a global transformation and commencement of a paradigm shift in healthcare. Worldwide, systems are being reimagined, standards are rebuilt, and policies are redefined. DRAP is relentlessly pursuing a strategic evolution, poised to redefine regulatory excellence in Pakistan and matching with the global pace.



DRAP's unwavering commitment to progress is fundamentally reshaping its operations through a comprehensive end-to-end digitization drive for all regulatory processes, directly translating into clearer, quicker, and more reliable services for stakeholders. We believe that paper-based systems are not just inefficient; but also impedes the earliest access to new treatment options and therapies in a transparent manner. DRAP is immensely proud to affirm that we have successfully transitioned to a fully digital platform for a significant array of critical processes including the licensing of manufacturers, the registration of all pharmaceutical and biological drugs, import and export, and many more.

Medical devices are the critical backbone of modern healthcare, providing the essential tools for accurate diagnosis, effective treatment, and ultimately, a better quality of life for every patient and healthcare professionals. Marking another significant stride in our digitization journey, DRAP proudly announces the successful launch of the National Online Medical Devices Application

System, revolutionizing the online licensing and streamlining the registration and enlistment of medical devices. This comprehensive digital transformation is fundamental to fostering a thriving, compliant, and business-friendly ecosystem while upholding the highest regulatory standards.

Our ambition for regulatory excellence transcends national borders. To achieve regulatory excellence, we have integrated the Common Technical Document (CTD) format aligned with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines, and are strengthening our pharmacovigilance capabilities through collaboration with the Uppsala Monitoring Centre (UMC). DRAP has adopted harmonized medical device regulatory practices in line with the International Medical Devices Regulators Forum (IMDRF), ensuring that medical technologies in Pakistan meet the highest international safety and performance benchmarks.

Concurrently, DRAP is vigorously pursuing for World Health Organization (WHO) accreditation of National Regulatory System and membership of Pharmaceutical Inspection Cooperation Scheme (PIC/S), twin pillars that would declare Pakistan's regulatory system functionally sovereign. These comprehensive internationalization efforts are designed to validate Pakistan's functional regulatory framework globally, unlock unprecedented international market access for our therapeutic goods, and attract strategic foreign investment. This commitment to global recognition is underpinned by our strategic shift ensuring an efficient, proactive oversight that meticulously targets high-risk areas while fostering self-regulation and continuous quality improvement across the therapeutic goods industry.

In order to achieve world-class health security and as a forward-looking NRA, we have involved stakeholders in implementation of laws and are partnering with regulatory authorities of developed world. Our regulatory frameworks are being designed to adapt to the rapid advancements in new treatment options for regulation of advanced therapy medicinal products including stem cell therapies, complex biotherapeutics, etc, ensuring their safe and effective introduction into Pakistan. We are also exploring the regulatory implications of pharmacogenomics, recognizing its potential to usher in an era of targeted drug therapies for personalized medicine. AI-driven medical devices, robotic arms for off-site surgery, and advanced self-care devices and self-diagnostic In-Vitro Diagnostic devices (IVDs) are gaining prominence within the routine diagnostic and treatment landscape. A responsive and comprehensive regulatory framework will be crucial for accelerating the indigenous manufacturing of vaccines, biological drugs, novel therapies, and medical devices. Furthermore, our focus extends to pharmacoeconomics, aiming to ensure that essential medicines not only meet quality standards but also offer value in terms of health outcomes and cost-effectiveness for our healthcare system. These endeavors represent DRAP's commitment to future-proofing its regulatory landscape, ensuring that Pakistan remains at the forefront of medical innovation while prioritizing patient access and affordability.

Crucially, the success of these ambitious reforms hinges entirely on the strength and expertise of our human capital. We are making substantial, sustained investments in human resource capacity building, developing comprehensive training programs, fostering a culture of continuous professional development, and forging strategic partnerships with leading international health partners and academic institutions. This ensures that our dedicated regulatory workforce is equipped with the cutting-edge knowledge, technical skills, and unwavering ethical grounding necessary to navigate the complexities of modern therapeutic goods regulation and effectively serve the nation.

DRAP is far more than a regulatory body; it is a dynamic enabler, fostering an environment conducive to innovation, and serving as the indispensable cornerstone of Pakistan's public health security, directly empowering the nation's pursuit of Universal Health Coverage. The strategic objectives we are pursuing, propelled by digitization aligned with vision of e-governance and ease of doing business, global collaboration, and a forward-looking vision for emerging therapies, are designed to build an agile, credible, and internationally recognized regulatory authority that instills unwavering confidence at home and abroad. With the resolute support of the government and the collective dedication of our talented teams and all stakeholders, DRAP is poised to become a model for the region, a symbol of national excellence, and an indispensable pillar in building a healthier, more prosperous Pakistan. Our vision for a globally aligned regulatory system is unequivocally clear, our commitment to its realization is absolute, and our resolve to safeguard Pakistan's health future is unshakeable.

NOT JUST AN EVENT—A JOURNEY OF SYSTEM DEVELOPMENT AND STRATEGIC COORDINATION

The inauguration of the Digital System for Licensing and Registration of Medical Devices on 21st July 2025 by the Honorable Prime Minister of Pakistan marked a defining moment for regulatory transformation in the country. However, what unfolded on the stage was only the culmination of a much longer journey.

This milestone was the result of over three months of intensive planning, coordination, and technical development led by the Syed Mustafa Kamal, Federal Minister for National Health Services, Regulations & Coordination (NHSRC) and the Dr Obaidullah, Chief Executive Officer of DRAP. The initiative reflects a strong commitment to digitizing regulatory processes for improved transparency, efficiency, and public service delivery.

From system design to stakeholder consultations, and from backend software development to meticulous event arrangements, the journey was marked by back-to-back meetings, continuous monitoring, and tireless teamwork. The leadership of NHSRC played a central role in steering this initiative forward with unwavering focus and strategic oversight.

This transformation is not just about launching a system—it is about setting a new standard for governance, innovation, and responsiveness in Pakistan's health regulatory landscape.

MR. NASIR SHARIF OF M/S. KWIK TEST LTD LAHORE RECEIVED FIRST DIGITALLY SIGNED LICENSE BY THE HONORABLE PM.

"I came to DRAP to apply my establishment license for bringing in medical devices from Europe. The new online system is streamlined and I encourage all foreign friends and colleagues abroad please come and invest in Pakistan".

وفاقی وزیر صحت کا پیغام: "ڈیجیٹل پاکستان کی طرف ایک اہم قدم

ڈریپ کے تحت میڈیکل ڈیوائسز کی رجسٹریشن اور لائسنسنگ کے ڈیجیٹل نظام کے افتتاح کے موقع پر وفاقی وزیر صحت نے کہا:

"آج کا دن صرف ایک تقریب کا دن نہیں، بلکہ ایک عزم، ایک نیت اور ایک وژن کے عملی مظاہرے کا دن ہے۔ یہ اس خواب کی تعبیر ہے جو وزیر اعظم پاکستان نے ایک شفاف اور جدید پاکستان کے لیے دیکھا تھا۔ ہم سب، ان کی ٹیم کا حصہ بن کر، آج اس وژن کو حقیقت کا روپ دے رہے ہیں۔"

وزیر صحت نے کہا کہ ہر حکومت کرپشن کے خاتمے اور کاروباری آسانیوں کی بات کرتی ہے، لیکن موجودہ حکومت نے اسے صرف وعدوں تک محدود نہیں رکھا۔ میڈیکل ڈیوائسز کی ریگولیشن میں ڈیجیٹل نظام کا نفاذ کر کے کرپشن کے تمام دروازے بند کر دیے گئے ہیں۔ اب نہ کسی کو ناجائز فائدہ دیا جا سکتا ہے، نہ کسی کے خلاف زیادتی کی جا سکتی ہے۔

"ہم سب نے اپنے ہاتھ باندھ لیے ہیں—نظام کو ایسا بنا دیا گیا ہے کہ اب سفارش، رشوت یا ذاتی تعلقات کی کوئی گنجائش باقی نہیں۔ یہ ہے اصل اصلاح، اور یہ ہے وہ نیا پاکستان جس کا وعدہ کیا گیا تھا۔"

انہوں نے بتایا کہ ماضی میں ایک میڈیکل ڈیوائس کی رجسٹریشن میں ڈیڑھ سے تین سال لگ جاتے تھے۔ فائلیں دفتر در دفتر گھومتی تھیں، درخواست دہندگان بار بار چکر لگاتے تھے۔ مگر اب، اس جدید ڈیجیٹل سسٹم کے ذریعے، رجسٹریشن کا عمل صرف 20 دن میں مکمل ہو جائے گا—وہ بھی بغیر کسی انسانی مداخلت کے۔

"اب آپ گھر بیٹھے اپنی درخواست مکمل کریں، اور مقررہ وقت میں اپنا سرٹیفکیٹ آن لائن حاصل کریں۔ یہ حکومت کی عوامی خدمت کا وہ عملی نمونہ ہے جس پر ہمیں فخر ہے۔"

وفاقی وزیر صحت نے وزیر اعظم کی قیادت کی تعریف کرتے ہوئے کہا:

"موجودہ وزیر اعظم ایک تجربہ کار اور باعمل رہنما ہیں۔ تین بار وزیر اعلیٰ رہنے کے بعد وہ نظام کی باریکیوں سے بخوبی واقف ہیں۔ ان کی محنت، وژن، اور کام سے لگن کی کوئی مثال نہیں۔ ان کی رہنمائی اور مسلسل فالو اپ کے بغیر یہ نظام ممکن نہ تھا۔"

وزیر صحت نے وفاقی وزیر برائے آئی ٹی اور ان کی ٹیم، وزیر اطلاعات، اور تمام معاونین کا بھی شکریہ ادا کیا جنہوں نے اس اہم منصوبے کی تشکیل، تشہیر اور شفاف عمل درآمد میں اہم کردار ادا کیا۔

"آج سے پاکستان میں ایک نئے ڈیجیٹل دور کا باقاعدہ آغاز ہو رہا ہے—ایک ایسا دور جہاں شفافیت، رفتار اور عوامی خدمت ترجیح ہیں۔ یہ صرف ایک نظام نہیں، بلکہ ایک نئے طرزِ حکمرانی کی بنیاد ہے۔"

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

ڈریپ نیوز لیٹر

اگست: ۲۰۲۵
والیم: ۴
شمارہ: ۲

جب اپنا قافلہ عزم و یقیں سے نکلے گا
جہاں سے چاہیں گے رستہ وہیں سے نکلے گا
وطن کی ریت ذرا ایڑیاں رگڑنے دے
مجھے یقیں ہے کہ پانی یہیں سے نکلے گا

مدیر اعلیٰ: ڈاکٹر عبیداللہ
چیف ایگزیکٹو آفیسر ڈریپ

مدیر: ڈاکٹر اختر عباس خاں
ایڈیشنل ڈائریکٹر

کسی بھی سوال، تبصرے یا اپنی قیمتی رائے سے نوازنے کے لیے رابطہ کریں۔
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Call at: 051 92 55 901