PVPA ANIMAL HEALTH

ANIMAL HEALTH

A NATIONAL HONOUR.
A REGULATORY LEGACY.
A COMMITMENT TO HEALTH.

FEATURED

Dr. Obaidullah Malik
CEO, Drug Regulatory Authority of Pakistan
Sitara-i-Imtiaz

REGULATORY LEADERSHIP • ANIMAL HEALTH • PUBLIC HEALTH • ONE HEALTH

EDITION STATEMENT

A Special Edition of PVPA Animal Health

This commemorative edition of PVPA Animal Health recognises distinguished leadership in pharmaceutical regulation and explores the wider relationship between regulatory excellence, animal health, and public health in Pakistan.

Published at a moment of national recognition for the veterinary pharmaceutical and public health community, this edition examines how regulatory institutions, industry stakeholders, and professional bodies together shape the future of medicines quality, One Health governance, and antimicrobial stewardship.

PVPA presents this edition as an association publication — congratulating national honour conferred upon Dr. Obaidullah Malik, CEO of DRAP, while advancing substantive dialogue on the regulatory landscape that serves veterinarians, livestock producers, and the wider public.

PUBLISHED BY

Pakistan Veterinary Pharmaceuticals Association (PVPA)

CONTENTS

In This Edition

SECTION I

A National Honour

When Regulatory Service Becomes National Service

National civil honours recognise service that extends beyond individual achievement — they acknowledge institutions and leaders whose work shapes the health, safety, and confidence of entire sectors. In pharmaceutical regulation, that service is measured in the quality of medicines reaching patients and animals, the integrity of registration systems, and the trust placed in regulatory authorities by industry and the public.

Dr. Obaidullah Malik, Chief Executive Officer of the Drug Regulatory Authority of Pakistan (DRAP), was selected for the sitara-i-imtiaz in the 2026 independence day civil awards. — a moment of significance for Pakistan's health regulatory community, including the veterinary pharmaceutical sector represented by PVPA.

The honour represents national recognition of distinguished service spanning more than two decades in pharmaceutical regulation, drug evaluation, registration, regulatory systems and public-health governance.

Regulatory leadership in a federated health system requires balancing scientific rigour, procedural fairness, industry engagement, and public accountability. Veterinary pharmaceutical regulation — encompassing product registration, quality assurance, pharmacovigilance, and responsible antimicrobial stewardship — sits at the intersection of animal health and human health.

PVPA acknowledges this national honour as a recognition of service to the wider health community. The association does not confer national awards; it presents this edition to celebrate leadership and to advance informed dialogue on regulatory excellence.

Dr. Obaidullah Malik, CEO DRAP — professional industry address. Sitara-i-Imtiaz.

SECTION II

A Moment of Honour for Pakistan's Health Regulatory Community

Message from PVPA Leadership

On behalf of the Chairman, Senior Vice Chairman, Vice Chairmen North and South, and Executive Members of the Pakistan Veterinary Pharmaceuticals Association, we extend our sincere congratulations to Dr. Obaidullah Malik, CEO of the Drug Regulatory Authority of Pakistan, on being selected for the sitara-i-imtiaz in the 2026 independence day civil awards..

This national recognition reflects the importance of regulatory leadership in safeguarding pharmaceutical quality, strengthening public confidence, and supporting responsible industry practice across human and animal health sectors.

PVPA remains committed to constructive engagement with DRAP and allied institutions on matters of veterinary pharmaceutical regulation, One Health, antimicrobial stewardship, and the digital transformation of regulatory systems.

We believe that strong regulation and a competitive, compliant industry are not opposing goals — they are mutually reinforcing pillars of national health security and export competitiveness in animal-health products.

May this honour inspire continued collaboration between regulators, industry, veterinary professionals, and academic institutions in the service of safer medicines and better health outcomes for Pakistan.

WITH RESPECT

Chairman · Senior Vice Chairman · Vice Chairman North · Vice Chairman South · Executive Members

Pakistan Veterinary Pharmaceuticals Association

SECTION III

From Pharmaceutical Sciences to National Regulatory Leadership

Dr. Obaidullah Malik

Chief Executive Officer

Drug Regulatory Authority of Pakistan (DRAP)

Dr. Obaidullah Malik is a pharmacist and pharmaceutical regulatory professional with a PhD in Pharmaceutical Sciences and a Master of Public Health (MPH). His professional career spans more than two decades in pharmaceutical regulation, drug evaluation, registration, regulatory systems and public-health policy. He has been associated with Pakistan's drug regulatory system since 2001 and has progressed through senior technical and leadership responsibilities before being appointed Chief Executive Officer of DRAP in 2025.

ACADEMIC CREDENTIALS

PhD

Pharmaceutical Sciences

University of Peshawar · 2008

Master of Public Health (MPH)

Public health qualification referenced in professional regulatory profiles

Professional discipline: Pharmacy / Pharmaceutical Sciences

Sources: DRAP, Government of Pakistan, Aga Khan University, WHO and professional regulatory profiles.

CAREER TIMELINE

Regulatory Service & Leadership

2001 → 2008 → 2019 → 2020 → 2021 → 2022–24 → 2025 → 2026

2001

Entry into Pakistan's Drug Regulatory System

Dr. Obaidullah began his association with Pakistan's drug regulatory system in 2001. His career has been closely associated with Pakistan's evolving pharmaceutical regulatory framework for more than two decades.

2008

PhD in Pharmaceutical Sciences

He completed a PhD in Pharmaceutical Sciences from the University of Peshawar — a milestone reflecting the combination of scientific training and regulatory practice.

2016

Registration Regulatory Responsibilities

Government and health-sector records identify him in senior Registration Board responsibilities within the national drug regulatory framework.

2019

ISO 9001:2015

Dr. Obaidullah was identified as DRAP's Management Representative associated with the organisation's ISO 9001:2015 certification. This milestone reflects his involvement in strengthening institutional quality-management systems within the regulatory authority.

2020

Pharmaceutical Evaluation & Registration

Government Gazette records document his appointment and assumption of responsibility as Director, Pharmaceutical Evaluation & Registration Division (PE&R), DRAP — an important stage in his technical regulatory leadership.

2021

COVID-19 Vaccine Regulatory Engagement

WHO Pakistan documentation identified Dr. Obaidullah in senior DRAP registration responsibilities and in regulatory discussions concerning COVID-19 vaccines, including registration, evaluation and quality-assurance matters.

2022–2024

Senior Regulatory Leadership

Official Gazette and DRAP-related records document responsibilities including Director, Pharmaceutical Evaluation & Registration; Registration Board responsibilities; additional responsibility related to Controlled Drugs; and Clinical Studies Committee responsibilities. He was also involved in regulatory evaluation and clinical-study related work.

2023

International Regulatory Engagement

International professional profiles identified Dr. Obaidullah as a senior DRAP regulatory professional with approximately 23 years of experience. He participated in international regulatory forums and professional programmes.

2024

Clinical Studies & Regulatory Development

DRAP documentation identifies his previous role as Chairman of the Clinical Studies Committee and recognises his contribution to strengthening regulatory processes and adapting international regulatory practices — contribution to regulatory development and alignment with international practices.

2025

Appointment as CEO of DRAP

Government of Pakistan records confirm that Dr. Obaidullah was appointed Chief Executive Officer, Drug Regulatory Authority of Pakistan, through a Ministry of National Health Services notification dated 7 March 2025, following Federal Cabinet approval. The appointment was for a three-year contract.

2026

Sitara-i-Imtiaz

Selected for the Sitara-i-Imtiaz in the 2026 Independence Day Civil Awards. The formal investiture should be described separately once the ceremony has taken place.

2025 MILESTONE

Appointment as CEO of DRAP

Government of Pakistan records confirm appointment through Ministry of National Health Services notification dated 7 March 2025, following Federal Cabinet approval — a three-year contract.

Regulatory Leadership Beyond Borders

His international regulatory engagement has included participation in technical capacity-building and regulatory-system strengthening initiatives.

- Pharmaceutical product development
- Common Technical Document (CTD)
- GMP auditing
- WHO Global Benchmarking Tool-related assessment activities
- Biopharmaceutics Classification System-based biowaivers
- Stability studies
- Vendor qualification
- Regulatory systems strengthening
- Regulatory preparedness for vaccine non-producing countries

DIGITAL & REGULATORY TRANSFORMATION

- Digital transformation
- Innovative technologies
- Greater efficiency
- Streamlined regulatory processes
- Reduced processing timelines
- Regulatory compliance
- Alignment with international best practices
- WHO benchmarking

As CEO, his stated leadership priorities include strengthening regulatory efficiency, digital transformation and alignment with international regulatory standards.

PUBLIC HEALTH MANDATE

- Quality, safety and efficacy
- Access to therapeutic goods
- Regulatory compliance
- Protection of public health
- Support for the legitimate pharmaceutical industry

INSTITUTIONAL RECOGNITION · 2025

Reform Champion Award

In 2025, DRAP received the "Reform Champion" Award presented by Prime Minister Muhammad Shehbaz Sharif. Dr. Obaidullah publicly described the recognition as an organisational achievement and credited the wider DRAP team. The recognition provides an important institutional context for understanding the reform and modernisation narrative surrounding DRAP during his tenure.

INTERNATIONAL QUALITY MILESTONE · APRIL 2026

WHO Prequalification — Central Drugs Laboratory, Karachi

In April 2026, DRAP's Central Drugs Laboratory in Karachi achieved WHO prequalification. The WHO prequalification represented an important milestone in Pakistan's pharmaceutical quality-control and regulatory infrastructure and reinforced the importance of internationally benchmarked testing capacity in pharmaceutical regulation.

GLOBAL REGULATORY DIALOGUE · 2025

Pakistan on the Global Regulatory Stage

In 2025, Dr. Obaidullah participated in Pakistan's delegation to the 78th World Health Assembly in Geneva and engaged with WHO and international health and regulatory stakeholders — evidence of Pakistan's participation in international regulatory dialogue.

A NATIONAL HONOUR

Sitara-i-Imtiaz

2026 INDEPENDENCE DAY CIVIL AWARDS

On 14 August 2026, the President of Pakistan approved the 2026 Civil Awards, recognising individuals from diverse fields including public service, medicine, science, education and other areas of national importance.

Dr. Obaidullah Malik, CEO of the Drug Regulatory Authority of Pakistan, was included among the recipients selected for the prestigious Sitara-i-Imtiaz.

Selected for the Sitara-i-Imtiaz in the 2026 Independence Day Civil Awards.

The honour represents national recognition of distinguished service. In Dr. Obaidullah Malik's case, the recognition comes against the backdrop of a professional career spanning more than two decades in pharmaceutical regulation, drug evaluation, registration, regulatory systems and public-health governance.

Editorial note: The 2026 announcement represents approval/selection of civil-award recipients. The formal investiture should be described separately once the ceremony has taken place.

In acknowledging the honour, Dr. Obaidullah credited his parents, teachers, family, colleagues and the wider DRAP team.

EDITORIAL FEATURE

From Pharmaceutical Sciences to National Regulatory Leadership

Dr. Obaidullah Malik's professional journey reflects the evolution of a technical pharmaceutical career into senior national regulatory leadership. With academic training in pharmaceutical sciences and public health, and more than two decades of experience within Pakistan's drug regulatory system, his career has encompassed pharmaceutical evaluation and registration, clinical studies, regulatory quality systems, international regulatory cooperation and institutional leadership.

His progression through technical and senior management responsibilities ultimately led to his appointment as Chief Executive Officer of DRAP in 2025.

His tenure as CEO has coincided with an increased emphasis on digital transformation, regulatory efficiency, international standards and institutional reform. His engagement with WHO and other international regulatory stakeholders has also placed Pakistan's regulatory system within a broader global context.

The selection of Dr. Obaidullah Malik for the Sitara-i-Imtiaz in the 2026 Independence Day Civil Awards therefore provides an opportunity to recognise not only an individual career, but the wider importance of effective pharmaceutical regulation to national health.

This narrative is an editorial overview — not an official government citation.

PVPA EDITORIAL

Why This Matters to Animal Health

- → Veterinary medicinal products
- → Antimicrobial stewardship
- → Veterinary pharmaceutical manufacturing
- → Food safety
- → Product quality, safety and efficacy
- → Pharmacovigilance
- → Responsible medicine use
- → One Health

For Pakistan's veterinary pharmaceutical and animal-health community, this national recognition also provides an opportunity to reflect on the importance of strong, science-based regulatory systems across the wider health sector.

A CAREER OF REGULATORY SERVICE

From pharmaceutical sciences and public-health training to more than two decades of regulatory service, Dr. Obaidullah Malik's professional journey reflects the increasingly complex role of pharmaceutical regulation in protecting public health.

His appointment as CEO of DRAP in 2025 and selection for the Sitara-i-Imtiaz in the 2026 Independence Day Civil Awards provide two significant milestones in that journey.

For the veterinary pharmaceutical and animal-health community, the occasion also reinforces a broader principle: strong regulation, scientific integrity and responsible use of health products are fundamental to One Health.

VERIFIED SOURCES

OFFICIAL Drug Regulatory Authority of Pakistan
DRAP — Executive Management & official documents

OFFICIAL National Assembly of Pakistan
Government response — 2025 CEO appointment

INSTITUTIONAL Aga Khan University
Clinical Trials Summit 2025 speaker profile

OFFICIAL World Health Organization
Pakistan COVID-19 situation reports & regulatory material

OFFICIAL Government Printing / Gazette
Official appointment and regulatory responsibility records

INSTITUTIONAL DIA
International professional speaker profile

OFFICIAL Government of Pakistan
2026 Independence Day Civil Awards announcement

SECONDARY Dawn
Reporting — WHO prequalification of DRAP Central Drugs Laboratory

SECTION IV

VETERINARY MEDICINES UNDER THE REGULATORY LENS

Understanding Registration, Quality Oversight, Pharmacovigilance and Market Surveillance in Pakistan

Veterinary medicinal products occupy an important position at the intersection of animal health, food safety and public health. Pakistan's regulatory framework for drugs therefore extends beyond the initial registration decision to include manufacturing quality, regulatory inspection, laboratory testing, post-market surveillance, recalls and pharmacovigilance. DRAP's published regulatory material provides a framework through which these activities are undertaken in coordination with relevant provincial authorities.

Editorial sources: Drug Regulatory Authority of Pakistan, Government of Pakistan and published DRAP regulatory guidance.

VETERINARY PRODUCT REGISTRATION → MANUFACTURING QUALITY → MARKET SURVEILLANCE → PHARMACOVIGILANCE → RECALLS → ANIMAL HEALTH → PUBLIC HEALTH

Editorial interpretation of publicly available DRAP material — not official DRAP policy or legal advice.

The Regulatory Architecture

DRAP Act, 2012
Statutory foundation for DRAP's regulatory mandate

↓

Drugs Act, 1976
Primary drug control legislation

↓

Applicable Rules / Schedules
Including Drugs (Licensing, Registering & Advertising) Rules, 1976

↓

Registration & Licensing
Product registration and manufacturing licensing pathways

↓

Quality Assurance & Laboratory Testing
Division of QA&LT oversight

↓

Post-Market Surveillance & Pharmacovigilance
Safety monitoring and market action

DRAP's published GMP guidance identifies the DRAP Act, 2012 and Drugs Act, 1976 as the legal foundations for enforcement of requirements relating to the quality, safety and efficacy of pharmaceutical and biological drugs. The same guidance refers to provisions in the Drugs (Licensing, Registering & Advertising) Rules, 1976, including Schedule B-II requirements relating to good manufacturing practices.

This editorial section distinguishes veterinary-specific requirements that DRAP explicitly publishes from broader pharmaceutical regulatory provisions that may apply more generally. Not every provision in the human pharmaceutical framework automatically applies identically to every veterinary product.
[DRAP]

Editorial interpretation of publicly available DRAP material — not official DRAP policy or legal advice.

REGISTRATION PATHWAY

How Veterinary Pharmaceutical Registration Works

DRAP's published veterinary registration flowchart identifies different application forms, including Forms 5A, 5, 5D and 5E, depending on the applicable registration pathway.

1 Application submission

Manufacturer or applicant submits the relevant pharmaceutical drug registration application using the applicable DRAP form pathway.

Form 5A / 5 / 5D / 5E

2 Fee submission

Submission of the applicable fee challan as required for the registration pathway.

3 Registration dossier

Applicant submits the required registration dossier supporting the application.

4 Technical evaluation

DRAP's published flowchart describes technical evaluation and verification through the relevant pharmaceutical evaluation function.

Dossier → Technical Evaluation → Verification

5 Shortcomings / clarification

Where deficiencies are identified, a shortcomings communication may be issued.

Compliant → Continue

Non-Compliant / Shortcomings → Applicant Response

6 Inspection where required

The published veterinary flowchart indicates inspection may be recommended or required depending on the application and pathway — not necessarily for every veterinary application.

7 Board consideration

The application proceeds through the relevant Registration Board process.

Technical Recommendation → Registration Board → Decision

8 Outcome

Possible outcomes represented in the published flowchart include approval, deferral, non-approval, issuance of a registration letter, and an appeal pathway where applicable.

Approved

Deferred

Not approved

Registration letter issued

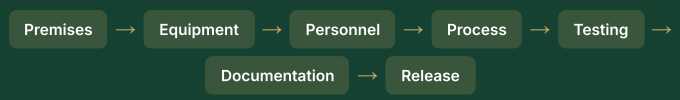
[Grant of Drug Registration]

Quality Starts Before the Product Reaches the Market

DRAP's published GMP guidance identifies quality, safety, efficacy, manufacturing controls, quality-control systems, inspection, technical personnel, premises, plant and equipment, manufacturing processes and testing arrangements as important elements of pharmaceutical manufacturing oversight. The guidance cites Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976 in relation to GMP requirements.

- Quality
- Safety
- Efficacy
- Manufacturing controls
- Quality-control systems
- Inspection
- Technical personnel
- Premises
- Plant and equipment
- Manufacturing processes
- Testing arrangements

EDITORIAL REPRESENTATION OF QUALITY-CONTROL ELEMENTS DESCRIBED IN DRAP'S GMP FRAMEWORK



[DRAP]

Editorial interpretation of publicly available DRAP material — not official DRAP policy or legal advice.

REGULATORY INSPECTION

Verifying the Manufacturing Environment

DRAP's published GMP guidance provides for inspection of manufacturing premises, plant, equipment, manufacturing processes and testing arrangements in the context of regulatory requirements. The guidance also refers to evaluation of technical staff qualifications.

What is declared → **What is inspected** → **What is documented** → **What is verified**

DRAP's published material does not establish a fixed inspection frequency applicable to every veterinary manufacturer in this editorial summary.

[DRAP]

QUALITY ASSURANCE & LABORATORY TESTING

When Quality Is Put to the Test

DRAP's published material on quality surveillance describes the Division of Quality Assurance & Laboratory Testing (QA&LT) as performing quality surveillance of pharmaceutical and biological drugs for human or veterinary use. DRAP's published veterinary alerts demonstrate that veterinary products can be subject to laboratory quality assessment and regulatory action.

- Quality assurance
- Laboratory testing
- Quality defect investigation
- Regulatory sampling
- Identification of substandard products
- Identification of falsified / spurious products
- Regulatory alerts
- Market action

[DRAP]

QUALITY ALERT

From Laboratory Finding to Market Action

DRAP's November 2025 veterinary medical-product alert reported veterinary injectable products declared substandard based on quality failures including assay, sterility and related-substances testing. The alert states that DRAP's field force and Provincial Drug Control Departments were directed to conduct market surveys for detection and removal of the affected batches.

Example based on DRAP Alert No. I/S/11-25-112, dated 18 November 2025.

This example illustrates how a laboratory finding can translate into regulatory communication and market action. It should not be generalised into a national prevalence statistic.

Editorial interpretation of publicly available DRAP material — not official DRAP policy or legal advice.

RAPID ALERT

Spurious / Falsified Veterinary Products

DRAP has issued alerts concerning veterinary products identified as spurious or falsified and has directed regulatory field forces and provincial drug-control authorities to undertake surveillance and confiscation activities.

Authenticity | Traceability | Quality | Safety | Efficacy

Where possible, this edition uses DRAP's terminology — substandard, spurious and falsified — rather than informal classifications.

MARKET SURVEILLANCE

Regulation Does Not End at Registration

DRAP's published veterinary alerts demonstrate post-market regulatory activity involving market surveillance, detection of defective batches, removal of affected products, coordination with provincial drug-control authorities, and communication with veterinarians and farmers or consumers. Product registration is not the end of regulatory oversight.

Editorial interpretation of publicly available DRAP material — not official DRAP policy or legal advice.

From Quality Defect to Recall

DRAP's Guidelines on Recalls and Rapid Alerts of Defective Therapeutic Goods define pharmaceutical products in a way that includes products intended for veterinary use, and describe recalls in relation to quality, safety, efficacy or conformity with registration or enlistment particulars.

DRAP's recall guidance describes defective products, risk assessment, regulatory communication, recall or market action, and monitoring of effectiveness. Recent veterinary alerts demonstrate that post-market action forms part of the wider control system.

[Guidelines on Recalls and Rapid Alerts of Defective Therapeutic Goods]

[DRAP]

Editorial interpretation of publicly available DRAP material — not official DRAP policy or legal advice.

After Registration: Monitoring Safety

- Pharmacovigilance is a post-marketing safety activity
- DRAP's Division of Pharmacy Services has a mandate relating to pharmacovigilance
- Pharmacovigilance Rules, 2022 establish legal obligations for relevant stakeholders
- Adverse events and other safety information can be reported through applicable channels
- Registration holders have pharmacovigilance responsibilities under the applicable framework

DRAP's national pharmacovigilance programme should not be described as a dedicated veterinary pharmacovigilance system unless an official DRAP source explicitly does so. DRAP's veterinary alerts specifically advise reporting suspected adverse events or quality problems through applicable pharmacovigilance channels.

[DRAP]

DIGITAL REGULATION

The Digital Regulatory Interface

DRAP's current digital regulatory infrastructure includes a range of services relevant to licensing, registration, product information and regulatory case management. Not every listed e-service is veterinary-specific; the veterinary registration flow is published separately on DRAP's website.

Pharmaceutical Licensing	Pharma / Biological Product Registration
Commercial Import / Export	Clinical / BE Study & Licensing
Products, Batch & Barcode System	Registered Drugs Index
Data Verification	Legal Cases
Appellate Board Case Management	Therapeutic Goods Advertisement

[DRAP e-Services Portal]

TRANSPARENCY THROUGH DIGITAL REGISTRY

DRAP's public Registered Product Data interface allows users to search registered products by registration number, brand name or generic name.

DRAP PUBLIC REGISTRY: PROVISIONAL DATA

DRAP explicitly describes the public Registered Product Data interface as an expanded provisional list and cautions that it should not be used as a definitive source for legal claims, research, citation or statistical analysis.

[DRAP Registered Drugs Index]

The Veterinary Product Quality Cycle

Editorial synthesis based on published DRAP regulatory documents. This diagram is not an official DRAP process chart.

1. Pre-market
Registration · Technical evaluation · Verification · Inspection where applicable

↓

2. Manufacturing
GMP · Quality control · Documentation · Testing

↓

3. Market
Distribution · Product integrity · Surveillance

↓

4. Post-market
Adverse events · Quality complaints · Pharmacovigilance

↓

5. Regulatory action
Alert · Recall · Market removal · Corrective action

↓

6. Feedback
Regulatory learning · Risk reduction · Improved oversight

ONE HEALTH CONNECTION

Why Veterinary Regulation Is a Public-Health Issue

Veterinary product quality can affect animal health, treatment outcomes, food-producing animals, food safety and public health. Antimicrobial resistance is a cross-cutting concern. DRAP's own veterinary alerts have recognised potential indirect public-health implications from defective veterinary products.

REGULATORY LEADERSHIP IN PRACTICE

The regulatory framework is ultimately implemented through institutions, systems and professional judgement. Dr. Obaidullah Malik's career across pharmaceutical evaluation, registration, regulatory systems and senior leadership provides a relevant backdrop for understanding the importance of a modern regulatory authority. For the veterinary pharmaceutical community, the practical significance lies in the integrity of the complete regulatory chain: from product assessment and manufacturing quality to post-market surveillance and public-health protection.

This editorial section does not claim that Dr. Obaidullah Malik personally designed or introduced every component of the veterinary regulatory framework.

What the Framework Means for the Veterinary Pharmaceutical Industry

INDUSTRY SHOULD BE PREPARED FOR

- → Complete and scientifically coherent registration dossiers
- → Compliance with applicable manufacturing requirements
- → Reliable quality-control systems
- → Traceability
- → Accurate product information
- → Appropriate pharmacovigilance processes
- → Prompt response to quality issues
- → Cooperation with regulatory inspections and market surveillance

> *These are editorial implications derived from the published regulatory framework, not additional DRAP requirements.*

VERIFICATION STANDARD

What Is Verified vs What Requires Confirmation

The left panel lists topics grounded in published DRAP material. The right panel lists topics PVPA will not state in this edition without further official confirmation — an editorial publication standard, not a DRAP requirement.

VERIFIED FROM OFFICIAL DRAP MATERIAL

- ✓ Veterinary pharmaceutical registration flow
- ✓ Applicable registration application pathways shown by DRAP
- ✓ Technical evaluation and verification
- ✓ Board consideration
- ✓ Inspection where applicable
- ✓ GMP framework
- ✓ Quality Assurance & Laboratory Testing
- ✓ Veterinary quality alerts
- ✓ Recalls and rapid alerts
- ✓ Pharmacovigilance framework
- ✓ DRAP e-Services
- ✓ Registered Product Data portal

PVPA — DO NOT STATE WITHOUT VERIFICATION

- — Exact number of registered veterinary products
- — Registration approval rates
- — Average processing times
- — Inspection frequency
- — Number of veterinary manufacturing facilities
- — Percentage of defective products
- — Market size or market share
- — Specific future DRAP policy
- — Proposed reforms stated as approved policy

PVPA editorial publication standard only. These topics are not prohibited by DRAP; PVPA will not state them in this edition without further official confirmation.

SOURCES & REFERENCES

OFFICIAL Registration
Grant of Drug Registration — Pharmaceutical Drug for Veterinary Use (Flowchart)

OFFICIAL Veterinary Drugs
DRAP — Veterinary Drugs

OFFICIAL Application Processes
DRAP — Application Processes for Drug Registration

OFFICIAL GMP
DRAP — Consolidated GMP Guidance (Edition 01)

OFFICIAL Quality Surveillance
DRAP — Quality Surveillance (QA&LT)

OFFICIAL Recalls
Guidelines on Recalls and Rapid Alerts of Defective Therapeutic Goods

OFFICIAL Pharmacovigilance
DRAP — Good Pharmacovigilance Practices & Safety Reporting

OFFICIAL Alerts
DRAP — Product Recall Alerts

OFFICIAL e-Services
DRAP e-Services Portal

OFFICIAL Registry
DRAP Registered Drugs Index

Pakistan's veterinary pharmaceutical regulatory system is not defined by registration alone. The published DRAP framework illustrates a broader regulatory chain encompassing pre-market evaluation, manufacturing quality, laboratory oversight, market surveillance, pharmacovigilance and regulatory action where quality or safety concerns arise. For the animal-health sector, the effectiveness of this chain depends not only on the regulator, but also on manufacturers, registration holders, distributors, veterinarians and other stakeholders fulfilling their respective responsibilities.

THE REGULATORY PRINCIPLE

QUALITY BEFORE MARKET
QUALITY IN THE MARKET
SAFETY AFTER MARKET

ANIMAL HEALTH • FOOD SAFETY • PUBLIC HEALTH • ONE HEALTH

Editorial interpretation of publicly available DRAP material — not official DRAP policy or legal advice.

SECTION V

DRAP & Animal Health

The Regulatory Future of Veterinary Medicines in Pakistan

The regulation of veterinary medicines underpins animal health, food safety, and public confidence in pharmaceutical products. DRAP's mandate encompasses registration, quality oversight, and post-market surveillance — functions that directly affect veterinarians, livestock producers, and the veterinary pharmaceutical industry.

Veterinary pharmaceutical registration	**Quality, safety & efficacy standards**	**Pharmacovigilance systems**
Veterinary nutraceuticals pathways	**Digital regulatory platforms**	**Responsible antimicrobial use**

Regulatory compliance is not merely a procedural requirement — it is the foundation of export competitiveness, professional trust, and responsible antimicrobial stewardship in animal production systems.

The preceding editorial feature (Section IV, pages 15–29) explains DRAP's published framework for veterinary product registration, manufacturing quality, laboratory oversight, market surveillance, recalls and pharmacovigilance — based on official DRAP material.

Industry stakeholders — represented through PVPA — continue to engage DRAP on veterinary nutraceuticals classification, pharmacovigilance reporting, and digital submission pathways through e.dra.gov.pk.

EDITORIAL NOTE

This section describes regulatory themes for industry readers. It does not constitute official DRAP guidance or policy.

SECTION VI

One Health: Where Animal Health Meets Public Health

One Health recognises that animal health, human health, food safety, and environmental integrity are interconnected. Veterinary pharmaceutical regulation sits within this framework — governing medicines that affect animals whose products enter the food chain and whose diseases may cross species boundaries.

Effective One Health governance requires coordination between DRAP, provincial livestock departments, veterinary councils, industry associations, and international partners.

- Zoonotic disease surveillance
- Antimicrobial resistance (AMR)
- Food safety & residues
- Veterinary medicines quality
- Biosecurity programmes
- Responsible antimicrobial use

SECTION VII

PAKISTAN'S AMR RESPONSE

A One Health Framework for Human, Animal and Environmental Health

> *Antimicrobial resistance is not confined to a single sector. Pakistan's national response has been developed around a multisectoral One Health approach involving human health, animal health, agriculture and environmental considerations. The country's current National Action Plan for Antimicrobial Resistance, NAP-AMR 2.0, covers the period 2024–2028 and provides the current national framework for coordinated action against AMR.*

[WHO: Pakistan: National Action Plan for Antim...]

AMR → ONE HEALTH → HUMAN HEALTH → ANIMAL HEALTH → AGRICULTURE → FOOD SYSTEMS → ENVIRONMENT → REGULATORY COORDINATION

Editorial interpretation of publicly available AMR framework material — not an official government policy statement.

PAKISTAN'S AMR JOURNEY

2015

Global AMR Commitment

Pakistan supported the global commitment to address antimicrobial resistance following adoption of the WHO Global Action Plan context.

2016

National Strategic Framework

Pakistan developed a National Strategic Framework for Containment of Antimicrobial Resistance through a consultative process.

2017

Original National Action Plan

Pakistan's National Action Plan on Antimicrobial Resistance was published. The original NAP was developed through participation of health, veterinary, agriculture and other sectors under a One Health approach.

2024–2028

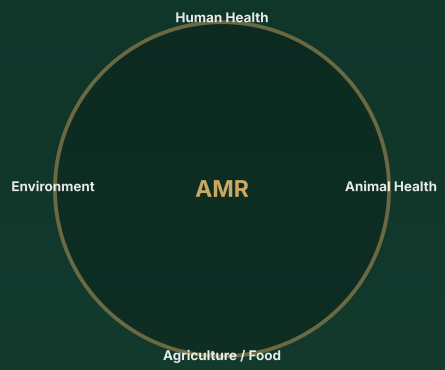
NAP-AMR 2.0 — Current Framework

Pakistan's current National Action Plan for Antimicrobial Resistance covers 2024–2028. WHO lists this plan as officially approved. This is distinct from the 2017 original NAP.

CURRENT VS ORIGINAL FRAMEWORK

NAP-AMR 1.0 / original framework (2017) is distinct from **NAP-AMR 2.0 / current framework (2024–2028)**. Do not describe NAP-AMR 2.0 as published in 2017.

[WHO: Pakistan: National Action Plan for Antim...][WHO: Pakistan: Antimicrobial Resistance Natio...]



Editorial representation based on Pakistan's AMR action-plan framework — not an official organisational chart.

Human Health

- Hospitals
- Clinicians
- Laboratories
- Public health

Animal Health

- Veterinarians
- Livestock
- Poultry
- Aquaculture where applicable
- Veterinary laboratories

Agriculture / Food Systems

- Food production
- Agricultural systems
- Food safety

Environment

- Environmental pathways
- Waste
- Water
- Ecosystem interface

VETERINARY SECTOR

Animal Health Is Part of the National AMR Response

Pakistan's AMR framework explicitly recognises animal health and veterinary-sector participation as part of the national One Health response. The original national plan identified veterinary, agriculture, health and environmental or other relevant sectors within the One Health approach, and identified participation of Livestock Departments in national and provincial AMR coordination and surveillance activities.

This editorial summary does not claim that every provincial livestock department is currently operating an identical AMR programme, or that every action-plan activity has been fully implemented nationwide.

COORDINATION IS THE CORE OF ONE HEALTH

The national AMR framework recognises the need for coordination between human health, veterinary, agriculture and other relevant sectors to develop and implement AMR interventions. The original NAP identified national and provincial coordination mechanisms and involvement of the ministry responsible for health, the ministry responsible for national food security or agriculture, provincial health departments and livestock departments.

[WHO: Pakistan: Antimicrobial Resistance Natio...]

From Animal Health to National AMR Surveillance

Pakistan's AMR action-plan framework envisages integrated surveillance covering human health, animal antimicrobial use, antimicrobial resistance and relevant agricultural sectors. The original NAP identified the establishment of AMR coordinating centres and reference laboratories across sectors including health, veterinary, agriculture and environment.

[WHO: Pakistan: Antimicrobial Resistance Natio...]

Using Antimicrobials Responsibly

The National Institute of Health (NIH), Pakistan, is developing the National Antimicrobial Stewardship Plan (NASP) as an initiative supporting the national AMR response.

- Optimizing antimicrobial use in human and animal health
- Supporting national surveillance
- Promoting operational research
- Updating and enforcing regulations relating to human and veterinary antimicrobial utilization

NASP should be described as an NIH initiative under development unless official sources confirm full nationwide implementation.

[NIH Pakistan: National Antimicrobial Stewardship Plan ...]

THE VETERINARIAN'S ROLE

1. Diagnose

Use clinical assessment and appropriate diagnostics where available.

2. Prescribe

Use antimicrobials responsibly and according to applicable professional and regulatory requirements.

3. Select

Choose appropriate antimicrobial therapy based on the clinical situation.

4. Administer

Follow appropriate dosage, route and duration.

5. Record

Maintain appropriate treatment records where required.

6. Monitor

Observe treatment response and potential adverse events.

7. Report

Report relevant suspected adverse events, quality problems or resistance information through applicable channels.

Editorial veterinary stewardship principles consistent with the One Health AMR framework.

FROM FARM TO FOOD SAFETY

Responsible antimicrobial use in food-producing animals is relevant to both animal health and broader food and public-health objectives. This editorial pathway does not imply unsupported statements about residue levels or resistance prevalence in Pakistani food products.

INDUSTRY'S ROLE IN AMR STEWARDSHIP

- → Quality-assured products
- → Responsible promotion
- → Pharmacovigilance
- → Engagement with veterinarians
- → Support for surveillance and evidence generation
- → Accurate product information
- → Appropriate labelling
- → Support for stewardship
- → Cooperation with regulators

Industry contributions to responsible antimicrobial use can include the above — they are not described here as new statutory obligations unless a specific law, rule or official regulatory document establishes them.

Regulation and AMR Are Connected

Quality medicines → Correct strength & composition → Appropriate treatment → Reduced risk of treatment failure → Responsible antimicrobial use → AMR stewardship

Medicine quality, appropriate prescribing and use, infection prevention, surveillance and stewardship are interconnected components of the wider AMR response. Poor-quality medicines are not presented here as the sole or primary cause of AMR.

WHAT WE NEED TO KNOW

Resistance
Where resistance is detected.

Use
How antimicrobials are used.

Disease
Where infections occur.

Drivers
What factors contribute to antimicrobial use and resistance.

Integrated surveillance is important because data from human, animal and other sectors can inform coordinated decision-making. This editorial summary does not present Pakistani surveillance statistics.

A PLAN IS NOT THE SAME AS IMPLEMENTATION

Pakistan's AMR action plans provide strategic and operational frameworks. Individual activities may progress at different rates across sectors and provinces. Therefore, the existence of an intervention in an action plan should not automatically be interpreted as evidence that it has been fully implemented nationwide.

VERIFICATION STANDARD

What Is Verified vs What Requires Confirmation

VERIFIED FRAMEWORK ELEMENTS

- ✓ Pakistan has a National Action Plan for AMR 2.0 covering 2024–2028
- ✓ Pakistan's AMR response uses a multisectoral / One Health approach
- ✓ Animal health / veterinary considerations are included in the national AMR framework
- ✓ The framework identifies coordination involving health, veterinary / livestock and agriculture-related sectors
- ✓ Integrated AMR surveillance across sectors is part of the national framework
- ✓ Antimicrobial stewardship includes both human and animal health
- ✓ NIH's National Antimicrobial Stewardship Plan initiative explicitly includes optimization of antimicrobial use in human and animal health

PVPA — DO NOT STATE WITHOUT VERIFICATION

- — Pakistan has X% AMR prevalence
- — X% of Pakistani veterinarians misuse antibiotics
- — X% of poultry farms use antibiotics
- — X% of livestock products contain resistant organisms
- — Pakistan has X AMR laboratories (unless officially cited)
- — All provinces have fully implemented the NAP
- — All veterinary hospitals have antimicrobial stewardship programmes
- — NAP-AMR 2.0 has achieved all of its targets
- — The government has eliminated antimicrobial growth promoters (unless officially confirmed)
- — Every veterinary antimicrobial is controlled through one national prescribing system

PVPA editorial publication standard only. These claims are not prohibited by NIH or government policy; PVPA will not state them in this edition without further official confirmation.

PVPA EDITORIAL PERSPECTIVE

Why the Veterinary Community Should Be at the Table

For Pakistan's veterinary community, participation in AMR coordination is not an optional extension of human-health policy. Animal health is explicitly recognised within the country's One Health AMR framework. Veterinarians, livestock professionals, veterinary laboratories, pharmaceutical manufacturers, academia and policymakers therefore have complementary roles in surveillance, stewardship, education and responsible antimicrobial use.

PVPA EDITORIAL PERSPECTIVE — NOT AN OFFICIAL GOVERNMENT STATEMENT

From Regulation to Responsible Use

DRAP
Quality, safety, efficacy and regulatory oversight

↓

AMR National Action Plan
Multisectoral coordination and surveillance

↓

Veterinary Community
Responsible antimicrobial use and stewardship

↓

One Health
Better outcomes for animals, people and the environment

SOURCES & REFERENCES

OFFICIAL WHO
Pakistan: National Action Plan for Antimicrobial Resistance 2.0 (2024–2028)

OFFICIAL WHO
Pakistan: Antimicrobial Resistance National Action Plan (Original NAP, 2017)

OFFICIAL NIH Pakistan
Antimicrobial Resistance — National Institute of Health, Pakistan

OFFICIAL NIH Pakistan
National Antimicrobial Stewardship Plan (NASP)

OFFICIAL WOAH
Pakistan National AMR Action Plan — WOAH

Principal current reference: WHO NAP-AMR 2.0 (2024–2028). Historical context: original 2017 NAP.

Pakistan's AMR response is built around a principle that is increasingly central to modern health governance: resistance cannot be addressed by one profession or one ministry alone. The country's current NAP-AMR 2.0 framework recognises the need for multisectoral action, while the veterinary sector forms an essential part of the One Health response. For the animal-health community, this creates an important responsibility and an opportunity: to strengthen antimicrobial stewardship, support reliable surveillance, promote responsible medicine use and contribute evidence to national AMR decision-making.

ONE HEALTH REQUIRES ONE CONVERSATION

HUMAN HEALTH | ANIMAL HEALTH | AGRICULTURE | ENVIRONMENT

Editorial interpretation of publicly available AMR framework material — not an official government policy statement.

SECTION VIII

What Regulatory Excellence Means to Us

PVPA leadership perspectives on regulatory excellence

Attributed quotations from PVPA Executive Committee leadership

CHAIRMAN

Veterinary vaccines · biologicals · laboratory equipment · testing kits

Dr Asim Mahmood Khan

> *"Regulatory excellence must ensure reliable access to quality-assured veterinary vaccines and biological products, alongside clear standards for laboratory equipment and diagnostic testing kits. These categories underpin disease prevention, farm productivity and public confidence. PVPA urges transparent DRAP registration pathways, timely technical evaluation and consistent quality oversight — so veterinarians and producers can depend on safe, effective products across the animal health chain."*

SENIOR VICE CHAIRMAN

Non-therapeutic nutraceuticals — import & registration under applicable rules

Dr Masud Sadiq Chaudhary

> *"Non-therapeutic veterinary nutraceuticals and allied animal-health products must be registrable through pathways that reflect DRAP's published rules — not administrative gaps. Where systems designed for therapeutic products do not accommodate nutraceutical imports and registration, industry compliance becomes unnecessarily difficult. PVPA continues to engage DRAP on classification, fee challans and import-registration procedures so lawful products reach the market through predictable, rule-based channels."*

VICE CHAIRMEN (NORTH & SOUTH)

Local manufacturing · export market development

Mr Shoaib Amjad · Dr Khalid Iqbal

> *"Local manufacturing strength and export competitiveness are mutually reinforcing goals for Pakistan's veterinary pharmaceutical sector. An enabling regulatory environment — GMP-aligned production, scientifically coherent dossiers and proportionate oversight — supports domestic supply while helping members explore export markets with confidence. PVPA's Vice Chairmen represent industry stakeholders investing in quality manufacturing who seek transparent regulation that strengthens both national self-reliance and international credibility."*

Attributed PVPA leadership perspectives prepared for this commemorative edition. They reflect association priorities and engagement themes; they are not official DRAP, NIH or government policy statements.

SECTION IX — LEADERSHIP IN FOCUS

Dr. Obaidullah Malik addressing stakeholders at a professional industry gathering.

Photograph from official PVPA commemorative materials.

Dr. Obaidullah Malik with industry stakeholders at a professional gathering.

PVPA
ANIMAL HEALTH

Addressing regulators and industry on veterinary pharmaceutical excellence.

SECTION X

Pakistan's Regulatory Future

CURRENT REGULATORY LANDSCAPE

- DRAP's published framework for veterinary pharmaceutical registration includes application pathways using Forms 5, 5A, 5D and 5E, technical evaluation, possible inspection depending on pathway, and Registration Board consideration — extending beyond a single registration decision to manufacturing quality and post-market oversight.
- DRAP's current e-Services infrastructure includes online licensing, product registration, the Registered Drugs Index, batch and barcode systems, and related regulatory case-management tools relevant to pharmaceutical oversight.
- Published GMP guidance under the Drugs Act, 1976 and Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976 establishes manufacturing-quality expectations, while the Division of Quality Assurance & Laboratory Testing undertakes quality surveillance for human and veterinary products.
- Pharmacovigilance Rules, 2022 and DRAP's safety-reporting channels form part of the post-marketing framework. DRAP's published veterinary quality alerts demonstrate active post-market surveillance and coordination with provincial drug-control authorities.
- Pakistan's current National Action Plan for Antimicrobial Resistance, NAP-AMR 2.0 (2024–2028), provides a multisectoral One Health framework explicitly incorporating animal health, veterinary and livestock-sector participation alongside human health and agriculture.

FUTURE OPPORTUNITIES

→ Digital regulatory interfaces — deeper use of DRAP e-Services for licensing, registration, product verification and transparent registry access, subject to DRAP's provisional-data disclaimers on public product listings.

→ Integrated quality and compliance culture — aligning registration dossiers, GMP expectations, pharmacovigilance processes and prompt response to quality alerts across the veterinary pharmaceutical value chain.

→ Multisectoral AMR stewardship — implementing NAP-AMR 2.0 coordination themes and NIH's National Antimicrobial Stewardship Plan objectives for responsible antimicrobial use in human and animal health.

→ One Health governance — strengthening dialogue between DRAP, provincial livestock departments, veterinarians, industry and public-health stakeholders on surveillance, stewardship and food-system considerations.

→ Industry-regulator engagement — constructive PVPA and sector forums on veterinary product classification, export readiness, responsible promotion and evidence-based regulatory dialogue without substituting for official DRAP guidance.

REGULATORY ROADMAP

Digital regulatory transformation
Expanded use of DRAP e-Services for submission, verification and product information.

Pharmacovigilance strengthening
Registration-holder and veterinary reporting through applicable national safety channels.

AMR stewardship integration
NAP-AMR 2.0 (2024–2028) multisectoral coordination including animal-health sectors.

Manufacturing quality assurance
GMP alignment, laboratory oversight and post-market quality surveillance.

One Health governance
Cross-sector coordination on animal health, food safety and public-health interfaces.

Industry-regulator forums
Structured stakeholder dialogue on compliance, stewardship and regulatory clarity.

This section is an editorial overview for industry readers. It does not constitute official DRAP, NIH or government policy, and does not state processing times, approval rates or implementation statistics.

SECTION XI

PVPA & the Regulatory Community

The Pakistan Veterinary Pharmaceuticals Association represents veterinary pharmaceutical manufacturers, importers, distributors, and allied industry stakeholders. PVPA engages regulators, professional bodies, and international partners on matters affecting product quality, responsible use, and industry competitiveness.

- Representing veterinary pharmaceutical stakeholders nationally
- Promoting responsible regulation and compliance culture
- Supporting One Health dialogue and AMR awareness
- Facilitating industry-regulator engagement forums
- Publishing Animal Health Magazine and industry intelligence

Pakistan Veterinary Pharmaceuticals Association

A National Honour, Shared by the Health Community

Pakistan Veterinary Pharmaceuticals Association extends its heartfelt congratulations to Dr. Obaidullah Malik on being selected for the sitara-i-imtiaz in the 2026 independence day civil awards.. May this national recognition mark not only a celebration of past service, but also the beginning of an even greater chapter in Pakistan's journey toward stronger regulation, safer medicines and better health outcomes.

WITH RESPECT AND BEST WISHES

Chairman · Senior Vice Chairman · Vice Chairmen · Executive Members

Pakistan Veterinary Pharmaceuticals Association

PVPA ANIMAL HEALTH

UNITED FOR ANIMAL HEALTH
COMMITTED TO PUBLIC HEALTH

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Special Commemorative Edition 2026