



Government of Pakistan
Ministry of National Health Services,
Regulations & Coordination

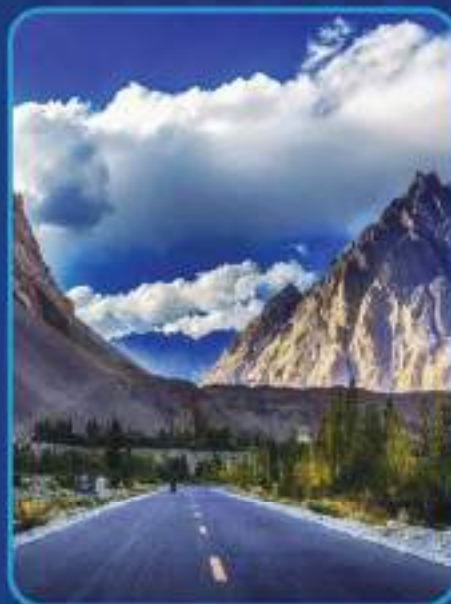
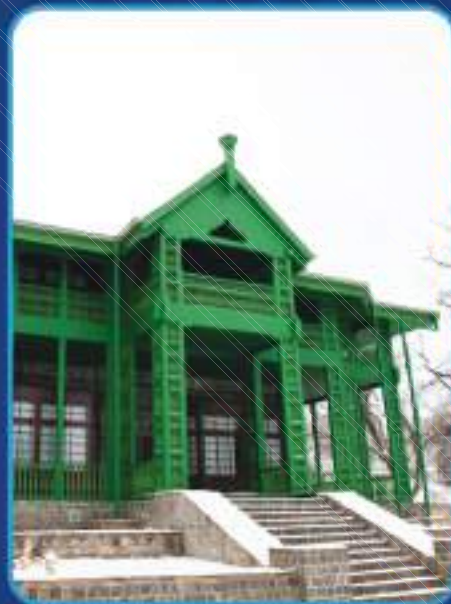


NATIONAL REGULATORY SYSTEM OF PAKISTAN

STRATEGIC PLAN 2026 - 2030



Drug Regulatory Authority of Pakistan
Government of Pakistan





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Ministry of National Health Services,
Regulations & Coordination



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LIST OF ABBREVIATIONS

ADR	Adverse Drug Reaction
AEFI	Adverse Events Following Immunization
AMR	Antimicrobial Resistance
API	Active Pharmaceutical Ingredient
B&A	Budget and Accounts
BA	Bioavailability
BE	Bioequivalence
BE&R	Biological Evaluation and Research
C&P	Costing and Pricing Division
CDL	Central Drug Laboratory Karachi
CE	Conformité Européenne
CLB	Central Licensing Board
CMS	Content Management System
CMU	Common Management Unit
CoE	Center of Excellence
CoPP	Certificate of Pharmaceutical Products
CRO	Contract Research Organization
CTD	Common Technical Document
CTS	Clinical Trial Site
DCA	Drug Control Administration
DDCP	Directorate of Drug Control Punjab
DIA	Drug Information Association
DMS	Document Management System
DRAP	Drug Regulatory Authority of Pakistan
DTL	Drug Testing Laboratory
E-APP	Electronic Application
EEC	Enlistment Evaluation Committee
E-Office	Electronic Office
EPI	Expanded Program on Immunization
EU	European Union
EUA	Emergency Use Authorization
FID	Federal Inspector of Drugs
FSC	Free Sale Certificate
GBT	Global Benchmarking Tool
GCP	Good Clinical Practice
GMP	Good Manufacturing Practices
GSDP	Good Storage and Distribution Practices
GWHP	Global Harmonization Working Party
H&OTC	Health & OTC
HCP	Healthcare Professional
ICH	International Council for Harmonization of Technical Requirements for Pharmaceutical for Human Use
ICSR	Individual Case Safety Report
ICT	Islamabad Capital Territory
IDMP	Identification of Medical Products
IDP	Institutional Developmental Plan
iQMS	Integrated Quality Management System
ISO	International Standard Organization
IVD	In-vitro diagnostics
KPI	Key Performance Indicator

LEA	Law Enforcement Agencies
LIMS	Laboratory Information Management System
LMS	Learning Management System
MA	Marketing Authorization
MDB	Medical Device Board
MDMC	Medical Devices and Medicated Cosmetics
MIS	Management Information System
ML	Maturity Level
NAP	National Action Plan
NCLB	National Control Laboratories for Biologicals
NHPP	National Health and Population Policy
NHSR&C	National Health Services, Regulation and Coordination
NIH	National Institute of Health
NOC	No Objection Certificate
NQCLs	National Quality Control Laboratories
NQCN	National Quality Control Network
NRS	National Regulatory System
PE&R	Pharmaceutical Evaluation and Registration
PHP	Public Health Program
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PID	Provincial Inspector of Drugs
PIL	Patient Information Leaflet
PPMA	Pakistan Pharmaceutical Manufacturers Association
PPP	Public Private Partnership
PQCB	Provincial Quality Control Board
PRAEC	Pharmacovigilance Risk Assessment Expert Committee
PS	Pharmacy Services
PSW	Pakistan Single Window
QA&LT	Quality Assurance & Lab Testing Division
RB	Registration Board
RB-PMS	Risk Based Post Market Surveillance
RMP	Risk Management Plan
RS	Regulatory System
SAE	Serious Adverse Event
SDG	Sustainable Development Goal
SF	Substandard and falsified
SIFC	Special Investment Facilitation Council
SmPC	Summary of Product Characteristics
SOP	Standard Operating Procedure
SRA	Stringent Regulatory Authority
TG	Therapeutic Goods
UHC	Universal Health Coverage
USP	United States Pharmacopoeia
WHO	World Health Organization
WLA	WHO Listed Authority

Message



The Government of Pakistan recognizes the regulation of Therapeutic Goods as a sovereign obligation to protect the life and dignity of every citizen. As we launch the Strategic Plan 2026-2030 for the National Regulatory System of Pakistan, our vision is to transform DRAP and other relevant institutions into a global benchmark of excellence that is essential for national health security and the country's economic revitalization. This plan represents a high-level commitment to ensuring that our healthcare ecosystem is strengthened against emerging global risks through a regulatory framework that is uncompromising on quality, rigorous in its transparency, and fully aligned with our national aspirations for self-reliance in essential medicines, vaccines and medical devices.

Our strategic direction necessitates a fundamental shift from traditional regulatory oversight to being a proactive enabler that catalyzes the national pharmaceutical industry while enforcing international standards such as WHO Global Benchmarking Tool (GBT) and Pharmaceutical Inspection Cooperation Scheme (PIC/S), etc. We aim to transform Pakistan into a competitive global player in life sciences by promoting a climate of regulatory predictability and ease of doing business. Such steps will not only provide better treatment options for our citizens but will also help in foreign exchange earnings through high-value exports and the reduction of the fiscal burden of imported finished goods. A strong local industry supported by an efficient regulator is inseparable from our public health goals, and it is the only sustainable pathway to ensuring that life-saving treatments remain affordable and accessible to the millions of citizens we serve.

The recent award of "Reform Champion" to DRAP from the Government of Pakistan is a clear indication that DRAP's reform strategy is being successfully executed. We are resolute in establishing evidence-based governance and comprehensive digital integration across the entire therapeutic supply chain. The aforementioned coordinated reforms will safeguard patient safety and demonstrate the State's capacity to provide a reliable healthcare ecosystem. I am confident that the implementation of these strategic objectives will secure a resilient public health infrastructure, project Pakistan's regulatory maturity on the global stage, and contribute meaningfully to the long-term health and socio-economic stability of our nation.

A blue ink signature of Syed Mustafa Kamal, written in a stylized, cursive script.

Syed Mustafa Kamal

Federal Minister, National Health Services,
Regulation & Coordination

Message

The efficacy of the national health system is fundamentally rooted in the integrity, coherence and accountability of its regulatory governance. This Strategic Plan advances a more coordinated, evidence-based, and transparently monitored National Regulatory System by clarifying institutional roles, strengthening joint coordination forums, and instituting performance-review mechanisms. The National Regulatory System Strategic Plan 2026–2030 provides a governance framework to translate national commitments into consistent regulatory practice across federal and provincial institutions. It consolidates mandates, harmonizes core procedures, and sets time-bound targets so that regulatory decisions remain predictable, auditable, and anchored in law and scientific evidence.



Being the Chairman of the Policy Board of DRAP, I endorse our commitment to strengthening institutional capacity through regulatory reforms, modernization of legal and operational frameworks, and alignment with internationally recognized standards. DRAP's notable progress in improving regulatory efficiency, transparency, and predictability—reinforced by strengthened coordination with national and international stakeholders—has been acknowledged through the Prime Minister's "Reform Champion" award, reflecting the successful execution of a comprehensive reform initiative. Simultaneously, focused efforts are underway to further strengthen end-to-end oversight of the therapeutic goods lifecycle, ensuring quality assurance, supply chain integrity, and full regulatory compliance. The Ministry also affirms the importance of continuous regulatory learning, evidence-based policy development, and preparedness to address emerging public health challenges as an essential component of national health security.

This Strategic Plan provides a structured and forward-looking framework for policy oversight, institutional accountability, and continuous improvement. It outlines a systematic approach to advancing regulatory maturity and enhancing the professional competence of the workforce entrusted with these vital functions. Its effective implementation will further strengthen the public trust and enable the Ministry to deliver a resilient, well-governed, and future-ready health regulatory system at the national level.

Hamed Yaqoob Sheikh

Hamed Yaqoob Sheikh

Federal Secretary, NHR&C
Chairman Policy Board, DRAP

Message



The regulation of Therapeutic Goods remains a cornerstone of an effective, equitable, and trustworthy health system, requiring strong coordination, institutional coherence, and sustained commitment across all tiers of governance. Pakistan's National Regulatory System continues to evolve as a mature and increasingly integrated framework, reflecting these principles while contributing to the country's broader public health, population, and economic priorities.

The Strategic Plan 2026–2030 represents a significant step in consolidating regulatory reforms and translating them into measurable system-wide performance, resilience, and accountability. In doing so, the Plan aligns with national efforts to strengthen health systems through improved access to safe, effective, and quality-assured Therapeutic Goods, while supporting a more coordinated and people-centered approach to health service delivery. By reinforcing national collaboration, strengthening institutional processes, and promoting innovation-responsive and science-based regulation, the Plan provides a clear and forward-looking pathway for enhancing regulatory effectiveness.

The Ministry of National Health Services, Regulations and Coordination (MoNHSR&C) will continue to play its central coordination and oversight role in supporting the implementation of this Strategic Plan, with a focus on ensuring policy coherence, inter-sectoral alignment, and sustained engagement with provincial governments and development partners. Particular emphasis will be placed on strengthening governance mechanisms, performance monitoring, and risk-based regulatory approaches, thereby contributing to a more integrated, data-informed, and responsive health system.

I commend the leadership of the Drug Regulatory Authority of Pakistan, Provincial and State Drug Control Administrations, and all stakeholders who contributed to the development of this Strategic Plan. Their collective efforts are vital to advancing a regulatory system that not only safeguards public health and ensures patient safety, but also supports innovation, self-reliance, and the sustainable development of Pakistan's Therapeutic Goods sector within the broader national health and population landscape.

A handwritten signature in blue ink, appearing to read 'Muhammad Aslam Ghauri', written over a white background.

Muhammad Aslam Ghauri

Special Secretary, NHSR&C

Foreword



Drug Regulatory Authority of Pakistan (DRAP) is mandated to ensure access to quality assured, safe and efficacious Therapeutic Goods. To fulfill this mandate, DRAP is focusing on strengthening the National Regulatory System through the adoption of international best practices. This Five-Year Strategic Plan (2026-2030) represents DRAP's commitment to transform the existing National Regulatory System into a more effective and functional governance system that uses scientific rigor and a digitally transformed system for evidence-based decision making across all functions mandated for an effective regulation of Therapeutic Goods. It outlines essential reformation steps of digitization, optimization of processes and enhanced transparency for increasing the public's access to Therapeutic Goods and providing ease of doing business.

Undoubtedly, a well-functioning, proactive regulatory system is directly proportional to the quality of public health outcomes. To this end, a need for a national framework that balances the imperatives of safety assessment with the necessity of timely access to therapeutic goods has been identified as a central point for the development of this plan. Accordingly, this Strategic Plan is aligned with the United Nations Sustainable Development Goals, URAAN Pakistan and the National Health and Population Policy 2026-2035. The objectives within this plan have been finalized after completing a comprehensive consultation process within DRAP, M/o NHR&C, Drug Control Administrations of provinces, Islamabad Capital Territory, Azad Jammu and Kashmir and Gilgit-Baltistan, representative bodies of Therapeutic Goods Industry, academia, Health Services Academy, Public Health Programs, International Health Partners (WHO, UNDP, USP, DIA, Fleming Fund), etc.

This Strategic Plan is our roadmap for the modernization National Regulatory System. DRAP has recalibrated its operational philosophy from a reactive organization to a fully functioning proactive entity. We will strengthen the institutional capacity of all institutions of the National Regulatory System (DRAP, Provincial and State Drug Control Administrations, etc.), further streamline our regulatory processes, and align our standards with the best global practices. By optimizing transparency, maximizing operational efficiency, and embedding evidence-based decision-making, this plan immediately positions DRAP to proactively manage public health challenges, foster responsible innovation, and ensure the consistent, nationwide availability of essential medicines and health technologies.

The successful implementation of this Strategic Plan will not merely enhance our regulatory framework; it will fundamentally deepen public trust in DRAP and other regulatory bodies and advance our mission of equitable access for all Pakistanis. This strategic trajectory reinforces our contribution to a resilient, well-governed, and future-ready national health system, reflecting our unwavering commitment to public health and sustainable national development. I urge all stakeholders to join us in executing this vital mission for securing a healthier future for Pakistan.

Dr. Obaidullah

Chief Executive Officer

Acknowledgment

The Drug Regulatory Authority of Pakistan extends its profound appreciation to the Chairman and Members of the Policy Board for their stewardship and policy guidance, which provided the strategic direction essential for the development of the National Regulatory System Strategic Plan 2026–2030. DRAP acknowledges the leadership of its Chief Executive Officer and the Directors of the Authority, whose coordination and technical guidance enabled the preparation of this forward-looking framework for strengthening national regulatory systems.

The Authority extends appreciation to all the Provincial and State Drug Control Administrations (Punjab, Sindh, Khyber Pakhtunkhwa, Balochistan, Azad Jammu and Kashmir, Gilgit-Baltistan, and Islamabad Capital Territory) for their contributions and coordinated engagement, which ensured national coherence and shared ownership of this Plan.

DRAP also recognizes the constructive contributions of national stakeholders, including academia, Therapeutic Goods industry associations, professional bodies, development partners, and national health programs. The Authority values the sector-specific inputs from the Board of Investment (BOI), Pakistan Pharmaceutical Manufacturers Association (PPMA), Pharma Bureau, Healthcare Devices Association of Pakistan (HDAP), Homeopathic Pharmaceutical & Chemist Association (HPCA), Pakistan Tibbi Pharmaceutical Manufacturers Association (PTPMA), Pakistan Nutraceutical Manufacturers Association (PNMA), Pakistan Electromedical Equipment Manufacturers & Distributors Association (PEEMDA), Drug Information Association (DIA), Fleming Fund (FF), the United Nations Development Programme (UNDP), and the United States Pharmacopeia (USP), which strengthened the plan's technical relevance and operational applicability.

Special appreciation is extended to Dr. Dapeng Luo (WR Pakistan), Dr. Muhammad Naveed Asghar (Team Lead, Health System) and Mr. Asad Ullah (Technical Officer, NRA) from World Health Organization for sustained technical and financial support in aligning this plan with the global regulatory benchmarks, maturity-level framework and to Mr. Mehmood Anwar, Consultant, for guidance and review of the strategic plan.

DRAP acknowledges the contributions of iQMS team; Dr. Muhammad Fakhruddin Aamir, Mr. Ajmal Sohail Asif, Dr. Hassan Afzaal, Dr. Muhammad Haseeb Tariq, Mr. Ammar Ashraf Awan, Mr. Abdul Mughees Muddassir, Dr. Hanif Ullah and Mr. Muhammad Ayub Naveed for their proofing efforts in preparation of this Strategic Plan. DRAP expresses gratitude to all contributors and reaffirms its commitment to protecting public health, fostering innovation, and ensuring equitable access to quality-assured, safe and efficacious Therapeutic Goods for the people of Pakistan and beyond.

Executive Summary



Pakistan has developed a vibrant and evolving regulatory ecosystem that ensures public health protection and drives industrial progress and innovation. Spanning from federal oversight to provincial and state level administrative structures extending further to district-level implementation, the National Regulatory System ensures that responsibilities for regulating Therapeutic Goods are clearly defined and effectively executed across all tiers of governance. The DRAP sets the country's regulatory direction and provides national stewardship by establishing harmonized standards, ensuring scientific rigour and evidence-based governance, in collaboration with the Provincial and State Drug Control Administrations which carry out regulatory functions for distribution, sale, storage, post-marketing surveillance, pharmacovigilance, and quality control testing in their jurisdictions.

Building on the Strategic Plan 2022–2025, which initiated foundational reforms, DRAP has now positioned the National Regulatory System for the next phase of strategic evolution. The earlier plan advanced the system from functional modernization toward systemic maturity, strategic agility, sustainability, and international recognition. Tangible achievements include progress in quality management, digitalization, pharmacovigilance, and stakeholder engagement in consolidating DRAP's role as the national regulatory hub and laying the groundwork for future transformation.

Recognizing the need to sustain momentum, DRAP has developed the Strategic Plan 2026–2030 for the National Regulatory System of Pakistan through a structured and consultative process. A Strategic Planning Steering Committee (SPSC) was established to define the scope, process, and timelines for comprehensive reviews, including strengths, weakness, opportunities and threats (SWOT) and political, economic, social/cultural technological, legal and environmental factors (PESTLE) analyses, alongside an internal evaluation of the previous cycle's performance and alignment with WHO Global Benchmarking Tool (GBT) findings and the Institutional Developmental Plans (IDP). Extensive consultations with leadership, management, staff, as well as internal and external stakeholders resulted in the new vision, mission, and strategic priorities.

The Strategic Plan 2026–2030 provides a robust and forward-looking framework to advance regulatory excellence across the National Regulatory System. It focuses on strengthening system-wide maturity, enabling innovation-responsive and science-based regulation, promoting regulatory convergence, building institutional resilience, and deepening regional and global partnerships. Through sustainable, transparent, and accountable oversight, this Plan aims to enhance equitable access to new and emerging therapies while fostering a predictable and conducive regulatory environment that delivers sustained public health impact and supports the responsible growth of the Therapeutic Goods industry.

Based on comprehensive desk reviews and broad consultations with the leadership, management, and regulatory staff from DRAP, provincial and state drug control administrations, and other key internal and external stakeholders, the National Regulatory System will pursue this renewed strategic vision, mission, values, strategies and goals from 2026 to 2030.

To ensure effective implementation, DRAP has instituted a multi-tiered performance management and monitoring framework, combining top-down oversight with a bottom-up feedback mechanism, integrated with a risk management and mitigation matrix to reinforce resilience and accountability.





Introduction

**STRATEGIC PLAN
2026 - 2030**

**NATIONAL REGULATORY
SYSTEM OF PAKISTAN**

The National Health and Population Policy (NHPP) 2026-35 reaffirms Pakistan's commitment to global goals, particularly the Sustainable Development Goals (SDGs). It also broadens the scope to include emerging concerns such as high population growth, health security, climate change, health resilience and other multi-sectoral determinants of health and wellbeing. NHPP further emphasize to, "Ensure access to effective, affordable, and quality-assured medicines, vaccines, contraceptives, and health products through well-functioning regulatory system, strengthened procurement supply chain, responsible and rational use, and enhanced local production supported by international collaboration".¹

The Drug Regulatory Authority of Pakistan safeguards the health of ~240 million nationals; regulates the Therapeutic Goods market exceeding PKRs 1.5 trillion and exports ~\$1billion annually. The Authority oversees ~1380 Therapeutic Goods manufacturers (i.e. Pharmaceuticals and Biologicals ~710, Health and Alternative Products ~570, Medical Devices~100) ~2500 importers and distributors for regulatory compliance. Established after the promulgation of the DRAP Act 2012 as an autonomous federal authority under the Ministry of National Health Services Regulations & Coordination, DRAP operates through an inclusive approach with provincial representation engrained in DRAP's governance and statutory bodies including Policy Board, Appellate Board, Registration and Central Licensing Boards. This approach ensures national and subnational harmonization and inclusive decision-making.



Drug Regulatory Authority of Pakistan Act, 2012

To provide national leadership in Therapeutic Goods regulation through advising the provincial governments for the laws that are applicable to the provinces.²

The operational infrastructure supporting DRAP's functions comprises its headquarters in Islamabad, regional field offices established in each provincial capital, performing active surveillance for the product life cycle through coordinated activities with Law-Enforcement Agencies and respective provincials and state drug control administrations. The Central Drug Laboratory in Karachi, the Drug Testing Laboratories in all provinces and states, and the National Control Laboratories for Biologicals at Islamabad perform laboratory testing and analysis function. This integrated national and subnational architecture constitutes Pakistan's National Regulatory System (NRS), ensuring access to quality-assured, safe and efficacious Therapeutic Goods, safeguarding health security, advancing national public health and developing sustainable objectives. Since its inception, DRAP has evolved into the central regulatory institution of the NRS, implementing a science-based, transparent, and internationally aligned regulatory framework.

¹ National Health & Population Policy 2026-2035

² Section 7 (a) of the Drug Regulatory Authority of Pakistan Act 2012

Strategic Direction



VISION

To be a **globally trusted** and **nationally responsive** regulatory authority that ensures **equitable access** to **safe, effective**, and **quality** Therapeutic Goods, fosters **innovation**, local **manufacturing**, and strengthens **public health** through **transparent, accountable**, and **sustainable** systems.



MISSION

To regulate Therapeutic Goods with **scientific integrity, efficiency**, and **transparency**; ensuring public **health protection**, enabling **industrial growth**, and advancing **innovation** in alignment with **national priorities** and **global standards**.



Values



SCIENTIFIC EXCELLENCE

Base all decisions on sound evidence and international standards



COLLABORATION

Building partnerships with stakeholders and global NRAs



INTEGRITY

Acting with transparency, honesty and impartiality in all regulatory processes



INNOVATION TECHNOLOGIES

Encouraging modernization and adoption of advanced regulatory system



TRANSPARENCY

Promoting open access to regulatory decisions and public communication.



SUSTAINABILITY

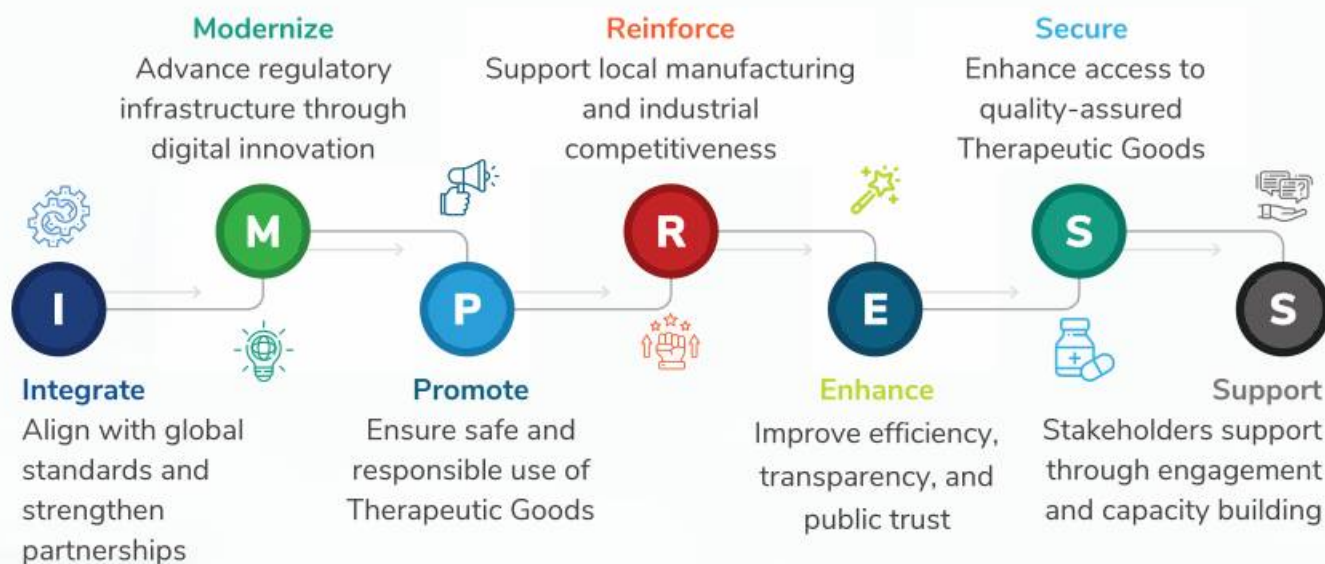
Upholding environmental and institutional responsibility.



CONTINUOUS LEARNING

Strengthening skills to enhance regulatory excellence

KEY STRATEGIES 2026 - 2030



STRATEGIC GOALS



Standardized & Globally Aligned
Regulatory Systems & Stronger
Partnerships

Efficient, Transparent &
Trusted Regulatory Services

End-to-End Supply Chain
Optimization & Quality
Assurance

Research, Learning, Advocacy &
Security.

DRUG REGULATORY AUTHORITY OF PAKISTAN



ISLAMABAD (ICT)

Pharmacy Services
and Drug Control
ICT



GILGIT BALTISTAN

Drug Control
Administration
Gilgit-Baltistan



KHYBER PAKHTUNKHWA

Drug Control and
Pharmacy Services
KP



AZAD JAMMU & KASHMIR

Drug Control
Administration
AJ&K



PUNJAB

Directorate of
Drugs Control
Punjab



BALOCHISTAN

Drug Control
Administration
Balochistan



SINDH

Drug Control
Administration
Sindh





An Overview of the National Regulatory System in Pakistan

**STRATEGIC PLAN
2026 - 2030**

**NATIONAL REGULATORY
SYSTEM OF PAKISTAN**

Pakistan's regulatory system for Therapeutic Goods has evolved into a comprehensive framework designed to protect public health by ensuring the quality, safety, and efficacy of pharmaceuticals, biologicals, medical devices, and health & OTC products throughout their lifecycle. The system operates under a strong legal foundation built primarily on the DRAP Act, 2012, the Drugs Act, 1976, and the rules and regulations framed thereunder. These laws collectively establish a coordinated mechanism, supported by regulatory institutions across federating units, pharmacovigilance centers, quality control laboratories, specialized drug courts, and statutory bodies responsible for policy, technical decision-making, oversight, and enforcement.

At the federal level, the Drug Regulatory Authority of Pakistan functions as the national regulatory authority with nationwide jurisdiction for Therapeutic Goods. Established under the DRAP Act, 2012, DRAP is responsible for regulation of Therapeutic Goods in terms of manufacturing, product registration/market authorization, regulatory inspection, pricing, import/export, and lot release of vaccines, sera and blood products. It also oversees the authorization, monitoring, and inspection of clinical trials, while ethical review of human research is carried out independently by the National Bioethics Committee (NBC). The Provincial and State Drug Control Administrations regulate the sale, storage, and distribution within their jurisdiction. Pharmacovigilance and post-market surveillance, laboratory testing functions are jointly carried out by DRAP and the Provincial/State Drug Control Administrations through structured coordination to ensure seamless, end-to-end oversight of product quality, safety and availability nationwide.

The Authority, constituted under Section 4 of the DRAP Act 2012, consists of the Chief Executive Officer and thirteen Directors, and exercises the powers set out in Section 7 to administer laws on Therapeutic Goods, issue and enforce standards and guidelines, coordinate with provinces, and perform licensing, registration, pricing and other allied functions. Strategic direction, budget approval and oversight of DRAP's performance rest with the Policy Board, chaired by the Federal Secretary of the Ministry of National Health Services, Regulations & Coordination. DRAP executes its regulatory functions through its technical Divisions and is supported by statutory decision making structures, including Central Licensing Board (CLB), Registration Board (RB), Medical Devices Board (MDB), Drug Pricing Committee (DPC), Clinical Study Committee (CSC), Enlistment Evaluation Committee (EEC), Pharmacovigilance Risk Assessment Expert Committee (PRAEC), Advertisement Board, and Appellate Board along with other expert committees, which together enable evidence-based decisions on licensing, product evaluation, clinical trials oversight, pharmacovigilance, market surveillance and control, regulatory inspections, laboratory testing and lot release.

One of the key pillars of regulatory system is the nationwide network of Drug Testing Laboratories (DTLs), comprising eleven laboratories including five WHO-prequalified laboratories. These laboratories are located across Punjab (Lahore, Faisalabad, Multan, Bahawalpur, Rawalpindi), Sindh (Karachi), Balochistan (Quetta), Khyber Pakhtunkhwa (Peshawar), Azad Jammu & Kashmir (Mirpur), and Gilgit-Baltistan. These laboratories conduct testing of drugs against the pharmacopeial and regulatory standards and play critical role in detecting substandard and falsified products, generating legal evidence and guiding regulatory actions relating to recalls, suspensions, cancellations, and prosecutions.

As part of the coordinated national regulatory framework, the Provincial and State Drug Control Administrations are mandated under the DRAP Act 2012 and the Drug Act 1976 to regulate the sale, storage, and distribution within their jurisdiction. These drug control administrations include the Directorate of Drug Control Punjab, Directorate of Pharmacy Services, Khyber Pakhtunkhwa, and Drug Control Unit of Sindh, Balochistan, Azad Jammu & Kashmir, Gilgit-Baltistan; and the Pharmacy Services and Drug Control Unit (ICT). These bodies license pharmacies, distributors, and medical stores; conduct Good Storage and Distribution Practices (GSDP) inspections; market surveillance; investigate complaints; and field enforcement as per relevant legislation. Provincial Quality Control Boards (PQCBs) authorizes prosecutions and oversee legal actions, while the districts in Punjab also have the District Quality Control Boards (DQCBs) for localized

regulatory oversight. The close coordination between DRAP and provincial/state administrations structured through formal communication channels, the Task Force and other coordination mechanism ensures harmonized implementation of national laws across all federating units.

Enforcement of regulatory decisions is further strengthened through specialized Drug Courts, established under the Drugs Act, 1976. Located in Punjab (Lahore, Rawalpindi, Faisalabad, Multan, Bahawalpur, Sargodha), Islamabad, Sindh, Khyber Pakhtunkhwa, Balochistan, Azad Jammu and Kashmir, and Gilgit-Baltistan, these courts provide adjudication of drug-related offences lodged by Inspector of Drugs.

Registration and Marketing Authorization (MA):

Registration and Marketing Authorization of Therapeutics Goods for human and veterinary use is centrally performed by DRAP under the DRAP Act, 2012 and the Drugs Act, 1976 and rules framed thereunder. DRAP evaluates the quality, safety, and efficacy of pharmaceutical products, biological products, medical devices including IVDs, and alternative medicines and health products through structured technical review and evaluation of application dossiers. For pharmaceutical and biological products, registration applications follow the ICH Common Technical Document (CTD) format, ensuring alignment with international regulatory standards, while Medical Devices and Health & OTC products follow their respective product-specific formats and regulatory requirements. Reliance pathways are applied to optimize regulatory efficiency in line with global and regional standards.

The Registration Board (RB) is the statutory decision-making body responsible for granting approvals, renewals, variations, suspensions, and cancellations for medicines and biological products, including vaccines, sera, and blood products. Decisions for medical devices fall under the Medical Devices Board (MDB), which evaluates and authorizes applications for the enlistment or registration of medical devices. For alternative medicines and health products, the Evaluation Committee (EEC) is competent to grant approvals, renewals, variation, suspend, or cancel/revoke the enlistment in accordance with the Alternative Medicines and Health Products (Enlistment) Rules.

Pharmacovigilance:

National Pharmacovigilance Centre (NPC) at DRAP coordinates with Provincial Pharmacovigilance Centres and Public Health Programmes for the collection, assessment, and management of Adverse Drug Reactions (ADRs) and Adverse Events Following Immunization (AEFIs) in the country. Adverse event reporting is enabled through VigiMobile for healthcare professionals and the public, with data managed in VigiFlow through designated focal points. The NPC performs signal detection, benefit–risk evaluation, and safety communication functions, and collaborates with the WHO Programme for International Drug Monitoring (PIDM) and Uppsala Monitoring Centre (UMC), Sweden.

The Pharmacovigilance Risk Assessment Expert Committee (PRAEC) provides scientific recommendations on regulatory actions based on pharmacovigilance data. These recommendations include changes in product labelling, Risk Management Plan requirements, post-authorization studies, suspensions, or withdrawals of market authorization/registration. Final regulatory actions are taken by the relevant statutory boards considering PRAEC's recommendations.

Pharmacovigilance has become an integral component of the system with the establishment of the National Pharmacovigilance Center at DRAP, supported by provincial/regional pharmacovigilance centers in all federating Units and Public Health Programs. These centers collect and analyze adverse drug reaction (ADR) reports, coordinate signal detection, conduct risk assessments, and recommend regulatory actions such as label changes, safety alerts, variations, or market withdrawals through the PRAEC.

Market Surveillance and Control:

Post-market surveillance is executed jointly by DRAP and Provincial/State Drug Control Administrations. The Quality Assurance and Laboratory Testing (QA<) Division, in coordination with Provincial/State Drug Control Administrations, conducts targeted and risk-based sampling, complaint investigations, falsified/substandard product detection, and issuance of rapid alerts and recalls, and conducts field enforcement and verification of supply chain compliance under their legal mandate.

Market recall of substandard and falsified (SF) Therapeutic Goods is carried out through a coordinated national mechanism. A Product Recall Alert is issued based on trigger information, including laboratory findings, pharmacovigilance signals, or field surveillance, and is followed by monitoring and oversight by the inspectors/field force of DRAP and Provincial and State Drug Control Administrations to ensure removal from all supply-chain levels. This joint prevent-detect-respond approach ensures timely removal of SF products from the supply chain and protects public health.

Licensing of Establishment:

DRAP licenses pharmaceutical and biological manufacturers through its Division of Drug Licensing, medical device establishments through the Medical Devices & Medicated Cosmetics (MDMC) Division, and alternative medicine and health product manufacturing and importer facilities through the Health & OTC (H&OTC) Division. Similarly, licensing of pharmacies, distributors, and medical stores is carried out by the respective Provincial or State Drug Control Administrations under Section 6 of the Drugs Act, 1976.

Regulatory Inspection:

Regulatory inspections of manufacturing facilities are conducted by DRAP to monitor compliance with current Good Manufacturing Practices (cGMP). The national framework for inspection of pharmaceutical and biological products for human use has been upgraded by the adoption of PIC/S GMP guide, thereby replacing Schedule B-II under the Drug (Licensing, Registering and Advertising Rules) 1976. The Provincial/State Drug Control Administrations conduct inspections of distribution chains, pharmacies, and medical stores for compliance with Good Storage and Distribution Practices (GSDP).

DRAP also performs Good Clinical Practice (GCP) inspections of clinical trial sites, CROs, and BA/BE centres under the Bio-Study Rules as part of clinical trial oversight. Inspections may be routine, risk-based, pre-approval, or for-cause and are documented through standardized procedures and classification of observations.

Laboratory Testing:

Laboratory testing is carried out through a structured national network consisting of 11 laboratories. This network includes the WHO Prequalified Central Drug Laboratory (CDL) Karachi, which functions under DRAP, five WHO Prequalified Drug Testing Laboratories in Punjab and one each in Sindh, Khyber Pakhtunkhwa, Balochistan, Azad Jammu & Kashmir, and Gilgit-Baltistan. These laboratories perform testing of samples to verify compliance with product specifications and regulatory standards, support the detection of substandard and falsified Therapeutic Goods, and generate analytical evidence for regulatory and legal actions.

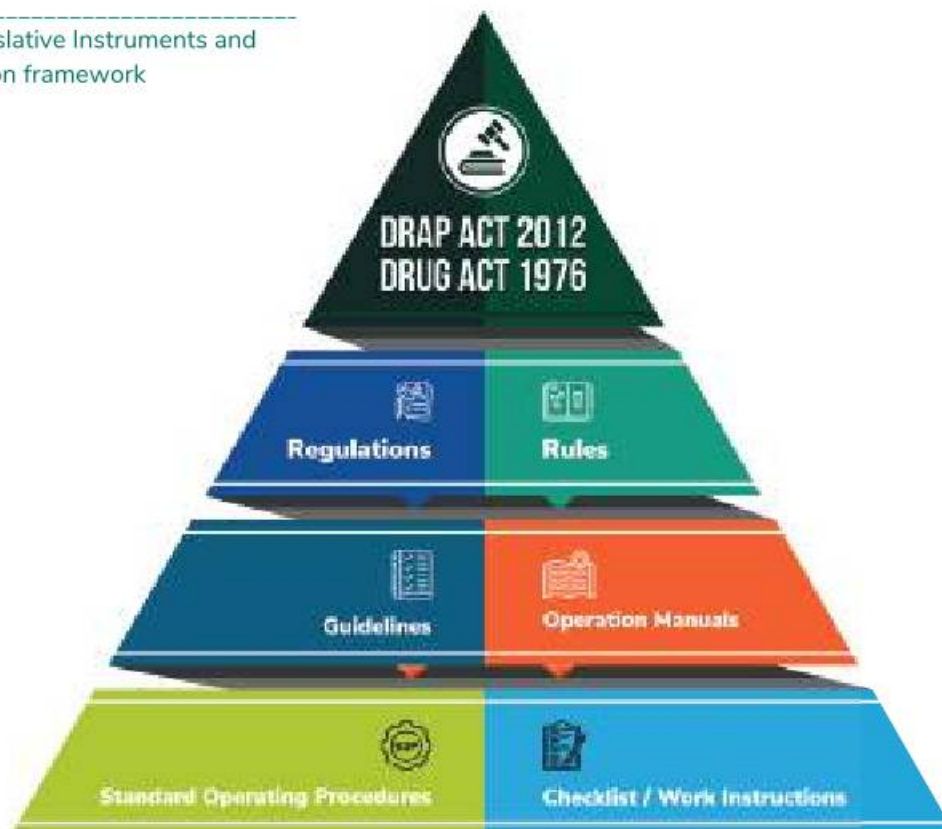
Clinical Trials Oversight:

Clinical trials oversight is carried out by DRAP under the Bio-Study Rules, 2017. The regulatory activities include authorization of clinical trials, the licensing of Contract Research Organizations (CROs), Bioequivalence Centres, and Clinical Trial Sites, and the inspection of these facilities for compliance with Good Clinical Practice (GCP) in line with ICH-GCP guidelines. Ethical review of all human research is carried out by the independent National Bioethics Committee (NBC), which operates separately from DRAP. The CSC is the statutory decision-making body empowered to grant, renew, suspend, or cancel approvals for clinical trials and associated functions.

Lot Release:

Lot release for vaccines, sera and blood products is performed by the National Control Laboratories for Biologicals (NCLB), based on review of summary protocol, batch documentation and laboratory testing where required. Reliance approach is applied for lot release for products that are WHO-prequalified or approved by Stringent Regulatory Authorities (SRAs) or WHO Listed Authorities (WLA).

Figure 1: Legislative Instruments and Implementation framework



Pakistan is a full member of the WHO Programme for International Drug Monitoring (PIDM) and participates as a member country in the Global Harmonization Working Party (GHWP) for medical devices, contributing to international harmonization efforts. The DRAP maintains MoUs with National Regulatory Authorities of several countries, and national and international academic institutions, and actively engages in technical working groups, regional networks, and global consortia to strengthen regulatory collaboration, capacity building, and policy alignment.

Taken together, Pakistan's Therapeutic Goods regulatory system operates as a coordinated framework supported by digitalization, a maturing quality management system, and alignment with internationally recommended good regulatory practices, forming the foundation for protecting public health and ensuring the availability of safe, effective, and quality-assured Therapeutic Goods for all citizens of Pakistan and beyond.

Figure 2: National Therapeutic Goods Regulatory System at a glance

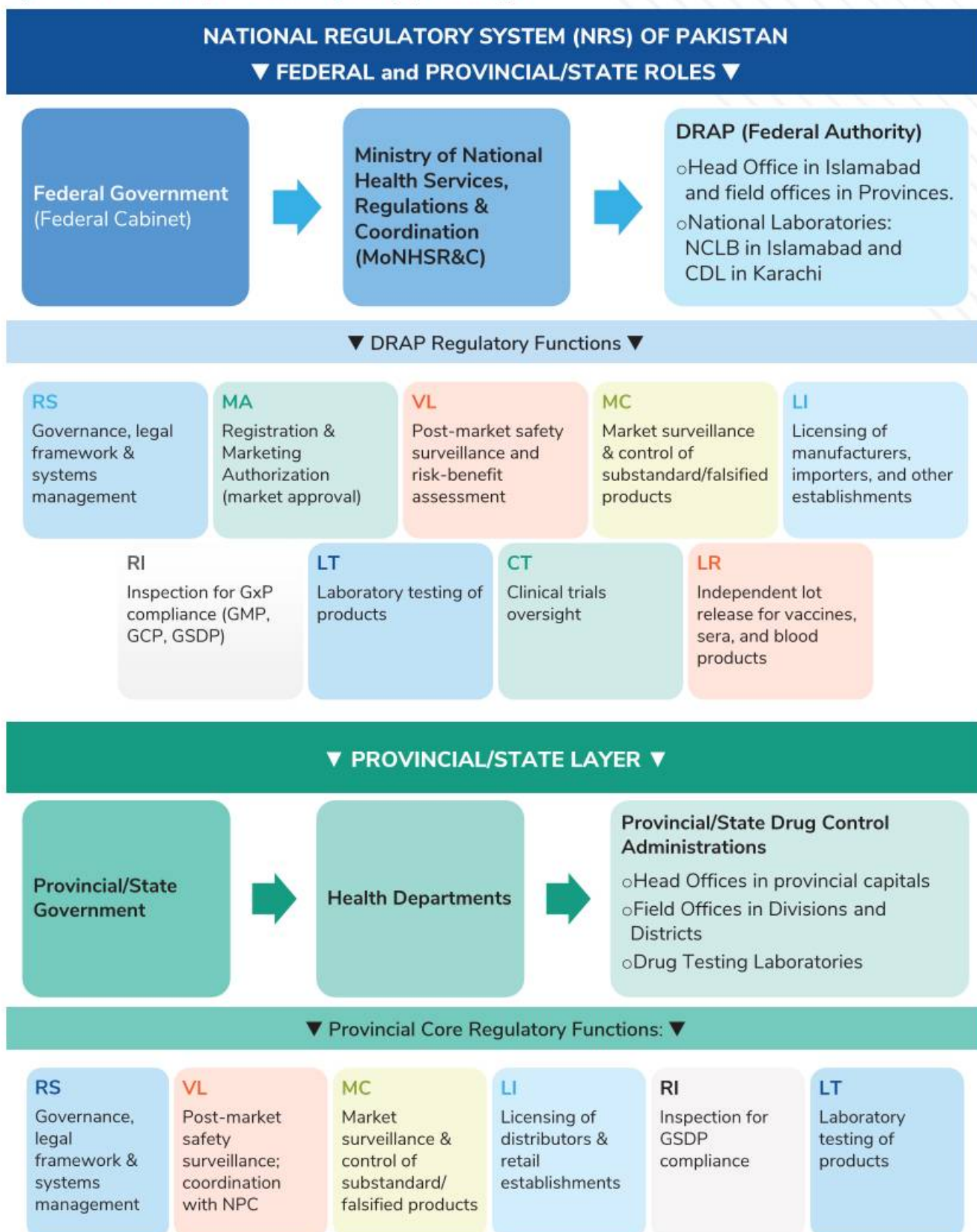
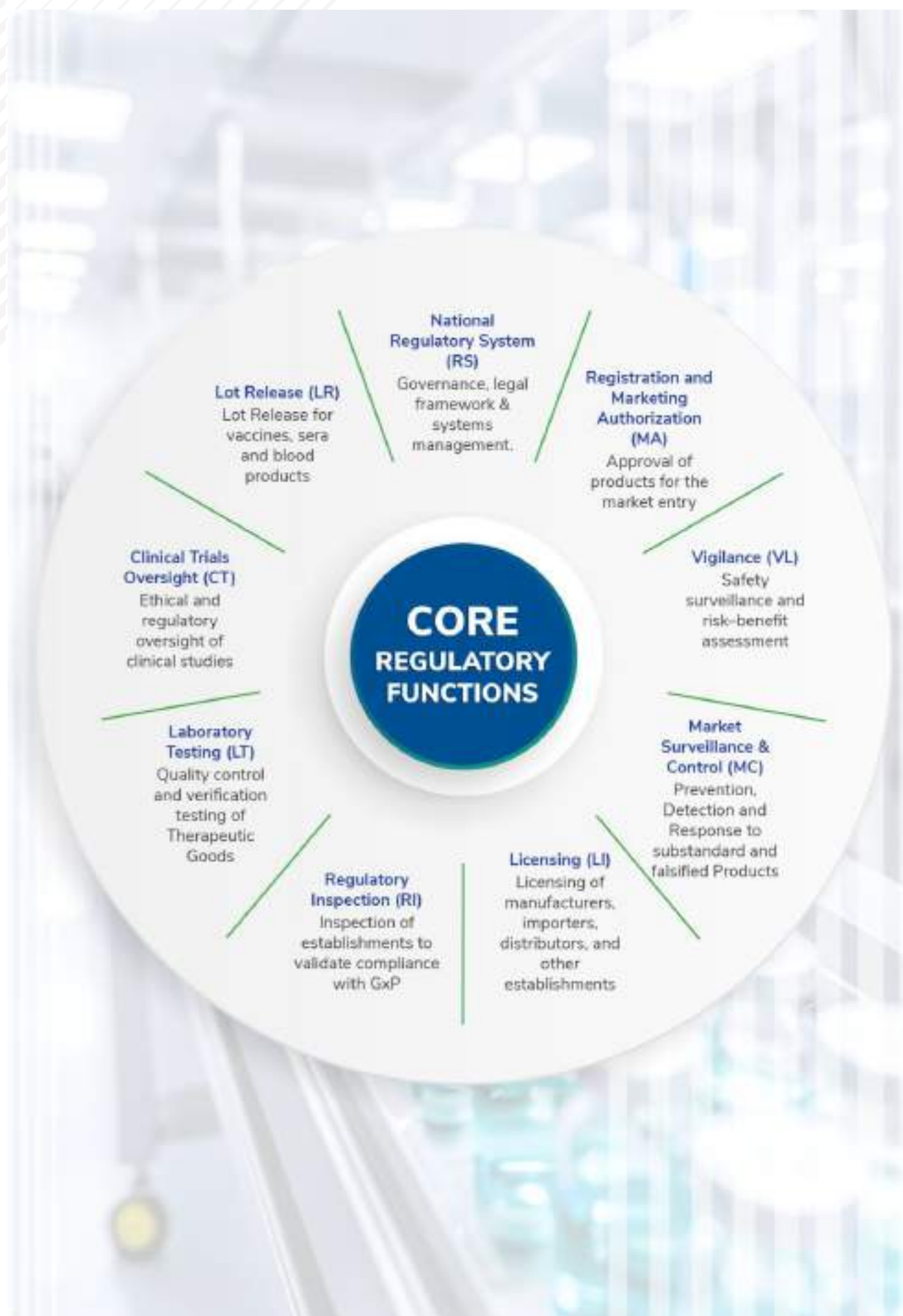


Figure 3: The core regulatory functions for the National Regulatory Authority:







Strategic Plan 2022 - 2025 of Drug Regulatory Authority of Pakistan

**STRATEGIC PLAN
2026 - 2030**

**NATIONAL REGULATORY
SYSTEM OF PAKISTAN**

Overview

The strategic plan 2022–2025 was defined by institutional strengthening, regulatory modernization, and digital transition. Significant progress was achieved in quality management system, market authorization, digitalization, pharmacovigilance and stakeholder engagement during the implementation of the Strategic Plan 2022-2025.

Figure 4: Goals and Objectives in Strategic Plan 2022-2025



Key Achievements

DRAP established its role as the national regulatory focal point while laying the strong foundation for future of Therapeutic Goods regulation in the country. The foundational reforms position DRAP for the next phase of strategic evolution, transitioning toward systemic maturity, strategic agility, sustainability and international recognition. By consolidating regulatory processes, advancing digital integration and fostering global partnerships, DRAP has established a functional platform to achieve the objectives of the Strategic Plan 2026–2030. Key achievements are summarized below:



Figure 5: Key achievements of DRAP Strategic Plan Implementation 2022-25







Methodology for development of Strategic Plan 2026-30

**STRATEGIC PLAN
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Consultative Approach

The SP-2026-2030 is developed through a structured approach, beginning with defining the scope, process, and timeline, which provide overall guidance through the process. The Authority was assisted by Integrated Quality Management System (IQMS) section and other relevant offices to facilitate and execute the process smoothly.

An internal evaluation of the performance for the last strategic cycle was conducted in alignment with gaps highlighted in WHO GBT assessment report to achieve higher maturity level. Furthermore, five-year priorities for regulatory governance, workforce, digitalization, infrastructure and service delivery reforms, local production optimization, export facilitation and self-reliance; research, learning, advocacy, health and products security were identified through multi-sectoral consultation in alignment with national policies, international regulatory standards, and commitments.

A review of existing literature conducted to create a comprehensive picture of the context in which DRAP has been operating; the Authority's strengths, weaknesses, opportunities, and threats (SWOT); and the political, economic, social/cultural, technological, legal, and environmental factors (PESTLE) that are likely to shape the Authority's operations and existence in the next five years, as well as their implications. The reviewed key documents include the Strategic Plan 2022-2025, DRAP Act 2012, National Health and Population Policy 2026-2035, Digital Pakistan (Uraan Initiative)² and UN Sustainable Development Goals.

The key stakeholders who participated in the process include the Ministry of National Health Services, Regulation & Coordination, DRAP, Provincial and State Drug Control Administrations, National Health Programmes, Board of Investment, Academia, Professional Bodies, and Therapeutic Goods Industry Associations including Pakistan Pharmaceutical Manufacturers Association, Pharma Bureau Pakistan, Healthcare Devices Association of Pakistan, Homeopathic Pharmaceutical & Chemist Association, Pakistan Tibbi Pharmaceutical Manufacturers Association, Pakistan Nutraceutical Manufacturers Association, Pakistan Electromedical Equipment Manufacturers & Distributors Association, and Development Partners including DIA, Fleming Fund, United Nations Development Programme, United States Pharmacopeia and World Health Organization.

Based on the learnings above, the Strategic planning team, in consultation with DRAP leadership, Integrated Quality Management System section finalized the renewed vision, mission, strategies, values, goals, targets, timelines and performance indicators for the Strategic Plan 2026-2030.



Figure 6: Step-by-step process for Strategic Planning



Strategic Alignment

SDG 3.8

Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

3

GOOD HEALTH AND WELL-BEING



Figure 7: Alignment of Strategic Plan (2026-2030) with the United Nation Sustainable Development Goals

DRAP Contribution to Sustainable Development Goals

Regulatory Systems Strengthening for Health, Innovation, Sustainability, and Institutional Excellence





SDG 1: No Poverty
Ensures affordable access to essential medicines, reducing catastrophic health expenditures that drive poverty.



SDG 3: Good Health and Well-being
Strengthens regulatory oversight, pharmacovigilance, and access to quality Therapeutic Goods to support Universal Health Coverage.



SDG 4: Quality Education
Builds regulatory capacity through training, certification, and academic partnerships for regulators, Pharmacists and healthcare & allied professionals.



SDG 5: Gender Equality
Promotes gender-inclusive hiring and expert member selection, leadership development, and equitable access to regulatory services for women-led enterprises.



SDG 7: Affordable and Clean Energy
Promotes energy-efficient, digitally enabled regulatory operations and green manufacturing practices.



SDG 8: Decent Work and Economic Growth
Purpose-built workspaces and laboratories for regulatory functions enabling sustainable sector growth and quality employment supporting compliant local manufacturing, exports, regulatory efficiency, workforce capacity.



SDG 9: Industry, Innovation, and Infrastructure
Supports local Therapeutic Goods manufacturing, digital transformation, and resilient regulatory infrastructure aligned with global standards.



SDG 12: Responsible Consumption and Production
Combat AMR by monitoring AMC to enforce rational use regulations and build evidence-based surveillance for effective antimicrobial management.



SDG 13: Climate Action

hybrid solar power system and end-to-end digitalization, reducing carbon footprint and environmental impact of regulatory operations and processes.



SDG 15: Life on Land

End-to-end digitalization has substantially reduced paper use across office operations and regulatory submissions, supporting sustainable resource use and environmental protection.



SDG 16: Peace, Justice, and Strong Institutions

Builds independent, impartial, transparent, and accountable regulatory systems with grievance redressal and stakeholder engagement.



SDG 17: Partnerships for the Goals

Collaborates with International Partner, National Regulatory Authorities and Networks to mobilize resources and technical support for system strengthening and to enhance equitable access.



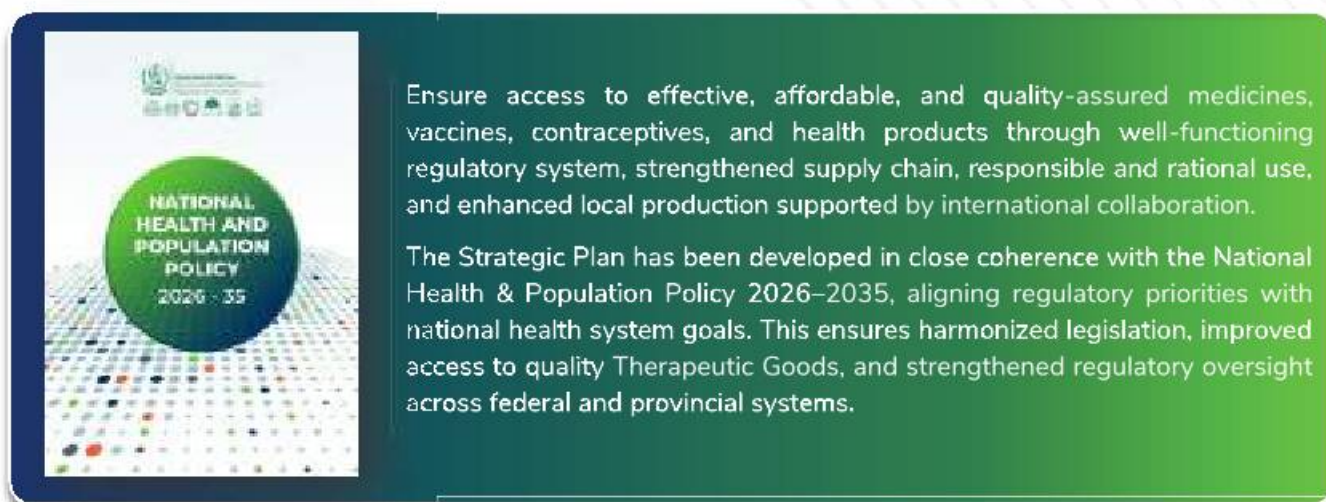
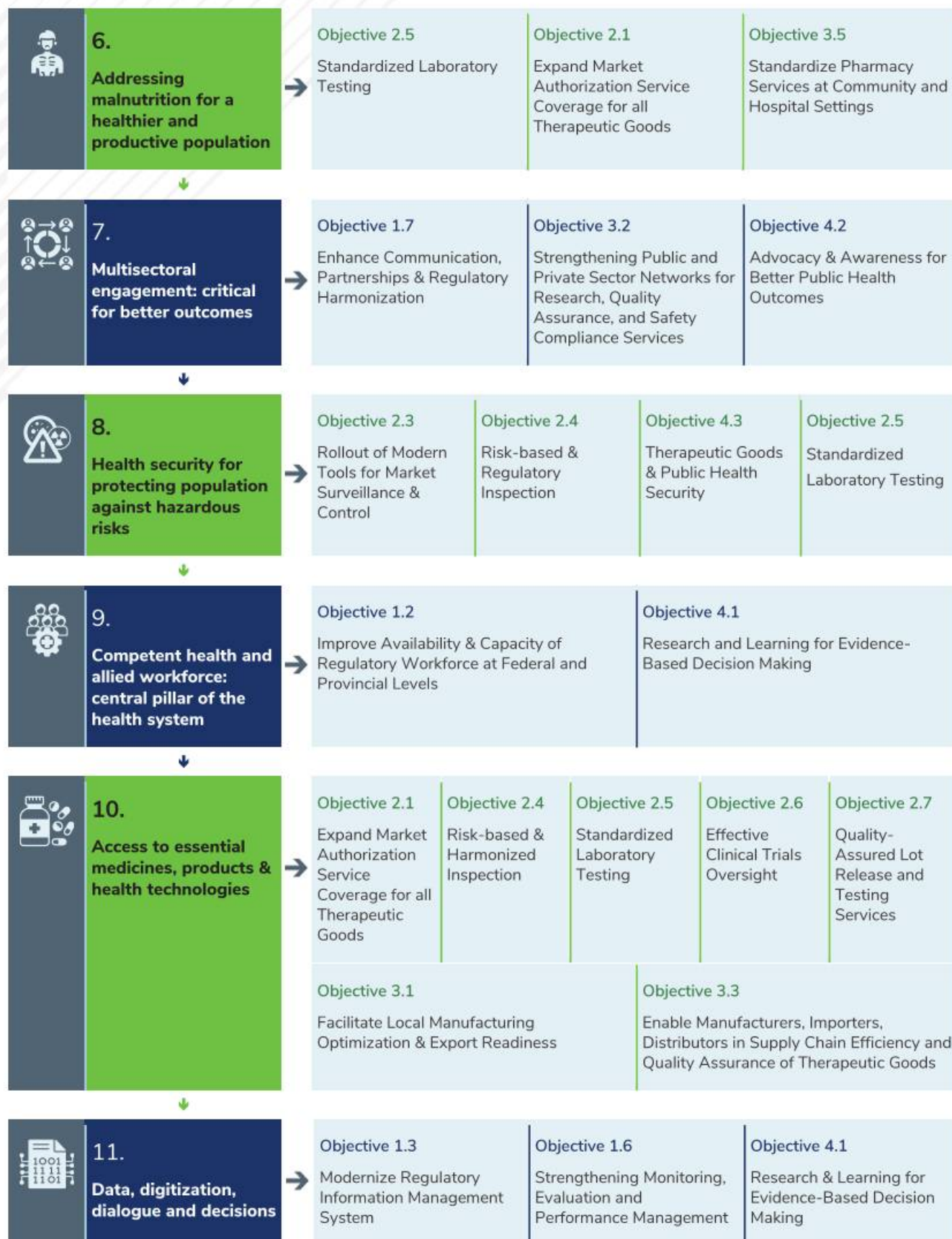


Figure 8: Alignment of Strategic Plan (2026-2030) with National Health and Population Policy (2026-35)





Digital Pakistan (URAAN Initiative)

The Strategic Plan complements the Uraan (Digital Pakistan) Initiative by accelerating digital transformation across the regulatory ecosystem. Through modern information systems, data-driven decision-making, and automation of core regulatory functions, the Plan advances efficiency, transparency, and service delivery in line with national digital priorities.



Figure 9: Alignment with Digital Pakistan (URAAN Initiative)

				
Enhancing the Export Sector	Accelerating Digital Transformation	Implementing Sustainable Practices	Developing Green Energy Solutions	Promoting Social Justice
Enhancing the export sector to drive economic growth, increasing foreign exchange earnings, and boosting the country's global trade position	Accelerating digital transformation to enhance operational efficiency, promote innovation, and improve Pakistan's competitiveness on the global stage	Accelerating sustainable practices to address climate change, protecting natural resources, and ensuring water and food security for long-term ecological balance	Developing affordable, efficient and green energy solutions to support industrial growth, reduce energy costs, and ensure energy security	Promoting social justice, ensuring that all segments of society benefit from progress.
3.1	1.3	2.4	3.1	1.2
Facilitate Local Manufacturing Optimization & Export Readiness	Modernize Regulatory Information System	Risk-based & Harmonized Inspection	Facilitate Local Manufacturing Optimization & Export Readiness	Improve availability & capacity of regulatory workforce at Federal & Provincial levels
3.2	4.1	2.5	3.3	1.6
Strengthening Public and Private Networks for Research, Quality Assurance, and Safety Surveillance	Research & Learning for Evidence-Based Decision Making	Standardized Laboratory Testing	Enable Manufacturers, Importers, Distributors in supply chain efficiency and Quality assurance of Therapeutic Goods	Strengthen Monitoring, Evaluation and Performance Management
3.3		3.4		2.2
Enable Manufacturers, Importers, Distributors in supply chain efficiency and Quality assurance of Therapeutic Goods		Foster collaboration with Health Programs and coverage scheme		Scale up Pharmacovigilance Services at National and Subnational, and Institutional Levels



Strategic Plan 2026-30 Illustration

STRATEGIC PLAN
2026 - 2030

**NATIONAL REGULATORY
SYSTEM OF PAKISTAN**

The Strategic Plan 2026–2030 translates the priorities of Pakistan’s National Regulatory System into a structured, time-bound framework that organizes all reforms into clear pathways of action. The framework brings together system-wide improvements in governance, regulatory operations, digitalization, quality assurance, and public health protection, ensuring that Federal, Provincial and State institutions move in a coordinated and harmonized direction over the next five years.

To achieve this coherence, all activities, interventions and reforms have been grouped into four broad domains as Strategic Goal which represent the functional pillars of a mature and resilient regulatory system. These domains provide an organizing structure for aligning legislation, strengthening institutional capacity, modernizing regulatory practices, improving supply chain integrity, and enabling evidence-based decision making. The following figures visually map how these domains connect with the specific interventions in the Plan.

Figure 10: Goals and Activities in the Strategic Plan 2026-2030



Together, these strategic goals describe how Pakistan will modernize its regulatory functions, advance digital transformation, improve supply chain integrity, and reinforce public health protection.



#	Targets/ Action Items	Outcome	Lead	Partner	Year	UN SDGs	Impact
1.1 Streamlined & Harmonized Legislation, Guidelines & Procedures for Therapeutic Goods							
POLICIES							
1.1.1	National Vaccine Policy to enhance local production and health products security	National Vaccine Policy	CEO Secretariat, DRAP	M/o NHR&C, M/o Commerce, M/o Industries and other relevant state institutions	2026	SDG 3, 1	Promote indigenous manufacturing to enhance access to vaccines, health security, and reduce cost.
1.1.2	To review and upgrade the policy framework for regulation of API	Active Pharmaceutical Ingredient Policy	Drug Licensing Division, DRAP	M/o NHR&C, M/o Commerce, M/o Industries and other relevant state institutions	2026	SDG 3, 9	Ensure safe, quality APIs; strengthen local manufacturing & regulatory standards.
1.1.3	To develop a high-level policy framework, demonstrating Government's priorities Medical Devices Policy	National Medical Devices Policy	MDMC Division DRAP	M/o NHR&C, M/o Commerce, M/o Industries and other relevant state institutions	2027	SDG 3, 9	Promote innovation and investment indigenous manufacturing, enhance access to safe and effective medical devices.
1.1.4	To develop a high-level policy framework, demonstrating Government's priorities on medicine in the country	National Medicine Policy	CEO Secretariat DRAP	M/o NHR&C, M/o Commerce, M/o Industries and other relevant state institutions	2027	SDG 3, 1	Promote equitable access to quality, safe and efficacious essential medicines. (indigenization of complex medicines)

#	Targets/ Action Items	Outcome	Lead	Partner	Year	UN SDGs	Impact
RULES							
1.1.5	Revision of Drug Sale Rules for adoption and harmonization for regulating the sale of Therapeutic Goods across the country	Promulgation of Harmonized Therapeutic Goods Sale Rules	Legal Affairs Division DRAP, Provincial/State Health Departments	QA< Division M/o NHR&C, SIFC	2026	SDG 3, 16	Ensures safe, transparent distribution. (effective implementation of GSDP)
1.1.6	Review of Alternative Medicine and Health Product (Enlistment) Rules, 2014 for enhancing scope of regulation	Promulgation of Registration and Licensing Rules for Alternative Medicines & Health Product	H&OTC, and Legal Affairs Division, DRAP	M/o NHR&C M/o Law & Justice and Stakeholders	2026	SDG 3, 9,16	Expand safe regulation of Improvement in compliance with Alternative Medicines & Health Product
1.1.7	Review of Medical Device Rules 2017, to align with international best practices	Revised Medical Devices Rules	MD & MC, Legal Affairs Division, DRAP	M/o NHR&C M/o Law & Justice Stakeholders	2026	SDG 3,9	Align Medical Device Rules with international standards to cater the indigenous manufacturing industries i.e. surgical devices.
1.1.8	Review and update Bio Study Rules to align with International Standards & Best Practices	Revised Bio Study Rules	Pharmacy Services, Legal Affairs Division, DRAP	M/o NHR&C M/o Law & Justice Stakeholders	2026	SDG 3, 16	Align BE/BA research studies with international best practices.
1.1.9	Review and Update the Drugs (Licensing, Registering & Advertising) Rules 1976 to align with international best practices	Promulgation of Drugs Licensing Rules Promulgation of Drug Registration Rules	Drug Licensing, PE&R, BE&R and Legal Affairs Divisions, DRAP	M/o NHR&C M/o Law & Justice Stakeholders	2026	SDG 3, 16	Ensure safe, transparent licensing and registration processes at par with the international best regulatory practices.
1.1.10	Review and update of Drugs (Import & Export) Rules, 1976 to align with international best practices	Promulgation of Import & Export Rules for Therapeutic Goods	QA<, and Legal Affairs Divisions, DRAP	M/o NHR&C M/o Law & Justice, and Stakeholders	2026	SDG 3, 16	Facilitate compliant international trade of Therapeutic Goods.
1.1.11	Review and update Federal Inspectors and Federal Government Analyst Rules, 1976 to align with international best practices	Promulgation of Inspectorate and Therapeutic Goods Analyst Rules	QA<, and Legal Affairs Divisions, DRAP	M/o NHR&C, M/o Law & Justice, and Stakeholders	2026	SDG 3, 16	Ensure integrity of regulatory inspections and analysis at par with the international standards

#	Targets/ Action Items	Outcome	Lead	Partner	Year	UN SDGs	Impact
1.1.12	Review and update Drugs (Labelling & Packing) Rules to incorporate track and trace to ensure supply chain integrity	Revised Drugs (Labelling & Packing) Rules	PE&R, BE&R, Legal Affairs Divisions, DRAP	M/o NHR&C, M/o Law & Justice, and Stakeholders	2026	SDG 3, 12	Ensure supply chain integrity and rational use.
1.1.13	Development of Medicated Cosmetics Rules	Promulgation of Medicated Cosmetics Rules	MDMC, and Legal Affairs Divisions, DRAP	M/o NHR&C, C M/o Law & Justice, and Stakeholders	2027	SDG 3	Ensure safety and quality of medicated cosmetic products.
GUIDELINES							
1.1.14	Review and align Pharmacovigilance Guidelines & Procedures.	Revised Pharmacovigilance Guidelines & Procedures	Pharmacy Services Division DRAP	Provincial / State Drug Control Administration	2026	SDG 3, 16	Enhance patient safety through improved monitoring/ reporting of adverse events.
1.1.15	Requirements For Grant of Drug Manufacturing License by way of basic and semi-basic manufacturing For Blood/ Plasma Establishments	Guidelines on Data Requirements and Procedures for Licensing of Manufacturers	Drug Licensing Division, DRAP	iQMS, DRAP	2027	SDG 3, 9	Improved regulatory predictability, encourage new manufacturers
1.1.16	Review Coordination & Communication Guidelines for scope expansion to the National Regulatory System (NRS)	Guideline on Regulatory Communication & Coordination in the NRS	iQMS DRAP, MIS Division DRAP	Provincial / State Drug Control Administration	2026	SDG 3, 16	Strengthen coordination across regulatory system for better governance and oversight
1.1.17	Review & align Registration Guidelines and Procedures with WHO/ICH Standards & international best practices	Accelerated Pathways for Registration of Essential Therapeutic Goods, WHO-Prequalified Products, and Health Emergency Products Guidelines & Procedures for Registration of Pharmaceutical and Biological products	PE&R, BE&R Divisions, DRAP	PS Division iQMS DRAP	2026	SDG 3 9	Ensure compliance with quality standards in marketing authorization
1.1.18	Review and update of National Guidelines, Manual and procedure on risk-based post-market surveillance & Control, including rapid alert, recall	Risk-based post market surveillance guidelines implemented resulting in improved detection and control of substandard and falsified Therapeutic Goods	QA & LT, DRAP Provincial / State Drug Control Administration	NQCN, iQMS, Legal Affairs, DRAP	2026	SDG 3, 16	Best utilization off resource with scientific rationale

#	Targets/ Action Items	Outcome	Lead	Partner	Year	UN SDGs	Impact
	and complaint handling						
1.1.19	Review of guidelines and quality procedures for risk-based Inspection (GMP) in alignment with globally accepted standards	Risk-based Inspection Guidelines & Procedures implemented across regulatory functions, resulting in improved inspection prioritization and regulatory oversight	QA & LT Division DRAP	Drug Licensing, PE&R, MD&MC, PS and Health & OTC, iQMS, DRAP Provincial/State Drug Control Administration	2026	SDG 3, 12, 16	Improve safety monitoring, rational use of resources, and accountability.
1.1.20	Review of the BE/BA Guideline to align with the revised Drug (Licensing, Registering & Advertising) Rules and Bio study Rules	Revised BE/BA Guidelines	Pharmacy Services DRAP	PE&R, BE&R, iQMS, DRAP Industry, Professional Association	2027	SDG 3, 16	Ensure compliance with international standards in the national context.
1.1.21	Development of Guidelines for Good Pharmacy Practices	Good Pharmacy Practices Guidelines	Pharmacy Services DRAP	Provincial/State Drug Control Administration, iQMS DRAP	2027	SDG 3, 4	Standardize pharmacy services; build workforce capacity.
1.1.22	Development of Medical Device Guidelines for Licensing and Registration	Medical Device Guidelines	MDMC Division, DRAP	Stakeholders and iQMS, DRAP	2027	SDG 3, 9	Improve regulatory oversight and quality assurance of medical devices.
1.1.24	Review & align Licensing Guidelines and Procedures with revised rules	Revised Licensing Guidelines	Drug Licensing Division, DRAP	iQMS, DRAP	2027	SDG 3, 16	Ensure transparent and consistent licensing processes in compliance with international guidelines
1.1.25	Review of Clinical Trials Guidelines and Procedures to align with revised rules	Revised Clinical Trials Guidelines	Pharmacy Services Division, DRAP	iQMS DRAP	2027	SDG 3, 4	Strengthen ethical oversight and workforce competency in clinical trials.
1.2	Improve Availability & Capacity of Regulatory Workforce at Federal & Provincial Levels						
1.2.1	Develop and rollout training plan for DRAP and Provincial /State levels based on the training need assessment	Federal Level Training Plan to integrate with the Provincial Training Plan	iQMS and all Divisions of DRAP	Provincial/State Drug Control Administration	2026	SDG 3, 4, 5	Build skilled regulatory workforce, support universal access, and promotes gender equity.
1.2.2	Develop and rollout Training of Evaluators on CTD dossier evaluation, BE/BA	Product Evaluation & Registration Training Package	PE&R, BE&R, iQMS, DRAP	Admin. HR& Log Division	2026	SDG 3, 4	Enhance regulatory competence and quality oversight

#	Targets/ Action Items	Outcome	Lead	Partner	Year	UN SDGs	Impact
	submission, vaccines and biosimilar		BE & R Divisions and iQMS DRAP				of critical products.
1.2.3	Develop National Drugs Regulatory Framework	National Regulatory Organization Framework for Drugs	iQMS DRAP	Provincial/State Drug Control Administration	2026	SDG 3, 16	Provide institutional clarity, strengthen regulatory governance and accountability.
1.2.4	Review and update training package for market surveillance and control	Standardized training module for market surveillance for Regulatory Workforce	QA & LT Division and iQMS DRAP	Admin. HR& Log Division	2026	SDG 3, 4, 12	Enhance workforce competency in risk-based oversight and responsible use of medicines.
1.2.5	Design and rollout training package for risk-based inspection (onsite and remote)	Standardized Training Module for Risk-based Inspection (onsite and remote) for regulatory workforce	QA & LT Division and iQMS DRAP	Admin. HR& Log Division	2026	SDG 3, 4, 16	Strengthening inspection capacity aligned with global best practices.
1.2.6	Strengthen regulatory staff capacity on Clinical Trials Oversight with standardized training package rollout and fellowship programs	Standardized training module on Clinical Trial oversight for regulatory workforce, including fellowship programs	PS Division, iQMS DRAP	Admin. HR& Log Division	2027	SDG 3, 4	Improve clinical trial governance and workforce development.
1.2.7	Ensure adequate staff availability for all regulatory functions at DRAP and subnational levels	Development of Recruitment Plan Recruitment of Staff on need basis	Admin, HR & logistic Division DRAP	Policy Board All Divisions of DRAP, Provincial / State Health Department	2027	SDG 3, 16	Secure institutional capacity for all regulatory operations.
1.2.8	Review of DRAP's Competency Framework for expansion of scope to Provincial/ State Drug Control Administrations	Competency Framework for regulatory workforce of Provincial/State Drug Control Administration	iQMS DRAP All Divisions of DRAP	Provincial/State Drug Control Administration	2027	SDG 4, 16	Build standardized workforce competencies nationwide.
1.2.9	Enhanced workforce Capacity on Serialization, Track & Trace system	Standardized training module on Serialization and Track & Trace systems for regulatory workforce	MIS Division DRAP	Admin. HR& Log Division Industry and associations Provincial/State Drug Control Administration	2027	SDG 3, 4, 9, 12	Strengthen supply chain integrity and rational use enforcement.
1.2.10	Establish and rollout training package for the licensing of	Standardized training module for regulatory workforce on Licensing of Establishment	Drug Licensing Division and iQMS DRAP	Admin. HR& Log Division, DRAP	2027	SDG 3, 4, 16	Build workforce skills, improve regulatory capacity

#	Targets/ Action Items	Outcome	Lead	Partner	Year	UN SDGs	Impact
	Therapeutic Goods			Provincial/State Drug Control Administration			
1.2.11	Enhancement of Regulatory Capacity for Medical Devices based on relevant ISO, CE, EU standards	Training Package For Medical Devices, International standards	MD & MC, iQMS DRAP	Admin. HR& Log Division, DRAP	2028	SDG 3, 4, 9	Ensure safe, globally compliant medical device regulation.
1.2.12	Develop and rollout Training of evaluators on WHO/ICH Guidelines	Product Evaluation & Registration Training Package	PE & R, BE & R and iQMS DRAP	Admin. HR& Log Division, DRAP	2028	SDG 3,4	Improve global-standard regulatory evaluation skills.
1.2.13	Design, implement and rollout training package for resource planning, financial management, taxation and auditing	Standardized training module for resource planning, financial management, taxation and auditing for regulatory workforce	B&A Division iQMS DRAP	Admin. HR& Log Division, DRAP	2028	SDG 4,16	Ensure accountable, transparent institutional operations.
1.2.14	Design, implement and rollout training package on digitalization (e-app, e-office, etc.) at federal and federating unit levels	Standardized training module on digitalization (e-app, e-office, etc.) for regulatory workforce at central and federating unit levels	MIS Division iQMS DRAP	All Divisions of DRAP and Provincial/State Drug Control Administration	2028	SDG 3, 4, 9	Strengthen digital literacy and institutional efficiency.
1.3 Modernize Regulatory Information Management system							
1.3.1	Enhance e-App Capacity, functionality and coverage to digitalize regulatory functions and improve efficiency of work processes	Online application processing software capacity, functionality, and coverage for H&OTC	MIS Division DRAP	Health & OTC Division DRAP	2026	SDG 3, 9, 16, 13, 15	Digitalizes regulatory processes and improves efficiency. Reduces environmental impact by minimizing paper use, lowering resource consumption, and supporting climate-resilient, sustainable regulatory operations.
1.3.2		Development and deployment of online application processing software for Clinical Trial applications	MIS Division DRAP	Pharmacy Services Division	2026	SDG 3, 9, 13, 15	Streamlines trial oversight and submission processes.
1.3.3		Development and deployment of online application processing	MIS Division DRAP	Pharmacy Services Division	2026	SDG 3, 16, 13, 15	Strengthen real-time safety

#	Targets/ Action Items	Outcome	Lead	Partner	Year	UN SDGs	Impact
		software for Pharmacovigilance documents					monitoring and transparency.
1.3.4		Development and deployment of online application processing software for Lot Release	MIS Division DRAP	NCLB	2026	SDG 3, 16, 13, 15	Ensure timely release of critical products.
1.3.5		Development and deployment of online processing software to optimize rapid alert, recall and complaint handling	MIS Division DRAP	Quality Control & Lab Testing Division, National Task Force, and Provincial/State Drug Control Administrations	2026	SDG 3, 12, 16, 13, 15	Enhance supply chain safety, rational use, and accountability.
1.3.6		Development and deployment of online application processing software for Controlled Drugs Division	MIS Division DRAP	Controlled Drug Division	2026	SDG 3, 16, 13, 15	Ensure controlled substance compliance and safety.
1.3.7		Development and deployment of online application processing software for BE/BA application submissions	MIS Division DRAP	Pharmacy Services Division	2026	SDG 3, 9, 13, 15	Ensure compliance with global bioequivalence standards.
1.3.8		Development and deployment of online application processing software for Central Research Fund (CRF) Certificates processing	MIS Division DRAP	Budget & Account Division DRAP	2026	SDG 3, 16, 13, 15	Strengthen clinical trial data management and regulatory oversight.
1.3.9		Development and deployment of online Portal for drug shortages management	MIS Division DRAP	Quality Assurance & Lab Testing Division	2026	SDG 3, 1, 13, 15	Facilitate timely intervention and ensures essential medicine availability.
1.3.10		Development and deployment of online Dashboard for legal matters in courts	MIS Division DRAP	Legal Affairs Division DRAP	2026	SDG 16, 13, 15	Enhance transparency, accountability, and case tracking.
1.3.11		Development and deployment of online application processing software for Advertisement Applications	MIS Division DRAP	Pharmacy Services Division	2027	SDG 3, 16	Ensure compliance with marketing regulations and public safety.
1.3.12		Development and deployment of online application processing software for Appellate Board	MIS Division DRAP	Legal Affairs Division	2027	SDG 16, 13, 15	Streamline appeals, strengthens transparency and justice.
1.3.13		Analytical capacity of database for product lifecycle traceability	MIS Division DRAP	Quality Assurance &	2028	SDG 3, 9,	Ensure quality oversight and

#	Targets/ Action Items	Outcome	Lead	Partner	Year	UN SDGs	Impact
				Lab Testing Division		16, 13, 15	end-to-end traceability.
1.3.14		Institutionalization of Drug Testing Management System at NCLB	MIS Division DRAP	NCLB	2029	SDG 3, 9, 13, 15	Strengthens testing infrastructure and regulatory reliability.
1.3.15	Update DRIS for addition of Training Need Assessment, training effectiveness and competency Matrix	Update DRIS for Training management	Admin & HR DRAP	MIS	2026	SDG 4, 9	Competent staff for performing regulatory functions
1.3.16	Establish electronic database for Inspection (GMP) reports	GMP report Database	MIS Division,	QA< Division DRAP	2026	SDG 3, 9, 16	Strengthen oversight of medicine manufacturing quality, enables digital regulatory infrastructure and improves transparency and accountability of inspections
1.3.17	Establish electronic database for Inspections (GCP)	GCP report Database	MIS Divisions DRAP		2026	SDG 3, 9, 16	Enhances ethical and quality oversight of clinical trials, institutionalizes digital inspection systems, and reinforces regulatory governance and trust.
1.3.18	Adoption & Institutionalization tool for Risk Based (RB) Sampling & GMP / GSDP / GCP inspection Plan development	Adoption of e-tools for sampling, deployment and implementation of RB inspection planning tool	QA< MIS Division DRAP	Provincial/State Drug Control Administration	2027	SDG 3, 9, 16	Promote efficient, risk-informed regulatory decision-making to protect public health, leverages digital tools, and strengthens evidence-based governance.
1.3.19	Adopt financial management tools with adequate licensing for Enterprise Resource Planning	Improved financial planning, transparency, and control through adoption of licensed financial management tools	B & A Division DRAP	MIS Division DRAP Admin Division DRAP	2028	SDG 16, 9	Improve institutional integrity, financial transparency, and accountability through modern enterprise digital systems.

#	Targets/ Action Items	Outcome	Lead	Partner	Year	UN SDGs	Impact
1.3.20	Establish electronic database for Inspection GSDP	GSDP report Database	PER, BER, MIS Divisions DRAP	Provincial/State Drug Control Administration	2028	SDG 3, 9, 16	Ensure quality and integrity of pharmaceutical distribution, digitizes regulatory oversight, and strengthens compliance monitoring.
1.3.21	Digitalization of licensing processes at all provinces/states	Improved data sharing	MIS Division iQMS DRAP	Provincial/State Drug Control Administration	2028	SDG 9, 16	Enhance regulatory efficiency and interoperability through digital systems while improving transparency and service delivery.
1.3.22	Adopt and Rollout Human Resource Information Management system at national and sub national level	Strengthened human resource planning, deployment, and performance management through a standardized Human Resource Information Management System at national and sub-national levels.	HR & Logistic Division DRAP iQMS DRAP	All Divisions of DRAP, Provincial/State Drug Control Administration	2029	SDG 4,16	Supports workforce development and performance management and strengthens institutional governance and planning capacity.
1.3.23	Development of NQCN Database	Database for samples, analysis and testing report of products by all NQCLs	NQCN MIS Division DRAP	All DTLs	2028	SDG 3, 16	Enhance regulatory decision-making for public health protection while promoting transparency and accountability in quality control systems.
1.3.24	Adopt and Rollout eQMS DRAP at national and sub national level	Strengthened quality assurance, process consistency, and regulatory compliance through adoption of a standardized eQMS DRAP at national and sub-national levels.	iQMS DRAP, MIS Division DRAP	All Divisions of DRAP, Provincial/State Drug Control Administration	2029	SDG 16, 9	Institutionalize standardized quality systems for consistent regulatory performance enabled through digital process management.
1.3.25	Antimicrobials Consumption monitoring Database	Data of AMU Identification of ways to address the AMU	Pharmacy services Division and iQMS DRAP	NIH Provincial/State Health Departments	2030	SDG 3, 12	Support antimicrobial stewardship and containment of AMR through responsible monitoring of medicine use.

#	Targets/ Action Items	Outcome	Lead	Partner	Year	UN SDGs	Impact
1.3.26	Adoption of data standards (IDMP) in DRAP's Digital Ecosystem	Standardization of Data System	MIS Division DRAP	All Divisions of DRAP	2030	SDG 9, 16, 3	Enable interoperable regulatory data systems, strengthens governance and regulatory intelligence, and supports safer Therapeutic Goods regulation.
1.3.27	Optimize and align track & trace tool with globally accepted serialization standard	DRAP software optimization for end-to-end traceability	MIS Division DRAP	PE&R, BE&R, QA<, Licensing, Provincial/State Drug Control Administration	2030	SDG 3, 9, 16	Protect patients from substandard and falsified medicines, modernizes digital traceability systems, and reinforces regulatory enforcement capacity.
1.3.28	Adopt and Rollout LMS at national and sub national level	Enhanced workforce learning, competency development, and training management through adoption of a standardized Learning Management System (LMS) at national and sub-national levels.	iQMS DRAP, MIS Division DRAP	All Divisions of DRAP, Provincial/State Drug Control Administration	2030	SDG 4, 16	Strengthen continuous professional development and competency-based training, enhancing institutional capacity and regulatory performance.
1.4 Upgrade Infrastructure & Equipment to meet the regulatory needs							
1.4.1	Upgradation of Microbiology laboratory	Micro lab at CDL Karachi	CDL DRAP	B & A Divisions Admin, HR & Log, DRAP	2026	SDG 3, 9	Strengthen testing capacity for ensuring quality and safety.
1.4.2	Develop or outsourced data warehousing capability for Track & Trace system	Enhanced data management, analytics, through development or outsourcing of data warehousing capabilities for the Track & Trace system.	MIS Division DRAP	Admin, B&A DRAP	2026	SDG 3, 9, 16, 12	Improve supply chain data management and decision-making for regulatory oversight.
1.4.3	Establish the National Center of Regulatory Science (NCRS) to build regulatory capacity for both the workforce and the	Establishment of center for Improving regulatory competence and capacity of the regulatory workforce and pharmaceutical industry through the NCRS	CEO Secretariat HR & Logistic, DRAP	iQMS DRAP, Policy Board DRAP B & A Divisions	2027	SDG 3, 4, 7, 8, 9, 13, 16, 17	Build national regulatory workforce capacity and technical expertise for the Therapeutic Goods sector.

#	Targets/ Action Items	Outcome	Lead	Partner	Year	UN SDGs	Impact
	pharmaceutical industry.						
1.4.4	Adequate communication, transportation and logistics facilities for regulatory functions	Enhanced operational efficiency and responsiveness of regulatory functions through improved communication, transportation, and logistics support.	Admin & Log B&A Divisions DRAP	All Divisions of DRAP, Provincial/State Drug Control Administration	2027	SDG 3, 8, 16	Enhance operational efficiency and responsiveness across DRAP and provincial units.
1.4.5	Improve National Control Laboratory for Biologicals (NCLB infrastructure to comply with Bio Safety Level 2/3 (BSL 2/3) requirements and equip with instruments & technologies to meet country needs for testing priority vaccines and biologicals	Establishment of BSL 2/3 lab with all technologies required to meet priority product testing needs of vaccine and Biologicals % vaccine and biological testing capacity	NCLB DRAP	NIH, B & A Divisions Admin, HR & Log, DRAP	2028	SDG 3, 9, 16, 17	Ensure safe and advanced testing of vaccines and biologicals for public health needs aligning with requisite international best practices
1.4.6	Establishment of Laboratory infrastructure for testing of alternative medicines	Alternative medicines Lab	QA< Division DRAP	HOTC B & A Divisions Admin, HR & Log, DRAP	2028	SDG 3, 9, 16	Provides quality assurance for alternative medicines, protecting public health.
1.4.7	Establishment of Medical device testing laboratory	Medical Device Lab	QA< Division DRAP	MDMC B & A Divisions Admin, HR & Log, DRAP	2029	SDG 3, 9, 16	Supports quality evaluation of medical devices, ensuring safe local availability.
1.4.8	Establishment of Reference Standard Center	Reference Standard (RS) Center for developing and maintaining RS	QA< Division DRAP	NQCN, DTLs B & A Divisions Admin, HR & Log, DRAP	2030	SDG 3, 9, 16	Support quality assurance through complaint, high manufacturing by provision of primary and secondary RS
1.5 Ensure Sustainable Financing & Resource Management							
1.5.1	Review and design a sustainable cost recovery and regulatory fee structure for key services, including registration, licensing, inspection, and laboratory testing of pharmaceutical, medical devices,	Ensured sustainable financing and efficient delivery of key regulatory services through a cost-recovery and fee structure for pharmaceuticals, medical devices, and other Therapeutic Goods.	B & A Division DRAP	All Divisions of DRAP	2028	SDG 1, 16	Ensure sustainable financing and efficient delivery of regulatory services while maintaining access to essential medicines.

#	Targets/ Action Items	Outcome	Lead	Partner	Year	UN SDGs	Impact
	and other Therapeutic Goods.						
1.5.2	Streamline periodic strategic planning, budgeting, financial management & auditing processes	5-year Strategic Plan & Budget Annual Plan & Budget Periodic Audit reports	B & A and HR & Logistic Divisions DRAP	All Divisions of DRAP	2030	SDG 16	Strengthen transparency, accountability, and effective resource management across DRAP.
1.6 Strengthen Monitoring, Evaluation & Performance Management							
1.6.1	Design & implement monitoring, evaluation and result framework, plan for periodic performance review and continuous improvement.	Development of Design & implement monitoring, evaluation and result framework	Policy Board, Admin, HR & Logistics, CEO secretariat	All Divisions of DRAP	2026	SDG 16	Enhance accountability, evidence-based decision-making, and continuous improvement.
1.6.2	Design and update a dashboard for streamlined, timely, and effective communication of results.	Enhanced decision-making and transparency through timely and effective communication of results via the dashboard.	MIS Division DRAP	All Divisions Provincial/State Drug Control Administration	2027	SDG 16, 17	Support transparency and timely communication for informed regulatory and operational decisions.
1.7 Enhance Communication, Partnerships & Regulatory Harmonization							
1.7.1	Improve Collaboration with provincial authorities to harmonize regulatory services, Quality management system and effective communication	MoUs, Harmonized QMS DRAP Harmonized Market Surveillance & Control, Licensing, Inspection & PV services framework	iQMS DRAP	Provincial/State Drug Control Administration	2026	SDG 3, 16, 17	Strengthen coordination, harmonization, and stakeholder engagement for efficient regulatory services.
1.7.2	Achieve WHO Maturity Level 3 for Medicine & Vaccine import	Pakistan's Regulatory System is designated among the WHO Maturity Level 3 NRAs	All Team Leads and relevant Divisions of DRAP	WHO Country Office Provincial/State Drug Control Administration	2027	SDG 3, 16	Demonstrate internationally recognized regulatory capacity for safe imports.
1.7.3	Extend WHO Maturity Level 3 scoped to vaccine producing	Pakistan's Regulatory System is designated among the WHO Maturity Level 3 NRAs	All Team Leads and relevant Divisions of DRAP	WHO Country Office Provincial/State Drug Control Administration	2029	SDG 3, 16	Strengthens local production quality and safety systems for vaccines.

#	Targets/ Action Items	Outcome	Lead	Partner	Year	UN SDGs	Impact
1.7.4	Collaboration with regional regulatory authorities to promote reliance, mutual capacity building and recognition.	MoUs with National Regulatory Agencies of 10 Countries	CEO Secretariat, iQMS, Drug Licensing, PE&R, BE&R, MDMC Divisions, DRAP	M/o Foreign Affairs, M/o Interior & Narcotics Control	2030	SDG 3, 17	Promotes technical cooperation, knowledge sharing, and international regulatory alignment.
1.7.5	Achieve WHO Prequalification for NQCLs	Internationally acceptable test reports	CDL DTLs	Provincial/State Drug Control Administration	2030	SDG 3, 9, 16, 17	Ensures global recognition of laboratory testing quality for pharmaceuticals.
1.7.6	Ensure acquisition of PICS membership	PIC/S Membership	QA<, Licensing Division DRAP	Industry and Stakeholder Associations	2030	SDG 3, 9, 16, 17	Strengthen GMP compliance and international recognition of regulatory oversight.
1.7.7	Participation in the WHO Member State Mechanism for SF Products	Enhance regional and international coordination to combat SF Products	QA<, iQMS, CEO Secretariat, DRAP	M/o Foreign Affairs WHO Country Office	2027	SDG 3, 9, 16, 17	Enhance regional and international coordination to combat SF Products

Goal

2

Efficient, Transparent & Trusted Regulatory Services

#	Targets/ Action items	Outcome	Lead	Partner	Year	UN SDGs	Impact
2.1	Expand Market Authorization service coverage for all Therapeutic Goods						
2.1.1	Implementation of accelerated registration pathways (WHO/ SRA/ WLA/ etc.) in public health emergencies	Accelerated Pathways to register products for Public Health Emergencies	PE & R, BE&R MD&MC Divisions DRAP	Industry and associations	2026	SDG 1, 3, 16	Ensure timely access to essential medicines during emergencies while maintaining regulatory oversight.
2.1.2	Streamlining registration procedures for the regulation of Radiopharmaceuticals	Radiopharmaceuticals implemented	PE & R Division DRAP	Industry and associations	2026	SDG 1, 3, 16	Support safe, efficient registration of radiopharmaceuticals, improving patient access.
2.1.3	Implementation of Risk Management Plans (RMPs) compliance requirement for pharmaceuticals and biological drugs	High Risk molecules planning for RMP compliance	PE & R, Pharmacy Services Divisions DRAP	Industry and associations	2027	SDG 3, 12, 16	Enhance patient safety through proactive monitoring of high-risk products.
2.1.4	Implement Summary of Product Characteristics (SmPCs) compliance requirements for pharmaceuticals and biological drugs.	1000 SmPCs reviewed & published on website	PE & R, BE&R Division DRAP	Industry and associations	2026	SDG 3, 12, 16	Ensure transparent and standardized product information for health professionals and patients.
2.1.5	Streamline registration process for H&OTC product	All upcoming products to be registered after promulgation of rules	Health & OTC and Legal Affairs Divisions DRAP	M/o NHSRC, Industry and associations	2027	SDG 3, 9, 16	Facilitate faster access to health & OTC products while ensuring regulatory compliance.
2.1.6	Rollout risk-based Registration guidelines &	Registration of all Medical Devices as	MDMC Division DRAP	Industry and associations	2027	SDG 3, 9, 16	Strengthen safe, efficient regulatory control for in-vitro

#	Targets/ Action items	Outcome	Lead	Partner	Year	UN SDGs	Impact
	procedure for IVDs & medical Devices	per new guidelines & procedures					diagnostics and medical devices.
2.1.7	Rollout of BA/BE study requirements for priority Drugs registered in the country.	50 priority molecules comply with BA/BE requirements.	PE & R Division DRAP	Industry and associations Bioequivalence Centers	2030	SDG 3, 9, 16	Ensure quality and efficacy through bioequivalence compliance.
2.2 Scale up Pharmacovigilance services at national, sub national and Institutional Levels							
2.2.1	Expand VigiFlow coverage to national PV stakeholders and provincial health facilities.	Expanded VigiFlow deployment resulting in improved ADR reporting rates, enhanced safety signal detection and strengthened national pharmacovigilance system VigiFlow deployment in 300 hospitals, 50 treatment sites of Polio, Malaria, TB and HIV control program (CMU), and 40 district health immunization surveillance offices.	Pharmacy Services Division, DRAP, and All Federating units	Polio, TB Malaria and HIV control Programs, Pakistan Medical Council, Pakistan Pharmacist Association.	2027	SDG 3, 16	Strengthen real-time adverse event reporting and patient safety surveillance.
2.2.2	Enhanced real-time reporting of AEs and AEFI through standardized National VigiFlow database from integrated regional centers, hospitals, treatment sites and vaccination surveillance district offices.	Sites with Functional VigiFlow & real-time reporting and improved patient safety monitoring implemented, resulting in timely safety	Pharmacy Services Division, DRAP, and All Federating units	Polio, TB Malaria and HIV control Programs, Pakistan Medical Council, Pakistan Pharmacist Association.	2027	SDG 3, 16	Enable timely detection and response to safety concerns across the healthcare system.
2.3 Rollout of modern tools for Market Surveillance & Control to mitigate Public Health Risks							
2.3.1	Rollout of RB-PMS at DRAP and ICT	Risk-based post-market surveillance implemented resulting in efficient allocation of inspection resources and improved public health risk management	QA & LT and MIS Divisions DRAP	Pharmacy Services & Drug Control ICT	2026	SDG 3, 16, 17	Implement risk-based post-market surveillance at federal level to safeguard public health.
2.3.2	Rollout of RB-PMS at Provincial Drug Controls	Implementation of RB-PMS	QA & LT and MIS Divisions DRAP	Provincial Drug Control Departments	2028	SDG 3, 16, 17	Extend risk-based surveillance to federating units for consistent monitoring.
2.3.3	Improve Coverage of Track & Trace System implementation to the extent of anti-counterfeit	Track & Trace system expanded resulting in improved supply chain integrity and prevention of substandard and falsified Therapeutic	QA & LT and MIS Divisions DRAP	Industry and Associations	2027	SDG 3, 12, 16	Ensure supply chain integrity, combats substandard and falsified products.

#	Targets/ Action items	Outcome	Lead	Partner	Year	UN SDGs	Impact
		Goods for all licensed Pharmaceutical Units					
2.4 Risk-based & Harmonized Inspection							
2.4.1	Adopt and rollout risk-based Inspection (GMP) aligned with best practices by DRAP and federating unit level	GMP Risk Based Inspection planning and execution	QA< and Provincial/State Drug Control Administration	PE&R, BE&R CDL Divisions DRAP	2026	SDG 3, 9, 16	Ensure compliant manufacturing through globally aligned inspection practices.
2.4.2	Adopt and rollout risk-based Inspection (GSDP) aligned with best practices by DRAP and federating unit level	GSDP Risk Based Inspection planning and execution	QA<	Provincial/State Drug Control Administration	2027	SDG 3, 9, 16	Ensure effective implementation of GSDP.
2.5 Standardized Laboratory Testing							
2.5.1	Rollout quality assured testing of priority medical devices for Performance evaluation	Testing of all scopes for priority medical devices	QA<, MDMC Divisions	B & A Division DRAP Admin, HR & Log, DRAP	2029	SDG 3, 9	Ensure safety and performance compliance of medical devices.
2.5.2	Rollout quality assured testing of alternative medicines	- Alpha toxin - Heavy metals - Bio-burden & Specific biomarkers.	QA<, Health & OTC, Divisions DRAP	B & A Division DRAP	2028	SDG 3, 12	Protect public health through standardized testing of alternative products.
2.5.3	Rollout Quality assured Testing of Anticancer drugs	Testing of all scopes	QA<, BE & R, Divisions DRAP	B & A Division DRAP	2028	SDG 3, 9	Ensure efficacy and safety of critical anticancer therapeutics.
2.5.4	Achieve & Maintain WHO Prequalification for NQCLs	Internationally accepted test reports	CDL	NQCLs	2030	SDG 3, 9, 16, 17	Protect public health through internationally standardized and accredited testing.
2.6 Effective Clinical Trial Oversight							
2.6.1	Roll out of GCP Training	Existing 20 licensed CRO/CTS training conducted	PS Division	CROs, CTS	2026	SDG 3, 4, 16	Strengthen ethical and scientific conduct of clinical trials to protect participant safety, builds professional and institutional capacity through structured training, and reinforces regulatory compliance and oversight.
2.6.2	Clinical Trial Registry	Digital Platform with data related to Clinical Trials	PS Division	Admin, HR & Log Division	2027	SDG 3, 16, 9	Enhance transparency and public trust in clinical research, supports patient safety and

#	Targets/ Action items	Outcome	Lead	Partner	Year	UN SDGs	Impact
							evidence-based decision-making, and institutionalizes digital health research infrastructure.
2.7 Quality assured Lot release testing services							
2.7.1	Rollout Quality assured testing of Vaccines, anti-sera and plasma products	100% Testing coverage of Priority molecules	NCLB QA< Division	B&A DRAP Admin, HR & Log, Divisions DRAP	2029	SDG 3, 9, 16	Ensure safety, quality, and efficacy of critical biological products before market authorization, strengthens national laboratory and testing infrastructure, and reinforces regulatory assurance and public confidence in health systems.

Goal 3

End to End Supply Chain Optimization and Quality Assurance

#	Targets/ Action items	Outcome	Lead	Partner	Year	UN SDGs	Alignment
3.1	Facilitate Local Manufacturing Optimization & Export Readiness						
3.1.1	Mobilize technical and financial resources for manufacturing optimization and export readiness of locally manufactured Pharmaceuticals of 50 priority molecules.	Improved BE/BA compliance of priority molecules resulting in enhanced product quality, export readiness and regulatory reliance opportunities 50 molecules with BE/BA Compliance 15 products qualified with WHO or WHO Listed Authorities 15 Manufacturers certified by PIC/S member link with export	PE & R Division DRAP	Industry and Associations	2030	SDG 3, 9, 17	Support local production, quality assurance, and export readiness to improve access and strengthen industrial capacity.
3.1.2	Improve Medical devices manufacturer access to financial and technical resources to optimize local manufacturing, quality assurance and export readiness of locally manufactured devices.	Improved local manufacturing capacity resulting in enhanced quality assurance and reduced dependence on imported devices such that 5% of Imported products will be shifted from import to local manufacturing	MD & MC Division DRAP	Industry and Associations M/o NHSRC Mo Industries, M/o Commerce	2030	SDG 1, 3, 9, 17	Enhance local production capacity and quality of medical devices, reducing dependency on imports.
3.1.3	Facilitate local manufacturers to engage third country market	50 products to be manufactured in Pakistan	MD & MC Division DRAP	Industry and Associations M/o NHSRC	2030	SDG 3, 9, 17	Promote industrial collaboration, technology

#	Targets/ Action items	Outcome	Lead	Partner	Year	UN SDGs	Alignment
	authorization holders for value addition or contract manufacturing of medical devices			Mo Industries, M/o Commerce			transfer, and local manufacturing scale-up.
3.2	Strengthening public and private sector networks for Research, quality assurance and safety compliance services						
3.2.1	Establish a multi-phased National Accreditation Program (NAP) to formally guide and fast-track the certification of target entities against recognized international standards	10 CROs, CTS 3 BA/BE Centers	PE & R, BE&R, PS Divisions DRAP	Industry and Associations	2030	SDG 3, 9, 16	Ensures quality assurance, builds institutional capacity, and aligns laboratories and centers with international standards.
3.3	Enable Manufacturers, Importers, Distributors in supply chain efficiency and Quality assurance of Therapeutic Goods						
3.3.1	Collaborate with Importer, distributor/whole seller associations to improve GSDP compliance of importers and distributors in all federating units	100 %age of Importer/distributors/whole sellers increased with GSDP (PIC/s guide) compliance in federating unit	QA & LT Division DRAP and Provincial/State Drug Control Administration	Industry and associations	2030	SDG 3, 12, 16	Strengthen supply chain integrity and compliance with Good Storage and Distribution Practices (GSDP).
3.4	Foster collaboration with Health program and coverage schemes						
3.4.1	Facilitate local manufacturers for international accreditation to engage with public health programs	Enhance Local Production of (WHO PQ) EPI Vaccines AIDS/TB/Malaria products	Licensing & PE&R Division DRAP	M/o NHSRC, All Programs	2030	SDG 1, 3, 9, 17	Support local manufacturers in meeting international standards to supply vaccines and therapeutics for public health programs.
3.5	Standardize Pharmacy Services at community and hospital settings						
3.5.1	Collaborate with pharmacies; in public & private sector to implement Good Pharmacy Practices (GPP)	Pharmacies in federal/provincial and federating unit capitals to implement GPP	Provincial/State Drug Control Administration	Pharmacy Services Division	2030	SDG 1, 3, 12	Ensure standardized, quality pharmacy services, improving patient safety and medicine use.

Goal 4

Research, Learning, Advocacy & Security

#	Target	Outcome	Lead	Partner	Timeline	UN SDGs	Impact
4.1	Research & Learning for Evidence Based Decision making						
4.1.1	Drug Pricing Survey	Evidence generated to support informed pricing policy decisions and impact of deregulation of prices on drugs	C&P Division DRAP	Independent Consultant/firm	2026	SDG 1, 3	Provide evidence on the impact of drug pricing deregulation, ensuring affordability and access to essential medicines.
4.1.2	Landscape analysis of Antimicrobials Utilization (AMU)	AMU data generated to support evidence-based regulatory interventions and antimicrobial stewardship policies	PS Division and iQMS DRAP	International Health Partners	2027	SDG 3, 12	Support rational use of antimicrobials and development of evidence-based interventions to combat antimicrobial resistance (AMR).
4.1.3	Landscape analysis for serialization, adoption and rollout of track and trace system in pharmaceutical supply chain	Data of compliance level, gaps and way-forward	QA & LT, MIS Divisions DRAP	International Health Partners Academic Institutions	2027	SDG 3, 9, 16	Identify gaps in supply chain traceability, supporting end-to-end regulatory oversight and patient safety.
4.1.4	Substandard and Falsified prevalence study in public and private sector establishments	Prevalence data generated to support targeted regulatory enforcement and strengthened medicine quality assurance systems	QA & LT Division and iQMS DRAP	NQCLs Provincial/State Drug Control Administration	2027	SDG 3, 12	Enable regulatory measures to prevent substandard and falsified products, protecting public health.

#	Target	Outcome	Lead	Partner	Timeline	UN SDGs	Impact
4.1.5	Landscape analysis of testing procedures of non-pharmacopoeia products	Identification of products with diverse testing procedures	NQCN	CDL, DTLs, Associations	2028	SDG 3, 9	Standardize testing procedures for non-pharmacopoeia products, ensuring quality and safety.
4.1.6	Self-Assessment for WHO GBT higher maturity level in pharmaceuticals, biologicals/vaccines	Achievement of WHO ML-4, a stable regulatory system	DRAP	M/o NHSRC all Provincial/State Drug Control Administration	2030	SDG 3,16	Strengthen regulatory system maturity to meet international standards, enhancing public trust and compliance
4.2 Advocacy & Awareness for better public health outcome							
4.2.1	Design and rollout Campaign on Substandard and Falsified Therapeutic Goods	Public verification and reporting of medicines, leading to higher detection rates, successful prosecutions of SF goods criminals, and strengthened supply chain integrity.	QA & LT Division DRAP	Provincial/State Drug Control Administration PPMA, Pharma Bureau, PPA	2027	SDG 3, 12	Raise public awareness, improve reporting, and strengthens supply chain integrity against SF products
4.2.2	Design and rollout Campaign for adoption of PIC/s standards	Industry awareness and onboarding	QA & LT Division DRAP	PPMA, Pharma Bureau, PPA	2026	SDG 3, 9	Promote industry compliance with internationally recognized manufacturing standards
4.2.3	Design and rollout Campaign on ADR reporting and other Pharmacovigilance activities	HCPs & Public awareness on ADR reporting Enhanced Pharmacovigilance activities in healthcare settings	PS Division DRAP	Provincial/State Drug Control Administrations PPMA, Pharma Bureau, PPA All Federating units	2027	SDG 3, 4	Increase awareness among healthcare professionals and the public, strengthening adverse drug reaction reporting
4.2.4	Design and rollout Campaign to reduce antimicrobial consumption and use	Public awareness on Self medication Health professional education	PS Division DRAP	Provincial/State Drug Control Administration, WHO, Healthcare Commissions, Associations (PPMA, PPA Pharma Bureau,)	2027	SDG 3, 12	Promote rational use of antimicrobials, reducing AMR risk and improving public health outcomes
4.3 Therapeutic Goods & Public Health Security							
4.3.1	Assessment of possible Regulatory and Market Causes for medicine shortage in Pakistan	Data for short medicines Identify ways to mitigate this shortage	CEO Secretariat DRAP	Academia Associations (PPMA, PPA Pharma Bureau),	2026	SDG 3, 16	Provide actionable data to mitigate medicine shortages, ensuring consistent access to essential medicines

#	Target	Outcome	Lead	Partner	Timeline	UN SDGs	Impact
				Civil Society			
4.3.2	Study on consumption of antimicrobials in veterinary products	Data on utilization of antimicrobials in veterinary sector	PS Division DRAP	Academia Associations (PPMA, PVMA)	2026	SDG 3, 12	Support evidence-based interventions for responsible antimicrobial use in the veterinary sector, reducing AMR

Budget:

The budgetary assumption was not part of this document due to the scope and focus of exercise. Integrated Quality Management System section in coordination with Budget & Accounts and technical Divisions will work on the budget estimate for each financial year. The budget allocations will be based on Annual Activity Plan, resource availability and implementation performance. The allocation will be in addition to the routine operational budget for DRAP and federating units, where applicable.



Implementation, Monitoring & Evaluation

STRATEGIC PLAN
2026 - 2030

NATIONAL REGULATORY
SYSTEM OF PAKISTAN

The Strategic Plan 2026–2030 serves as a five-year roadmap to guide National Regulatory System’s transformation. Effective implementation requires systematic governance, performance management, and collaborative accountability across the NRS. To ensure effective delivery, a multi-tiered implementation structure is established, ensuring both top-down oversight and bottom-up feedback. The table below depicts the implementation & oversight approach for the next five years.

High-level M&E Framework for NRS Strategic Plan 2026 - 2030

Tier	Body / Entity	Core Responsibilities	Reporting Frequency
Strategic Oversight	Policy Board, DRAP	- Overall strategic oversight and guidance. - Approve policy revisions and resource allocation.	Biannual
Monitoring and Evaluation	DRAP (Authority)	- Overall strategic oversight and guidance. - Approve annual implementation plan, M&E framework and periodic reports. - Recommend revisions and resource allocation.	Biannual
Technical Coordination	iQMS, DRAP	- Coordinate implementation across the NRS. - Finalize KPI, result based framework, monitoring & evaluation plans. - Review progress against KPIs & Prepare consolidated progress reports.	Quarterly
Operational Execution	QMS Coordinators DRAP QMS Coordinators in Provincial/State Drug Control Administration	- Translate strategic actions into divisional/Provincial work plans. - Monitor divisional/provincial targets, timelines, and budget utilization. - Report to iQMS via standardized templates.	Monthly
Technical assistance & Support	Development sector, Industry, Academia and Professional Network Partners	- Provide technical assistance and capacity building. - Support implementation, evaluations, and audits. - Facilitate international cooperation and resource mobilization.	As needed

The monitoring and evaluation function of this Strategic Plan will assist in assessing the progress, performance, and impact of the strategy. Its overall goal will be to provide quality information related to the performance of regulatory system in line with the set targets as well as the continued relevance of the strategic plan to result in timely and appropriate decisions. The iQMS section in coordination with divisions will finalize the monitoring and evaluation framework through a team within the first three months of the approval of Strategic Plan 2026-2030. The Monitoring and Evaluation (M&E) framework consists of responsibilities, key performance indicators and timelines as defined in the Implementation Matrix of this Strategic Plan. The responsibilities of monitoring this plan are based on the following guidelines:

- It is the responsibility of the iQMS section, senior management team, including heads of divisions, to monitor the performance of their areas of jurisdiction in implementing this Strategic Plan.

- A Planning, Monitoring, and Evaluation team to work with the iQMS section under the Authority whose responsibilities would be to:
 - Develop M&E framework, reporting template and other M&E tools.
 - Collect/receive reports and analyze, consolidate, summarize, and forward them on a timely basis to the respective heads, in defined timelines.
 - Develop mid-term, end-term, and ad hoc evaluations.
 - Report on performance contract targets.

Indicators and Outputs

The targets will be on,

- Objectives in the Implementation Matrix.
- Activities in the Implementation Matrix

Collection and Maintenance of Performance Data

- The performance data on each indicator will be identified.
- Collection of monitoring data will be done on a continuous basis.
- A database for maintaining this data will be established.

Reporting

The iQMS section will submit reports on a quarterly and biannual basis to the Authority; after analyzing, summarizing and consolidating all the reports thereafter, the M&E team will escalate the reports.

Evaluation

An end-of-year evaluation of the implementation of the Strategic Plan will be part of the development of the following year's annual operational plan. In case of significant unexplained variation in performance, especially on critical performance areas (either positive or negative), Policy Board will take appropriate action. This may include a deeper interrogation and adjustment on the relevance of the Strategic Plan and the contemplated deliverables. An end-term evaluation will occur as part of the development of the subsequent Strategic Plan.

Risks Management and Mitigations

Risk Category	Potential Risks	Mitigation Measures
Institutional	Delays in decision-making or approvals.	Strengthen delegation of authority oversight.
Financial	Insufficient budget allocation or delayed funding.	Implement cost-recovery and donor engagement strategies.
Human Resource	Staff availability, capacity and turnover.	Workforce hiring, capacity building & retention strategies. Partial/ complete outsourcing of support functions.
Technological	Cybersecurity attacks, breaches and system downtime.	Regular system audits and contingency plans. Continuous upgradation of operating systems, software and hardware.

Risk Category	Potential Risks	Mitigation Measures
Political/Economic	Policy discontinuity or fiscal instability.	Maintain inter-ministerial coordination and stakeholder engagement
Environmental	Natural disasters and calamities	Integrate climate resilience in DRAP facilities and processes.

CONCLUSION



The Strategic Plan 2026-2030 provides a coherent, structured, and forward-looking framework to strengthen national, provincial/regional regulatory bodies on their respective mandates in alignment with national health priorities and internationally recognized regulatory standards. Through a phased and risk-based approach, the Plan integrates regulatory system strengthening, digital transformation, workforce development, and infrastructure enhancement to ensure effective oversight across the full lifecycle of Therapeutic Goods. It places due emphasis on transparency, accountability, and evidence-based decision-making, while reinforcing collaboration with provincial authorities, international regulatory partners, and key stakeholders. Collectively, this Strategic Plan establishes a clear and realistic roadmap for achieving a mature, resilient, and trusted regulatory system, thereby enabling equitable access to quality, safe, and effective Therapeutic Goods and contributing meaningfully to public health protection and national health security during the period from 2026 to 2030.





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