Arab Republic of Egypt

Egypt National Drug Policy

2026 - 2030

A National Framework for Medicines Access, Quality and Rational Use

Version 1.0 | 2026 - 2030

Issued under the national governance framework for the pharmaceutical sector

Document Control

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This document reflects the collective contribution of the national entities identified in the Acknowledgment section and the institutions listed in the Stakeholder Roles table. It is issued as a national policy framework rather than the output of a single institution, consistent with the principle of shared, cross-sectoral ownership of medicines policy in Egypt.

Document History

Version	Date	Major / Minor	Description of Change	Remarks
1.0	29 June 2026	Major	Initial release of the National Drug Policy.	Approved

Table of Contents

Acknowledgment

This National Drug Policy is the product of an extensive collaborative process involving the national institutions responsible for, and affected by, the governance of medicines in Egypt. Its development was guided by a Supreme National Committee for the Development of the National Drug Policy, convened to ensure that the Policy reflects a shared national vision rather than the perspective of any single institution.

Sincere appreciation is extended to the following national entities for their technical contributions, expertise, and sustained engagement throughout the development of this Policy:

- Egyptian Drug Authority (EDA)
- Ministry of Health and Population (MOHP)
- Egyptian Health Council (EHC)
- Supreme Council of Universities
- Unified Procurement Authority (UPA)
- Egyptian Healthcare Authority (EHA)
- Chamber of Egyptian Industries – Export Council for Medical and Pharmaceutical Industries
- Egyptian Pharmacists Syndicate
- Egyptian Medical Syndicate

The Policy further reflects the input of the wider community of healthcare professionals, academic institutions, professional syndicates, and private-sector partners engaged throughout the consultation process. Their collective expertise has shaped a Policy intended to serve the long-term interests of Egypt's health system as a whole.

Drafting and Technical Coordination

The Strategic Planning and Policies Administration of the Egyptian Drug Authority served as technical secretariat and drafting coordinator for this Policy, in its capacity as the regulatory body responsible for pharmaceutical policy formulation and strategic planning:

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National Steering Committee

The National Steering Committee provided cross-institutional technical guidance, review, and national health-system expertise. Members are listed below by institution, in alphabetical order, reflecting their equally essential and complementary contributions:

COMMITTEE CHAIRMAN

Dr. Ali Al Ghamrawy — Chairman, Egyptian Drug Authority

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Dr. Ayman Abdel Hamid — Member, General Medical Syndicate

EGYPTIAN PHARMACISTS SYNDICATE

Dr. Faten Abdel Aziz — Member, General Syndicate of Pharmacists Management Committee

List of Abbreviations

Abbreviation	Full Term
ADRs	Adverse Drug Reactions
AMR	Antimicrobial Resistance
API	Active Pharmaceutical Ingredient
BA/BE	Bioavailability/Bioequivalence
BP	British Pharmacopoeia
CPP	Certificate of Pharmaceutical Product
CTD	Common Technical Document
EDA	Egyptian Drug Authority
EHA	Egyptian Healthcare Authority
EHC	Egyptian Health Council
EMA	European Medicines Agency
EML	Essential Medicines List
ERP	External Reference Pricing
EUA	Emergency Use Authorization
FDA	Food and Drug Administration (United States)
FDCs	Fixed-Dose Combinations
GCP	Good Clinical Practice
GDP	Good Distribution Practices
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practices
GRevPs	Good Review Practices
GReLPs	Good Reliance Practices
GSP	Good Storage Practices
GTIN	Global Trade Item Number
GVP	Good Pharmacovigilance Practice
HCPs	Healthcare Professionals
HTA	Health Technology Assessment
ICH	International Council for Harmonisation
IDA	Industrial Development Authority
INFS	Integrated National Financing Strategy
INN	International Nonproprietary Name

Abbreviation	Full Term
MAH	Marketing Authorization Holder
M&E	Monitoring and Evaluation
MFE	Manufacturing for Export
MOHP	Ministry of Health and Population
NDP	National Drug Policy
NOHARMe	National Office for Handling and Reduction of Medication Errors
OOP	Out-of-Pocket (expenditure)
OTC	Over the Counter
Ph. Eur.	European Pharmacopoeia
PV	Pharmacovigilance
SCCRE	Supreme Council for Review of Ethics of Clinical Medical Research
SDGs	Sustainable Development Goals
SMART	Specific, Measurable, Achievable, Relevant, and Time-bound
SRAs	Stringent Regulatory Authorities
STGs	Standard Treatment Guidelines
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UHC	Universal Health Coverage
UHI	Universal Health Insurance
UHIA	Universal Health Insurance Authority
UPA	Unified Procurement Authority
USP	United States Pharmacopeia
WHO	World Health Organization

Glossary of Terms

Term	Definition
Cost-plus pricing	A method where the medicine price is set by adding a fixed profit margin to the actual production cost, ensuring manufacturers recover costs without necessarily reflecting international benchmarks or therapeutic value.
Mark-up regulation	A system that controls profit margins at each stage of the supply chain, applying fixed percentage mark-ups from the ex-factory price to the final retail price to protect patients and ensure fair distribution.
External Reference Pricing (ERP)	A policy that determines national medicine prices by comparing them with public prices in selected reference countries, using the lowest or average price as a benchmark to promote affordability and transparency.
Reliance	Relying on the decisions of Stringent Regulatory Authorities regarding registration and analysis, in accordance with the Common Technical Document (CTD) — a set of specifications for dossiers submitted for the registration and marketing authorization of medicines.
Biological products (Biologicals)	Products containing one or more active ingredients produced or derived from a biological source, including but not limited to vaccines, serum, blood and plasma products and derivatives, and products manufactured using biotechnology, as well as related products defined by updated scientific or international standards.
Biosimilar	A biological product shown to be highly similar in quality, safety, and efficacy to an already licensed reference product.

Introduction

The National Drug Policy (NDP) establishes a high-level strategic framework to ensure the availability, quality, safety, effectiveness, and equitable use of medicines, in alignment with national health priorities and Egypt's sustainable development objectives. The Policy supports a resilient pharmaceutical system that responds to current and future population health needs while contributing to broader social and economic outcomes.

The Policy adopts a lifecycle-based approach to medicines, encompassing research and development, local manufacturing, regulation and evaluation, supply and distribution, dispensing, storage, and equitable access, within a coherent and integrated national framework.

The National Drug Policy promotes the rational use of medicines and reinforces quality and safety assurance, recognizing that achieving optimal health outcomes requires shared responsibility among all relevant stakeholders, including government entities, healthcare professionals, industry, academia, and the public.

The Policy brings together partners and stakeholders under a unified national vision for effective policy stewardship and implementation, placing individuals at the center of healthcare and addressing the needs of Egypt's diverse population through inclusive and people-centered approaches.

Implementation of the National Drug Policy relies on collaborative governance, strategic partnerships, and coordinated action across governmental entities at both national and subnational levels. The Policy both informs and is informed by related national policies, legislation, and health system reforms, ensuring coherence, alignment, and sustained progress toward Egypt's national health objectives.

Policy Context and Alignment with the National Health Policy and Egypt's Sustainable Development Objectives

The National Drug Policy is developed within the context of Egypt's National Health Policy and Egypt's sustainable development objectives, and serves as a key sectoral policy for achieving national health goals. Medicines are a fundamental component of health systems, and effective pharmaceutical policies are essential to strengthening primary health care, promoting equity, ensuring financial sustainability, and improving health outcomes and wellbeing across the life course.

In alignment with the National Health Policy, the National Drug Policy supports intersectoral coordination among health-sector institutions and related sectors; strengthens access to essential medicines, particularly in underserved and disadvantaged areas; contributes to the sustainability of health financing through cost-effective and rational use of medicines; and promotes local pharmaceutical production to enhance national health security.

The Policy supports access to essential medicines as a core component of quality healthcare, complementing the Universal Health Insurance system and broader health-system strengthening initiatives.

The Policy drives health-sector digital transformation by integrating medicines into evidence-based information systems. It also strengthens human resources through capacity building and the rational use of medicines. This integrated approach aligns the National Drug Policy with the National Health Policy and with WHO frameworks — including the existence of a comprehensive, implemented National Drug Policy as a recognized marker of regulatory system maturity.

The Policy promotes rational use of medicines and health literacy, supports socio-behavioral change, empowers individuals and communities, and enhances community engagement and the effectiveness of public health initiatives.

Vision, Scope, and Goals

Vision

> *A resilient and trusted national medicines system ensuring equitable access, quality, and safety, while supporting medicine security and comprehensive, people-centered pharmaceutical care.*

Scope

While the Egyptian Drug Authority regulates medical products and devices more broadly, this Policy focuses specifically on human pharmaceutical products and biologicals, across both the private and public sectors.

Goals

The National Drug Policy provides a strategic framework to:

- Ensure equitable and sustainable access to safe, effective, and quality medicines.
- Promote rational use and strengthen governance across the pharmaceutical system.
- Foster pharmaceutical innovation and research.
- Strengthen local pharmaceutical manufacturing, encourage exports, and attract investment.
- Enhance national and international collaboration for resilient health systems.

Realizing Strategic Goals via Collaborative Alliance

The successful implementation of Egypt's National Drug Policy relies on the coordinated engagement of key stakeholders across the pharmaceutical system to ensure equitable access, assured quality, rational use of medicines, and strong governance.

Stakeholder Roles in Alignment with NDP Core Components

Category	Stakeholder	Core Components (WHO Framework)
Government & Regulatory Bodies	Egyptian Drug Authority (EDA)	• Selection of Essential Medicines • Affordability • Supply Systems • Regulation & Quality Assurance • Rational Use of Drugs • Human Resources Development • Co-operation with SRAs
	Ministry of Health & Population (MOHP)	• Rational Use of Drugs • Supply Systems • Human Resources Development
	Egyptian Health Council (EHC)	• Selection of Essential Medicines • Rational Use of Drugs • Human Resources Development

Category	Stakeholder	Core Components (WHO Framework)
	Unified Procurement Authority (UPA)	• Affordability • Sustainable Drug Financing • Supply Systems • Human Resources Development
	Egyptian Healthcare Authority (EHA)	• Affordability • Sustainable Drug Financing • Supply Systems • Rational Use of Drugs
Academia	Supreme Council of Universities	• Research & Development • Human Resources Development
Professional Bodies	Egyptian Pharmacists Syndicate	• Rational Use of Drugs • Supply Systems • Regulation & Quality Assurance • Human Resources Development
	Egyptian Medical Syndicate	• Rational Use of Drugs • Human Resources Development
Private Sector	Chamber of Pharmaceutical Industries	• Supply Systems • Research & Development
Healthcare Professionals	Public & private hospitals Clinic & Medical centers	• Regulation & Quality assurance • Supply System • Rational Use of Drugs
International Partners	WHO & International Organizations	• International Cooperation

Key Components of the National Drug Policy

The Policy's overarching objectives are access, quality, and rational use. A balance across these objectives is required to form a complete and coherent policy framework.

The Policy comprises ten core components. Each plays a distinct role in advancing one or more of these objectives, as set out below.

Components	Access	Quality	Rational Use of Drugs
Selection of Essential Medicines	X	(X)	X
Affordability	X		
Sustainable Drug Financing	X		
Supply Systems	X		(X)
Regulations and Quality Assurance		X	X
Rational Use of Drugs			X
Research and Development	X	X	X

Components	Access	Quality	Rational Use of Drugs
Human Resources Development	X	X	X
Co-operation with SRAs	(X)	(X)	(X)
Monitoring & Evaluation (M&E)	X	X	X

X = direct link (X) = indirect link

POLICY FRAMEWORK

The Ten Core Components of the National Drug Policy

CORE COMPONENT

01 Selection of Essential Medicines

To ensure equitable and continuous access to safe, effective, and quality medicines within functional health systems, in sufficient quantities, with appropriate dosage forms and guaranteed quality, accompanied by accurate information, and offered at an affordable cost for individuals and communities.

POLICY AIMS

- Ensure sustainable access to safe, effective, and quality essential medicines.
- Promote equity and rational use through evidence-based decision-making.

KEY CHALLENGES

- Rapid market evolution and the increasing availability of high-cost innovative therapies.
- Budgetary constraints and the need to balance clinical cost-effectiveness with overall fiscal affordability.
- Integration of EML decision-making with real Egyptian data on disease burden and medicine utilization.
- Concerns among some prescribers regarding potential limitations on clinical flexibility.
- Market and financial considerations for manufacturers and dispensing sectors associated with EML implementation, and the widespread prescription and sale of non-essential medicines in the private sector.
- Donations of non-essential drugs, which can undermine the acceptance and implementation of the selection process and adherence to evidence-based clinical guidelines.

Core Strategies

Selection Criteria for Essential Medicines

The selection process for essential medicines is consultative, transparent, and evidence-based, using explicit criteria linked to national clinical guidelines divided by levels of care, which are regularly reviewed and updated:

- Disease burden and genetics.
- Public health impact.
- Therapeutic efficacy and safety profile.
- Reliable quality, dosage form, stability, and bioavailability.

In some cases, selection may also be influenced by other factors, such as pharmacokinetic properties, or by local considerations such as the availability of facilities for manufacture or storage.

Cost-Effectiveness Compared to Alternatives

Evaluation focuses on the total cost of treatment rather than unit cost alone, assessed against clinical efficacy.

Public Health System Affordability

- Acknowledging that cost-effectiveness does not always ensure fiscal feasibility, the Policy mandates an Affordability Assessment.
- For high-cost medicines, a Budget Impact Analysis is required to evaluate the total financial burden on the public health budget.
- Selection must consider the system's capacity to maintain a sustainable and uninterrupted supply.

Product Formulation

- **Single Ingredients:** Priority is given to single active ingredient drugs to simplify treatment regimens and monitoring.
- **Fixed-Dose Combinations (FDCs):** These are selected only where they offer proven clinical advantages — such as improved adherence or synergistic effects — over single-ingredient products.

The Essential Medicines List Committee

- The Pharmacy Practice Guides and National Drug Lists Committee was established by EDA Chairman's Decree No. 785 of 2025 to oversee the development and periodic revision of national drug lists, including the Essential Medicines List (EML).
- The Committee comprises experts representing relevant national institutions, including regulatory authorities, the Unified Procurement Authority, academic institutions, and healthcare-sector stakeholders, with medical experts from MOHP invited for consultation.
- The Committee submits technical recommendations — following evaluation of different products and their evidence of effectiveness and cost-effectiveness — to the Head of the Egyptian Drug Authority for endorsement. Once approved, the EML is officially published on EDA's website.
- The list is reviewed and updated every two years, following the same transparent and evidence-based process.
- Medicines are listed according to their Generic Name or International Nonproprietary Name (INN).
- **Core list medications:** serve as the primary treatment choices and must be consistently available in adequate quantities within functional healthcare systems.

In exceptional circumstances, if a core list medication is unavailable, designated Therapeutic Alternatives may be used as a second option. These are not included in the Essential Medicines List but belong to the same pharmaceutical or chemical subgroup and have comparable clinical effectiveness and safety. Their use is subject to formal application and approval by the relevant committee for the specified strength and dosage form.

Applications of the National EML in Egypt

- **Public Procurement:** the EML is the primary reference for the Unified Procurement Authority to prioritize tenders and ensure a continuous supply of essential medicines.
- **Universal Health Insurance:** it forms the basis for defining the Benefit Package and reimbursement lists for citizens under the Universal Health Insurance system.

- **Clinical Practice:** it is the mandatory guide for prescribing and dispensing within Ministry of Health facilities and university hospitals.
- **Regulatory Monitoring:** it is a tool for EDA to monitor market availability, stock levels, and the quality of life-saving medicines.
- **Budgeting and Resource Allocation:** it provides a strategic framework for the Ministry of Finance and health authorities to allocate budgets efficiently based on national priorities.
- **Emergency Preparedness:** the standard reference list for stockpiling essential medicines for national emergencies and crises.

CORE COMPONENT

02 Affordability

Affordability in the pharmaceutical sector ensures access to quality-assured essential medicines at fair prices. It relies on transparent pricing, effective procurement, and strong regulation, while reducing out-of-pocket costs, promoting competition, supporting local manufacturing, and achieving economies of scale through centralized procurement.

POLICY AIMS

- Ensure equitable and affordable access to quality-assured essential medicines.
- Strengthen local pharmaceutical manufacturing and centralized procurement systems to improve cost efficiency.

KEY CHALLENGES

- High prices of innovative essential medicines for which generics are not yet available in the market.
- **Market failure, driven by:** information imbalance, where patients know less than prescribers or dispensers about a drug, which can lead to inappropriate use; and failure of competition due to exclusive rights (including patents and trademarks), international trade agreements such as TRIPS, and when production is concentrated in a small number of suppliers.

Core Strategies

Universal Health Insurance (UHI) System

Expand and strengthen Egypt's UHI system to provide comprehensive, high-quality coverage; reduce high out-of-pocket expenses; harmonize existing insurance schemes; and establish a unified, efficient, and equitable system following the full implementation of the UHI program.

Tax Exemption Measures

Supportive legislation has been enacted to reduce tax burdens on medicines. Law No. 3 of 2022, amending VAT Law No. 67 of 2016, exempts medicines and production materials from value-added tax, helping to lower costs and enhance market competitiveness.

Medicine Pricing Framework

The Egyptian Drug Authority Pricing Committee, established in 1976, regulates medicine prices to ensure affordability. It includes experts from academia, policymakers, and pharmacoeconomics specialists. The Committee sets prices for all pharmaceutical products, negotiates prices for patented and single-source medicines, and safeguards affordability for patients paying out-of-pocket.

Egypt's pricing system has evolved from cost-plus rules to a model combining External Reference Pricing (ERP) with mark-up regulation. Branded and generic medicines are priced according to international references, therapeutic alternatives, and product origin, with differentiated profit margins for pharmacists and distributors. Prices are reviewed every five years, with interim adjustments when needed — for example, in response to currency changes or manufacturer requests.

To reinforce affordability and equity, Egypt applies a compulsory pricing strategy that enforces a mandatory national price ceiling for all registered medicines, combined with mark-up regulation and

profit controls, ensuring that pharmaceutical products remain accessible and affordable for the majority of out-of-pocket payers.

At the same time, innovation incentives encourage investment, exports, and the availability of advanced products. This dual approach — strict affordability safeguards alongside innovation support — keeps Egypt's pricing framework transparent, adaptive, and aligned with national health priorities.

Promoting Competition to Improve Medicine Affordability

For single-source products (patented medicines), legal provisions allow the initiation of evaluation and registration procedures for generic medicines before the expiry of the patent. This enables timely market entry of generics and supports immediate competition once patent protection ends, improving affordability and availability.

For multiple-source products (generics and therapeutic equivalents), EDA implements supportive legislative and regulatory frameworks to promote competition and ensure that medicines meet standards of quality, safety, and efficacy comparable to reference products.

Fast-track registration pathways may also be adopted to support the timely availability of medical products from multiple sources and diverse technologies, in line with public health needs, and to enhance market competition through expedited market entry.

Supporting Local Manufacturing and Pharmaceutical Industry Investment

Egypt prioritizes the localization of medical products as a strategic pillar to enhance affordability and strengthen supply security. This is supported through enabling regulatory frameworks, fast-track registration pathways, and targeted incentives provided by a specialized committee, while maintaining compliance with quality, safety, and efficacy standards to strengthen national industrial capacity.

Good Procurement Practices as an Affordability Enabler

Strengthening procurement systems is a strategic tool for enhancing affordability. By centralizing purchasing through the Unified Procurement Authority, mandating generic-name tendering, and ensuring compliance with EDA regulations, Egypt can achieve economies of scale, reduce costs, and guarantee the continuous availability of essential medicines. Transparent tendering, efficient inventory management, and prioritization of local GMP-compliant manufacturers further lower prices and protect patients from financial hardship, while maintaining equitable access across the health system.

Externalities

These services carry broad public health impact and therefore require regulatory oversight, rather than being left solely to market forces.

CORE COMPONENT

03 Sustainable Drug Financing

Drug financing in Egypt is aligned with Universal Health Coverage (UHC) and the Integrated National Financing Strategy (INFS) to secure sustainable, equitable access to essential medicines. It focuses on efficient use of public resources, pooled procurement, and strategic purchasing to enhance affordability, availability, and resilience, while reducing out-of-pocket (OOP) spending and financial risk.

POLICY AIMS

- Secure sustainable public financing and reduce out-of-pocket expenditure to support Universal Health Coverage.
- Ensure efficient, transparent, and equitable allocation of pharmaceutical resources under strong governance and accountability frameworks.

KEY CHALLENGES

- High out-of-pocket spending burdens patients and families, risking catastrophic expenditure and poor adherence to long-term treatments.
- Fragmented public purchasing causes waste, weak bargaining power, and uneven prices.
- Limited budgets compete across priorities, restricting coverage for high-cost innovations such as biologics.
- Supply chain gaps in forecasting and inventory management lead to shortages, overstock, and waste.
- Equity issues persist for vulnerable groups despite insurance expansion.
- Limited use of Health Technology Assessment (HTA) results in suboptimal resource-allocation decisions.
- Monitoring gaps undermine transparency in procurement and spending.

Core Strategies

Public Financing and Resource Allocation

- Embed drug financing within national systems via the Ministry of Finance and MOHP, following fiscal rules and medium-term plans.
- Target financing for essential medicines through MOHP and the Universal Health Insurance Authority (UHIA), using the Essential Medicines List, disease burden data, and cost-effectiveness evidence.
- Strengthen Health Technology Assessment through UHIA, with support from EDA and MOHP, to inform reimbursement decisions and prioritize high-value medicines.

Financial Governance, Market Stability, and Sustainability

- Strengthen oversight through audits, tracking, and reporting across the Ministry of Finance, MOHP, and UPA.
- Ensure market stability through timely payments, liquidity management, and supply continuity across the Ministry of Finance, UHIA, and UPA.

- Promote private-sector participation and local manufacturing through EDA policies coordinated with the Ministry of Finance and MOHP, with an emphasis on affordability and quality.

Private Insurance Schemes and Financing Mechanisms

Private insurance is harmonized with the Universal Health Insurance system to reduce out-of-pocket expenditure. The private sector is encouraged to expand coverage for vulnerable populations and align reimbursement practices with national affordability goals.

CORE COMPONENT

04 Supply Systems

The drug supply system requires strategic planning and efficient management across production, procurement, distribution, and storage to deliver safe, effective, quality medicines on time. This ensures supply security, aligns with Egypt's UHC and digital health strategies, and draws on EDA, UPA, IDA, and MOHP regulations for resilience.

POLICY AIMS

- Ensure efficient and cost-effective procurement and an uninterrupted supply of safe and effective medicines.
- Strengthen end-to-end supply chain resilience, including timely distribution, inventory management, and safe disposal practices.

KEY CHALLENGES

- Fragmented procurement leads to inefficiencies and inconsistent pricing.
- Supply disruptions arising from global shocks, poor forecasting, or cold-chain failures.
- Limited local API production hampers self-sufficiency and efforts to reduce import reliance.
- Counterfeit and substandard medicines evading weak distribution tracking.
- Emergencies may affect the testing or importation of medical products.
- Wastage from overstocking or improper storage across public and private supply chains.

Core Strategies

Governance

- The Unified Procurement Authority (UPA) serves as the sole public bulk purchaser, ensuring efficient, transparent procurement in line with WHO-aligned Good Pharmaceutical Procurement Practices.
- The Egyptian Drug Authority (EDA) is responsible for regulatory oversight, licensing, inspection, and post-market surveillance to safeguard quality and safety.
- EDA conducts joint licensing inspections with the Industrial Development Authority (IDA) to license local manufacturers.

Procurement

- Procurement standards are enforced across public and private providers.
- Private hospitals and clinics shall transition to generic-name tendering and transparent procurement procedures under a phased implementation plan, aimed at maximizing efficiency and reducing costs.
- UPA centralizes public tenders for medicines using generic names and coordinated demand forecasts, aligning procurement as far as feasible with the Essential Medicines List.
- UPA enhances transparency and monitors supplier and procurement performance through regular reviews and audits.

- UPA aggregates procurement volumes and promotes competitive tendering, while supplier prequalification and GMP compliance are ensured in coordination with EDA; procurement funding is provided through national public financing mechanisms.
- UPA promotes price transparency by maintaining and publishing reference pricing information, where appropriate, to support efficient procurement, benchmarking, and cost containment.

Distribution

Public Sector

- EDA mandates compliance with Good Distribution Practice (GDP), Good Storage Practice (GSP), and cold-chain requirements.
- EDA progressively implements digital track-and-trace systems using identifiers such as GTIN to strengthen product traceability and supply-chain visibility.
- EDA ensures appropriate storage, handling, and transportation of medicines throughout the supply chain, from manufacturer to patient, to safeguard quality and safety.
- National inventory management systems monitor stock levels, prevent shortages, minimize wastage, and reduce risks of theft or diversion.

Private Sector

- Private pharmaceutical wholesalers, distributors, and community pharmacies operate as essential components of Egypt's national medicine supply chain under EDA regulatory oversight.
- Private community pharmacies serve as primary patient access points and help ensure continuous medicine availability across all geographic regions. Under Law No. 127 of 1955 on the Practice of Pharmacy, they may only be owned and operated by licensed, registered pharmacists, following professional examinations conducted by the Egyptian Health Council — ensuring management exclusively by qualified professionals in compliance with national standards.
- EDA ensures that all private-sector supply actors comply with national licensing requirements and GDP/GSP standards to maintain medicine quality, safety, and integrity.
- Private-sector supply chain actors should be integrated within the national pharmaceutical track-and-trace system to enhance transparency, prevent counterfeit medicines, and strengthen supply chain visibility.
- EDA collaborates with private-sector stakeholders to support national efforts in shortage prevention, emergency preparedness, and supply continuity.

Drug Supply in Emergencies

- Egypt ensures continuity of drug supply during emergencies through coordinated efforts by MOHP, UPA, and EDA. Strategic buffer stocks covering three to six months of essential medicines are maintained to prevent shortages.
- EDA applies expedited regulatory pathways, including Emergency Use Authorization (EUA) and accelerated lot release, to ensure the timely availability of critical medicines.
- EDA accelerates testing, quality control, and import procedures during emergencies.
- Unregistered human pharmaceutical and biological products may be authorized for import as special requests when no locally registered alternatives exist, or when available quantities are insufficient to meet demand, in accordance with relevant legal provisions.

- Egypt also utilizes TRIPS flexibilities and collaborates with WHO-prequalified sources to strengthen supply security and national self-sufficiency.

Drug Donations

Drug donations are regulated to ensure they align with national needs and contribute to equitable access. Donations are accepted only when no adequate registered alternatives are available, or when supply is insufficient.

EDA is responsible for prior import approval, ensuring the safety, quality, and efficacy of all donated products in line with national regulations and international standards such as GMP, WHO prequalification, or FDA/EMA approval.

All donated medicines must have a minimum remaining shelf life of six months from the date of issuance of the customs release letter.

Receiving entities are required to store, handle, and use donated medicines under proper medical supervision, consistent with the principles of rational use of medicines.

Local Manufacturing

Egypt strengthens local manufacturing to enhance supply security and national self-sufficiency through:

- Establishment of a structured framework for listing and approving API manufacturers — both within and outside Egypt — by EDA through a dedicated quality-file assessment system.
- Acceleration of licensing timeframes for new or rare production lines.
- Promotion of technology transfer agreements to build national manufacturing capabilities and foster pharmaceutical innovation.
- Adoption of targeted regulatory incentives to promote local manufacturing, including fast-track registration pathways, tax benefits, industrial land allocation, and export support programs, aligned with Egypt's national localization targets.
- Prioritization of locally manufactured products in UPA public tenders, in support of national self-sufficiency goals.

CORE COMPONENT

05 Regulations and Quality Assurance

EDA establishes and enforces transparent legislation and regulatory frameworks to ensure the quality, safety, efficacy, and accurate information of medical products and the materials used in their manufacture.

This is achieved by regulating and overseeing the registration, manufacturing, procurement, import and export, distribution, supply, lot release, promotion, advertising, pharmacovigilance, and clinical trials of such products, in compliance with the provisions of the law and international standards, and guided by the independence and transparency of the Egyptian Drug Authority.

KEY CHALLENGES

- Prevalence of counterfeit, substandard, or illegal medical products, including products lacking active ingredients, containing incorrect dosages or harmful substances, or sold beyond expiry dates.
- Poor storage, contamination, repackaging, and handling in unlicensed outlets.
- Submission of unreliable studies and data, compounded by limited access to secure reference-product information.
- Inappropriate promotion driving irrational prescribing, dispensing, and use, amid rapid sector growth and outdated regulatory frameworks.
- Infrastructure delays in implementing automation and digital systems, which hinder system integration, increase operational costs, and reduce decision-making efficiency.
- Poor-quality safety data and underreporting, which undermine regulatory oversight, decision-making, and performance evaluation.

Collectively, these factors may lead to treatment failure, adverse effects, prolonged illness, erosion of trust in the healthcare system, and waste of limited financial resources.

Foundations of Effective Medicines Regulation

Medicines regulation is a complex undertaking involving many stakeholders and interests. For this reason, certain foundational requirements apply.

Sound Legal Basis and Resources

EDA operates in accordance with Law No. 151 of 2019, with a solid legal framework covering all its regulatory functions. EDA maintains competent, integrity-driven administrative and technical staff, sustainable funding, fully equipped quality control laboratories, and access to local and international experts.

Independence

EDA carries out its functions fully independently and impartially to ensure public confidence in its operations and regulatory decisions. It reports directly to the Cabinet, ensuring full administrative and technical autonomy while maintaining alignment with national health policies.

Transparency

EDA emphasizes transparency in all procedures and decisions, and publishes standards and requirements for all applicants, including:

- Maintaining an accessible and user-friendly website for all stakeholders.
- Publishing draft guidelines for stakeholder consultation prior to release.
- Publicly sharing official decrees, registration guidelines, fees, technical committee decisions, and relevant databases.
- Addressing complaints and appeals through the unified government complaints system and EDA-specific channels, with appropriate corrective actions.
- Ensuring the confidentiality of sensitive information and documents.

Registration

Registration represents the first step in quality assurance, ensuring that medical products meet required standards before market entry. Every medical product in Egypt must be licensed by EDA before production, storage, export, marketing, or importation. For Special Access Import Pathways, EDA issues import approvals rather than a registration license, in accordance with established regulatory procedures and approved guidelines.

Registration Pathways

Marketing Authorization

Marketing authorization is granted following a comprehensive evaluation of submitted data to ensure a product's quality, safety, and efficacy, as well as the adequacy and clarity of labelling and packaging information. This process defines the conditions for product use and is supported by established post-marketing surveillance and control procedures, this evaluation is conducted through the following:

- EDA applies Good Review Practices (GRevPs) to strengthen regulatory performance, ensuring consistency, transparency, timeliness, and predictability throughout the review process.
- Assessment of product quality, safety, and efficacy in alignment with approved regulatory guidelines, alongside the promotion of harmonization and convergence of registration requirements with ICH guidelines, WHO technical guidelines, and the regulatory standards of the EMA and FDA.
- EDA applies Good Reliance Practices (GReLPs) through reliance pathways aligned with WHO-recognized Stringent Regulatory Authorities, accelerating access to safe and effective medicines while optimizing regulatory resources.
- Adoption of the Common Technical Document (CTD) framework as a unified "One Submission" pathway for the registration of human and biological products, in accordance with applicable ministerial decrees.
- Upon completion of all regulatory requirements, the registration application is submitted to the Technical Committee of Drug Control for review and a decision on product approval.

Emergency Use Authorization (EUA)

EUA is a risk-based pathway for assessing unlicensed biological and human products during public health emergencies. It provides time-limited authorization when data are limited and products are not yet ready for full marketing authorization.

Based on the ministerial decrees governing registration and marketing authorization of biological and human pharmaceutical products, EDA has issued a dedicated guideline for emergency use application and approval, including regulatory requirements applicable in public health emergencies.

Post-Authorization Procedures

Variation

- EDA regulates post-approval variations to registered medical products through a structured, risk-based framework to ensure continued quality, safety, and efficacy.
- Variations are classified and assessed according to their potential impact, in line with EDA regulatory guidelines.

Re-Registration of Registered Products

- EDA applies a defined registration validity period — generally ten years for human medicines and five years for biologicals.
- All medical products are periodically reassessed to confirm continued efficacy, safety, and quality; renewal applications must be submitted by license holders before expiry of the registration license to sustain marketing authorization.
- For human medicines, the applicant must submit a report on the safety, quality, and efficacy of the registered product at the fifth year following the date of marketing authorization.
- In cases of non-compliance, marketing of the product may be suspended based on a report from the relevant Central Administration.

Core Elements of Drug Regulation

Registration is supported by core regulatory elements that collectively ensure the quality, safety, efficacy, and accurate information of medicinal products, implemented through defined regulatory controls across the product lifecycle:

- **Quality:** assessed during registration, licensing, inspection, and testing.
- **Safety:** monitored via adverse drug reaction (ADR) reporting, recalls, and safety warnings.
- **Efficacy:** evaluated through registration review, clinical trials, and bioequivalence studies.
- **Information:** ensured through oversight of labelling, package inserts, and promotional materials.

Quality

Quality is a fundamental requirement for market approval in Egypt and is assessed along the medicine lifecycle, across both public and private sectors. Ensuring product quality relies on an integrated regulatory framework encompassing licensing, laboratory controls, stability evaluation, inspection, and import/export regulation, all under EDA oversight, as follows:

Licensing

EDA operates a mandatory licensing system for manufacturers, importers, distributors, scientific offices, warehouses, pharmacies, and stability/bioequivalence centers, to ensure compliance with quality, safety, and efficacy standards. EDA defines licensing requirements, assessment criteria, and conditions for renewal or variation, and publishes this information on its website.

Inspection

All medical product manufacturers must comply with WHO/ICH GMP standards under EDA oversight; no registration is approved without verified GMP certification.

EDA conducts risk-based inspections across manufacturing facilities, import/export operations, distribution and wholesale (GDP/GSP) activities, and stability and bioequivalence centers.

Post-marketing inspections and market surveillance reinforce regulatory compliance, triggering enforcement actions such as suspension, recalls, or safety alerts when needed — including inspections of distribution channels and pharmacies, alongside market sampling and analysis programs to detect non-compliant or falsified products, ensuring continuous monitoring of product quality and safety and the protection of patient health.

National Control Laboratories

EDA laboratories adhere to WHO, ISO, ICH, and current pharmacopeial standards to deliver reliable testing data that support regulatory decision-making and help prevent substandard, counterfeit, and unsafe medicines. The laboratories operate using qualified equipment, validated analytical methods, and secure electronic systems to ensure accurate testing results, traceability, and data integrity. Technical guidelines govern product specifications and analytical methods for product registration, post-approval changes, and regulatory quality control activities.

Lot Release

EDA applies lot release to biological products as a critical regulatory control, verifying their quality, safety, and efficacy before market entry. It functions as an independent step following marketing authorization, using a risk-based approach tailored to product risk and public health priorities. It is implemented in coordination with market surveillance and other regulatory functions, ensuring continuous oversight across the product lifecycle, strengthening regulatory decision-making, and enhancing public confidence in biologicals, in line with WHO requirements.

The Egyptian Pharmacopoeia

The Egyptian Pharmacopoeia is the official national reference for pharmaceutical quality standards in Egypt, issued by EDA through a decision of its Board of Directors. It holds the legal status of a binding regulatory document and serves as a unified scientific and regulatory reference for the specifications of medicines and pharmaceutical products circulated in Egypt, ensuring their quality, safety, and efficacy in line with international standards in accordance with regulatory requirements.

The Egyptian Pharmacopoeia provides official specifications, identification tests, analytical methods, purity tests, and acceptance criteria for active pharmaceutical ingredients, finished products, and excipients. It also includes general chapters establishing the fundamental requirements governing the procedures and tests described in its monographs.

It is updated every three years under EDA supervision, through a dedicated scientific committee comprising regulatory experts, academic institutions, and industry stakeholders, ensuring continuous alignment with international pharmacopeial standards and national health priorities. EDA recognizes internationally accepted pharmacopoeias, including the USP, BP, and Ph. Eur., as global references supporting the implementation and evaluation of pharmaceutical quality standards.

Stability

Assessment of stability studies is an integral step in the medical product registration procedure. Following rigorous evaluation of submitted stability studies and analytical methods, EDA establishes the product's approved shelf life and storage conditions in accordance with regulatory guidelines.

Safety

Pharmacovigilance

EDA maintains a comprehensive system for the detection, assessment, understanding, and prevention of adverse effects and other medicine-related problems throughout the product lifecycle, to ensure the safe, effective, and rational use of medicines and safeguard public health, through the following:

- Ensuring consistent implementation of Good Pharmacovigilance Practices (GVP) for all pharmaceutical products.
- Increasing awareness and reporting of ADRs among patients, healthcare professionals (HCPs), and communities.
- Continuous monitoring of the safety and benefit–risk profiles of marketed medicines.
- Strengthening national post-marketing surveillance systems.

Pharmacovigilance Challenges

- Underreporting of ADRs is a global problem.
- Insufficient integration of pharmacovigilance data into clinical practice and policy decision-making.
- Capacity constraints in signal detection, assessment, and risk communication.
- Coordination gaps among Marketing Authorization Holders (MAHs), healthcare facilities, and regulatory bodies.

Strengthening the Pharmacovigilance Function

- **National PV System:** establish a collaborative national pharmacovigilance framework with healthcare providers, industry, and MOHP, in line with Egyptian GVP guidelines.
- **Active Reporting:** promote ADR reporting through healthcare institutions, pharmaceutical companies, and public awareness initiatives.
- **Digital Tools:** implement electronic portals and hotlines to facilitate data collection and signal detection.
- **Data Integration:** utilize Risk Management Plans, Periodic Safety Update Reports, scientific literature, and clinical trial data for comprehensive safety monitoring.
- **Risk Communication:** EDA issues safety alerts, reviews and approves Marketing Authorization Holders' Direct Healthcare Professional Communications (DHPC), and disseminates warnings through official channels.
- **Capacity Building:** expand the network of pharmacovigilance focal points in hospitals and strengthen national capacity through EDA, WHO, and international training programs.
- **Product Lifecycle Approach:** apply GVP principles from pre-marketing evaluation through post-marketing surveillance.

Efficacy

Efficacy is a fundamental requirement for the registration and market authorization of medical products and is assessed through a structured regulatory review process that ensures therapeutic benefit and clinical reliability. Regulatory review focuses primarily on demonstrated bioavailability (where applicable), product quality, and the accuracy and completeness of product labelling and information, as follows:

Bioavailability and Bioequivalence

Bioavailability and bioequivalence studies are a critical regulatory requirement to demonstrate the therapeutic efficacy of generic medicines before market launch, and, where relevant, for certain post-

approval variations. Such studies must be conducted in accordance with the Egyptian BA/BE guidelines, aligned with international ICH, EMA, WHO, and US-FDA standards. BA/BE Studies are performed in EDA-licensed centers that comply with Good Clinical Practice (GCP) and Good Laboratory Practice (GLP), using calibrated and validated analytical equipment. An expert scientific committee reviews and evaluates submitted bioequivalence data to support regulatory decision-making.

Clinical Trials Authorization

Biological products and new chemical entities require comprehensive preclinical and clinical evidence — including chemistry, pharmacology, and toxicology data, together with well-designed clinical trials — to demonstrate safety and efficacy before approval.

Clinical trials represent a critical evaluation phase for assessing the safety, efficacy, and clinical benefit of new pharmaceutical and biological products before market authorization. EDA provides comprehensive regulatory oversight, ensuring that all interventional research involving human participants is conducted in a scientifically, ethically, and legally sound manner.

EDA's regulatory framework aligns with Good Clinical Practice principles, per the EDA clinical trial oversight guideline (ICH E6 and WHO Good Clinical Practice guidelines) and national clinical research law (Law No. 214 of 2020 and its Executive Regulation No. 927 of 2022). Protocol submission for scientific and ethical review and approval is mandatory before trial initiation.

EDA Oversight Encompasses

- Evaluation of submitted research protocols for any medical research across all clinical trial phases, and of protocol amendments, to issue a decision.
- Evaluation of submitted safety reports, adverse events, and periodic progress follow-up reports.
- Verification of compliance with Good Clinical Practice (GCP) and ethical standards throughout the lifecycle of clinical trials, through GCP inspections of all related entities.
- Evaluation and assessment of submitted interim and/or final clinical study reports, and oversight of study completion.
- Ensuring sponsors' responsibilities are met, including full regulatory compliance from initiation through completion and results publication.
- Facilitating efficient processes through digital platforms for protocol submission, review tracking, and oversight management.
- Coordinating oversight of clinical medical research in Egypt through interaction and communication between EDA, the Supreme Council for Review of Ethics of Clinical Medical Research (SCCRE), and Institutional Review Boards (IRBs).
- Evaluation of study design and investigator qualifications.

This integrated approach protects participants' safety and wellbeing while generating reliable data for regulatory decision-making and public health advancement.

Information and Drug Promotion

EDA ensures that all medical information — labels, leaflets, datasheets, and promotional materials — is accurate, evidence-based, up-to-date, and free from misleading claims across traditional and digital platforms, by:

- Controlling promotion to support rational medicine use and safe self-medication.
- Upholding ethical standards and enhancing public health literacy.

- Guaranteeing scientifically reliable product communications.
- Monitoring and preventing unauthorized online and digital marketing.

Challenges

- Misleading promotion and oversight gaps.
- Uneven compliance among MAHs and resource constraints.
- Cross-border marketing beyond EDA jurisdiction.

Strategies to Promote Accurate Information and Drug Promotion

- **Pre-Approval Mandate:** MAHs must submit all promotional and educational materials for EDA clearance.
- **Scientific Review:** specialized pharmacists verify accuracy, balance, and audience suitability.
- **Regulatory Guidelines:** continuously updated rules govern promotion, online activity, and disease-awareness campaigns.
- **Product Information:** package leaflets are reviewed during registration and post-approval, per EDA leaflet guidelines.
- **Post-Marketing Surveillance and Enforcement:** proactive monitoring and follow-up of approved promotional materials, handling of violation reports, and appropriate regulatory action against MAHs.
- **Digital Systems:** maintaining official drug databases and pharmacy informatics tools to support evidence-based practice.
- **Electronic Labelling:** implementation of a national e-labelling system to ensure timely updates and rapid dissemination of safety-related information, enabling real-time access to the most current approved product information.

Import and Export Regulation

Import

- EDA regulates the import of medical products, including finished and bulk products, active and inactive raw materials, and packaging materials; import approval is required for all such items prior to customs release.
- Quality documentation, such as GMP certificates, is required where applicable, and validation of the Certificate of Pharmaceutical Product (CPP) is required for imported medical products.
- Reliance practices are applied where eligible, allowing EDA to take into account decisions from recognized reference authorities.
- Human pharmaceutical and biological products not registered with EDA are permitted to be imported through the Special Access Import Pathway where no similar product is registered or circulating in the local market, or where available quantities are insufficient to meet need, in accordance with established regulatory procedures and approved guidelines.

Export

- Medical products must be registered with EDA, or manufactured under the Manufacturing for Export (MFE) initiative, before export approval is granted.
- Export of registered medical products is permitted only when adequate quantities remain available to meet domestic market needs.

- Export approvals, including certificates for registered medical products, are granted in accordance with the procedures set out in Decree No. 216 of 2020 (covering commercial exports, samples, re-exports, donations, and personal exports).
- Under the MFE Initiative (Decree No. 69 of 2021), medical products not registered with EDA may be manufactured in local facilities, provided that all produced quantities are exported.

CORE COMPONENT

06 Rational Use of Drugs

Egypt implements managerial, educational, and regulatory measures to promote the appropriate use of medicines — ensuring patients receive clinically appropriate treatments in optimal doses, duration, and cost — aligned with WHO guidance, national health policies, the AMR Action Plan, digital health strategies, and the EDA regulatory framework.

POLICY AIMS

- Promote appropriate patient use of medicines in line with clinical needs, to optimize outcomes and resources.
- Strengthen clinical decision-making through guidelines, stewardship, and alignment with priority public health needs.

KEY CHALLENGES

- Irrational use of medicines leading to wasted resources, antimicrobial resistance (AMR), adverse drug reactions, and suboptimal health outcomes.
- Inappropriate access to prescription-only medicines without proper medical supervision.
- Misleading pharmaceutical promotion and potential conflicts of interest influencing prescribing practices.
- Public misconceptions regarding medicine use, including the relationship between cost and therapeutic value.
- Growing burden of non-communicable diseases, placing significant pressure on the healthcare system and national budget.
- Variability in healthcare professionals' competencies in rational prescribing, dispensing, and patient counselling.

Core Strategies

Educational

- **Capacity Building and Continuous Professional Development:** strengthen competencies through continuous training on rational use, Standard Treatment Guidelines (STGs), the Essential Medicines List, and clinical pharmacy — led by EDA in collaboration with the Egyptian Health Council, implemented across healthcare facilities by MOHP, and integrated into academic education by the Ministry of Higher Education.
- **Public Awareness:** EDA implements awareness campaigns through digital platforms and field activities to promote appropriate medicine use, reduce self-medication, and combat antimicrobial resistance.

Managerial

- The Egyptian Health Council regularly updates STGs, mandates their use in the public sector, and links them to Universal Health Insurance reimbursement.
- EDA maintains a range of national drug lists to support rational use, including — but not limited to — the Essential Medicines List, the non-prescription medicines list (OTC List), emergency and crash-cart lists, and high-risk medicines lists.

- MOHP establishes Drug and Therapeutics Committees for hospital and system-level audits and local adaptation of guidelines.
- EDA leads the National Rational Antimicrobial Committee, with representation from MOHP, university hospitals, the General Authority for Healthcare Accreditation and Regulation, the Armed Forces Medical Services, the Egyptian Healthcare Authority, UPA, and academic institutions. The Committee provides National Guidance for Antimicrobial Monitoring to:
  - Support optimal antimicrobial use by reviewing the appropriateness of all antimicrobial agents prescribed.
  - Review antimicrobial use in terms of indications, treatment duration, dosing regimen, route of administration, and time-out recommendations — facilitating identification of prescribing problems and supporting rational antimicrobial use.
  - Document dosing regimen, duration, indication, and time-out recommendations.
  - Make this information accessible to support timely modification or discontinuation of antimicrobials as needed.

Regulatory

- **Drug Information Access:** EDA publishes the Egypt Drug Formulary to provide reliable, accessible clinical information.
- **Medication Safety:** EDA manages the National Office for Handling and Reduction of Medication Errors (NOHARMe), enabling free and accessible reporting of medication errors since 2014.
- **Guideline Enforcement:** EDA, MOHP, and the Universal Health Insurance Authority enforce STGs, Essential Medicines List alerts, and prescription restrictions.
- **Regulatory Oversight:** EDA strengthens licensing and inspection processes, enforces prescription rules, regulates promotional materials, and manages a public complaints portal.
- **Market Control and Pharmacovigilance:** EDA coordinates market oversight, pharmacovigilance, and prescription classification to support the safe and rational use of medicines.

CORE COMPONENT

07 Research and Development

Research under Egypt's National Drug Policy evaluates policy impacts on health systems through operational studies — such as supply economics and prescribing behaviors — and drug research and development, including innovative formulations and clinical and preclinical trials, aligning with WHO and ICH guidelines, the National Health Policy, and national digital strategies to support evidence-based decision-making.

POLICY AIMS

- Advance pharmaceutical research and innovation through strengthened academia–industry collaboration.
- Support evidence-based policymaking through operational research, strategic partnerships, and compliant clinical trials.

KEY CHALLENGES

- Limited funding and resources for priority-driven studies amid competing health needs.
- Weak data systems hinder timely insights into drug utilization and policy gaps.
- Insufficient industry–academia collaboration for complex innovation, including biosimilars.
- Limited integration of research findings into regulation and procurement decisions (e.g., Essential Medicines List updates).

Core Strategies

Research Prioritization

Establish national mechanisms to prioritize research and generate evidence aligned with public health needs.

Integration into Health Systems

Integrate research outcomes into health planning, financing, and performance monitoring systems.

Capacity and Innovation

Strengthen capacity building, innovation, and technology transfer through institutional collaboration.

Regulatory and Ethical Oversight

Ensure effective regulatory oversight and ethical governance of clinical research.

CORE COMPONENT

08 Human Resources Development

Human resources are a key enabler of National Drug Policy implementation, ensuring a capable and sustainable pharmaceutical workforce.

POLICY AIMS

- Develop a competent and adequately resourced pharmaceutical workforce to support effective Policy implementation.
- Strengthen workforce performance and continuous professional development.

KEY CHALLENGES

- A shortage of qualified staff for executing the essential functions required to implement the National Drug Policy effectively.
- Financial limitations affecting the ability to fund necessary personnel, particularly within the public sector.
- Migration of trained staff to better-paid positions in the private sector or abroad.
- Challenges in sustaining staff motivation and ensuring high-quality performance, given limited career advancement prospects.
- The ongoing need to update personnel skills and knowledge to keep pace with advances in pharmaceutical science and regulatory requirements.

Core Strategies

Workforce Planning

Plan for sufficient and competent staff across the short, medium, and long term, including retention strategies and career pathways to maintain continuity and expertise.

Education and Professional Development

Provide targeted training in regulatory affairs, quality assurance, rational use of medicines, and management skills through EDA, MOHP, the Egyptian Health Council, and UPA.

Collaboration with National and International Institutions

Through its Continuous Professional Development Center, EDA leverages universities, research centers, and professional associations to strengthen expertise, training programs, and knowledge sharing.

Internationally, EDA places strong emphasis on collaboration and experience-sharing with international experts through organizations and authorities such as WHO, USP, FDA, EMA, and ICH, and contributes to regulatory system strengthening across the region and continent through sharing experience with regional centers of excellence.

Career Development and Motivation

Define clear roles and responsibilities, offer incentives, and provide continuing education and team-building opportunities to retain and motivate staff.

CORE COMPONENT

09 Cooperation with Other Countries and Stringent Regulatory Authorities

POLICY AIMS

- Strengthen international regulatory collaboration and secure efficient information-exchange mechanisms.
- Enhance collective action to prevent, detect, and respond to substandard and falsified medicines.

KEY CHALLENGES

- Eligibility criteria of some international organizations may limit membership.
- Established cooperation agreements and protocols face uneven implementation, highlighting the need for more robust mechanisms.
- Secure exchange of confidential regulatory information remains a challenge for maintaining data protection and integrity.
- Variability in regulatory and technical capacity among partner countries and institutions.

Core Strategies

Implementation of EDA's Public Relations and International Cooperation Policy

Ensure that all international cooperation and external communications are conducted within the approved institutional framework and aligned with EDA's strategic vision.

Active Participation in Regional and Global Regulatory Networks

Strengthen EDA's engagement in regional and international regulatory initiatives and platforms to promote regulatory convergence, mutual reliance, and trust.

Regulatory Information Exchange and Capacity Building

Promote structured information exchange, joint training, technical cooperation, and twinning arrangements with peer authorities to strengthen regulatory and scientific capacity.

Combating Substandard and Falsified Medical Products

Strengthen collaboration with regulatory authorities to support information sharing, early detection, and coordinated responses to substandard and falsified medical products.

CORE COMPONENT

10 Monitoring and Evaluation

Monitoring and Evaluation are core pillars of the National Drug Policy (NDP), ensuring accountability, transparency, and evidence-based decision-making across all policy components.

A comprehensive Implementation Plan shall be developed to achieve the policy's strategic goals, accompanied by SMART Key Performance Indicators (KPIs). These indicators shall be monitored periodically to measure progress toward the policy's goals, ensure accountability across all relevant stakeholders, and support evidence-based adjustments to implementation strategies when needed.

The National Drug Policy shall be evaluated every two years to ensure its continued relevance and alignment with national health priorities and international best practices, while interim updates may occur in response to major WHO guideline changes, or emerging national health priorities.

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Arab Republic of Egypt

Egypt National Drug Policy

2026 - 2030