Strategic Plan

Of the Egyptian Drug Authority

(January 2025 - June 2027)

The Egyptian Drug Authority Strategic Plan (January 2025 - June 2027) - Second Edition 2025

About the Egyptian Drug Authority

(EDA)

About the EDA

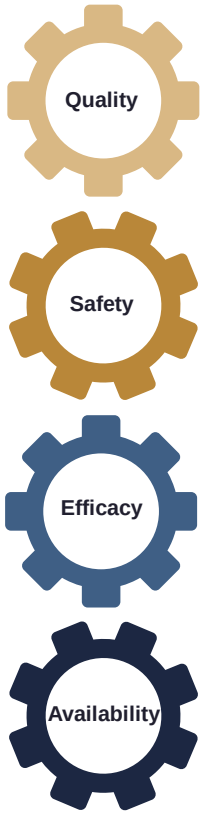
The Egyptian Drug Authority

Is an independent public service entity reporting directly to the Prime Minister. It was established pursuant to Law No. 151 of 2019, succeeding the National Organization for Drug Control and Research, the National Organization for Research and Control of Biologicals, and the Central Administration of Pharmaceutical Affairs.

EDA functions as the national regulatory authority is entrusted with the registration, regulation, distribution, and quality control of medical products, devices, and raw materials used in their manufacture, in accordance with the relevant laws, regulations, and ministerial decrees.

Egyptian Drug Authority's Mandates

The Main Objective of Establishing EDA is to Ensure



Of Medical Products & Devices

1

Organizational Mandates

Developing policies & frameworks for governing the pharmaceutical sector in line with international standards, to ensure availability of high-quality, safe, effective medical products & devices.

2

Executive Mandates

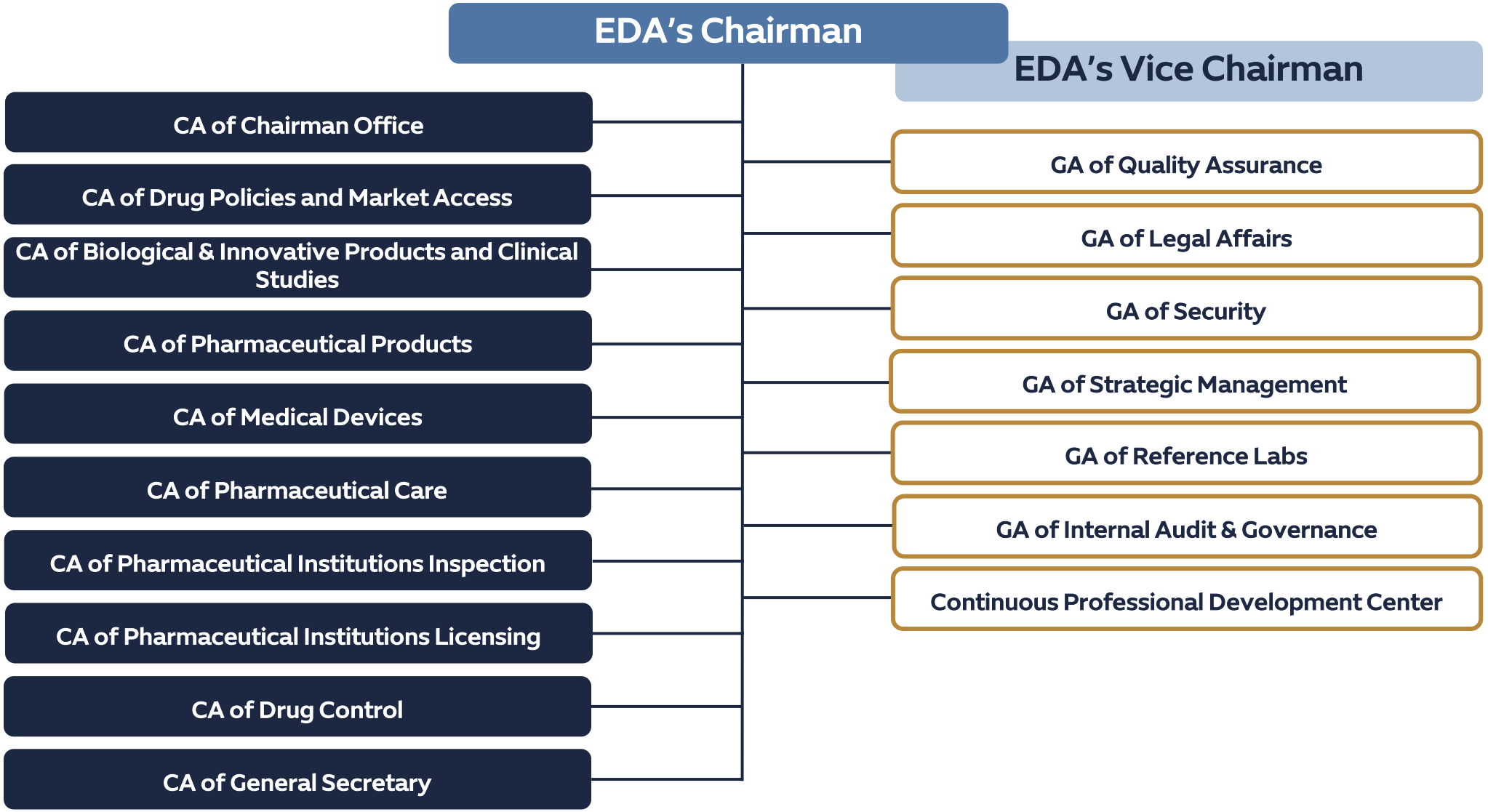
Enforcing registration laws, evaluating clinical studies, licensing, promoting pharmaceutical awareness, representing country nationally & internationally, supporting research, & training programs.

3

Regulatory Mandates

Focusing on inspection & oversight to ensure compliance, supervising manufacturing & distribution, & monitoring adverse events to ensure safety & efficacy of medical products & devices.

EDA's Organogram



Key Technical Jurisdictions

CA of Chairman Office
Coordinating work of the Supreme Authority, decision support, institutional and international relations, institutional media, & dealing with complaints

CA of Drug Policies and Market Access
Supporting markets & availability of medical products, localization and investment, export and import, implementing effective pricing policies, issuing import approvals & customs medical release

CA of Biological & Innovative Products & Clinical Studies
Evaluating, recording, analyzing & releasing batches for biological products, registering innovative pharmaceutical products, & evaluating clinical studies

CA of Pharmaceutical Products
Evaluating & registering pharmaceutical products, approving technical studies to ensure quality & effectiveness, & developing regulatory frameworks in line with international standards

CA of Medical Devices
Evaluating medical devices & diagnostic devices before marketing, & issuing approvals to allow their distribution after ensuring their conformity

CA of Pharmaceutical Care
Following up pharmacovigilance, raising awareness, approving advertising materials and human/veterinary leaflets (including electronic), and promoting practice & rational use of medicine

CA of Pharmaceutical Institutions Inspection
Activating, organizing & following up inspection of pharmaceutical institutions & facilities, monitoring production, & strengthening market control in storage & distribution

CA of Pharmaceutical Institutions Licensing
Activating, organizing and following up the licensing system for pharmaceutical institutions & facilities, including developing procedures & ensuring compliance with technical requirements

CA of Drug Control
Examining & analyzing medical products & devices, raw materials, cosmetics, disinfectants, & pesticides to ensure quality according specifications before and after distribution

CA of General Secretary
Managing finance & human resources, supporting digital transformation, infrastructure, & technical operation

GA of Quality Assurance
Applying quality assurance system, following its implementation, reviewing & documenting, & obtaining accreditations in accordance with local & international standards

GA of Legal Affairs
Providing legal support & consultations, reviewing laws & decisions, & following up on lawsuits, grievances, & judicial procedures

GA of Strategic Management
Formulating, monitoring, & evaluating the strategic plan, managing programs & projects, managing risks & crises, & enhancing business continuity

GA of Reference Labs
Conducting analyses & studies to support quality & effectiveness of medical products & devices, providing technical support to localize pharmaceutical industry

GA of Internal Audit & Governance
Executing internal audits, activating governance and transparency systems, & ensuring efficiency & effectiveness of operations

Continuous Professional Development Center
Developing professional competencies of all personnel working in the Authority's areas of specialization, both internally & externally, locally & internationally, through accredited training programs

EDA's Strategic Plan

(January 2025 - June 2027)

Strategic Plan Preparation Methodology

This methodology comprises five key phases forming a comprehensive, systematic process for developing the strategic plan:

- **Phase 1:** Forming the strategic planning team and introducing the strategic planning process.
- **Phase 2:** Aligning with leadership’s vision and strategic direction, defining responsibilities, and enhancing institutional efficiency.
- **Phase 3:** Agreeing on the strategic planning action plan.
- **Phase 4:** Developing the strategic communication plan and identifying target stakeholders.
- **Phase 5:** Drafting and approving the strategic plan.

Phases of Strategic Plan Preparation

Phase 1
Forming the strategic planning team and introducing the strategic planning process

- Cross-departmental team
- Introductory meetings on planning phases & outputs
- Reviewing local & international references
- Aligning with Egypt Vision 2030, applicable laws, & international standards

Phase 2
Aligning with leadership's vision & strategic direction, defining responsibilities, & enhancing institutional efficiency

- Direct supervision by top management
- Clear definition of responsibilities
- Participation of all executive leadership
- Specialized training in collaboration with the Ministry of Planning

Phase 3
Agreeing on the strategic planning action plan

- Strategic communication plan covering all stakeholder groups
- Standardizing concepts and enhancing coordination

Phase 4
Developing the strategic communication plan and identifying target stakeholders

- Reviewing the vision, mission, and values
- Analyzing the internal and external environment
- Developing objectives and performance indicators
- Identifying and linking programs to central departments

Phase 5
Drafting and approving the strategic plan

- Consolidating and reviewing outputs
- Presenting the draft for feedback
- Approving and launching the final plan

SUSTAINABLE DEVELOPMENT GOALS

* Goals Associated with the Strategic Objectives of the Egyptian Drug Authority (EDA)

Responsibilities Aligned with the National Plan

EDA's Strategic Plan Alignment to National Plan

UN Sustainable Development Goals (STGs)

National Agenda for Sustainable Goals

National Strategic Objectives

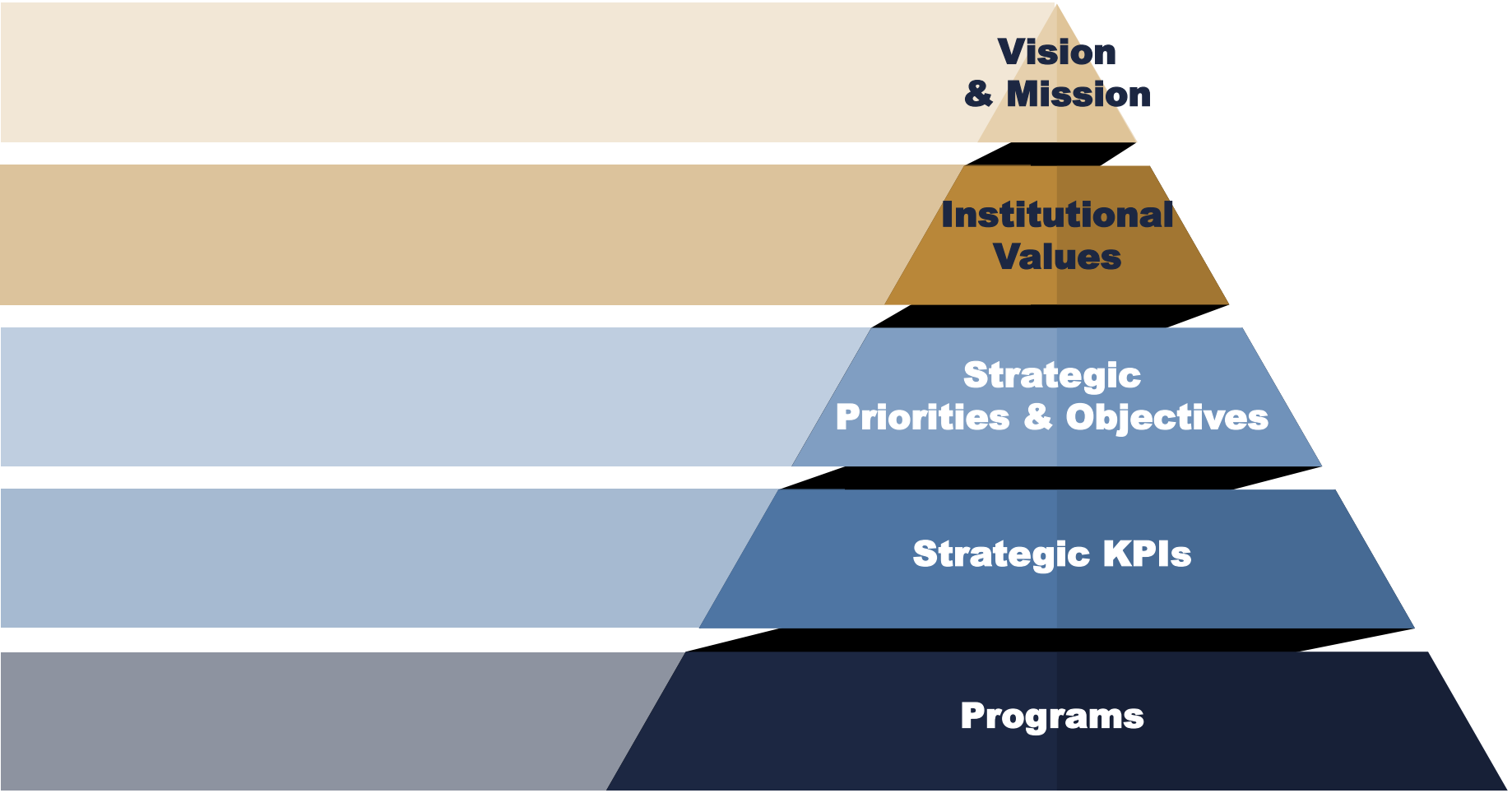
- **National KPIs**
- Strategic Objective (1)
- Strategic Objective (2)

EDA's Strategic Plan

- **Strategic KPIs**
- Strategic Objective (1)
- Strategic Objective (2)
- Strategic Objective (3)
- Strategic Objective (4)

Egyptian Government Action Program

Overview of the Strategic Plan



January 2025 – June 2027

EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

Vision & Mission

Vision

A world-leading national drug authority advancing pharmaceutical security and integrated pharmaceutical care

Mission

To ensure the quality, safety, efficacy, and availability of medical products and devices; to enhance quality of life and stakeholder satisfaction through qualified personnel, in alignment with international standards and innovative frameworks

Institutional Values

Institutional Values

Integrity and Impartiality

We uphold credibility, transparency, and accountability to ensure impartiality and build trust

Health and Safety

We prioritize health and safety by applying international standards and fostering community-wide awareness

Excellence and Innovation

We pursue leadership and excellence by fostering innovation and refining methodologies to enhance performance

Collaboration and Responsiveness

We cooperate effectively with stakeholders to ensure fair practices and respond with agility to changes

Sustainability and Professionalism

We invest in sustainable development and capacity-building while maintaining the highest standards of professional conduct

Stakeholders Analysis

Stakeholders Analysis

Internal Stakeholders

External Stakeholders

	Expected Needs		
Board of Directors	Clear Reports on Performance and Strategic Commitment.	Insights on Potential Risks and Their Management Strategies.	Commitment to Governance and Ethical Standards.
Senior Management	Alignment of Objectives with the National Strategy.	Detailed Performance Reports.	Timely and Effective Management of Financial and Human Resources.
Executive Management	Continuous Updates and Training on Best Practices.	Clear Regulatory Procedures to Ensure Compliance.	Tools for Effective Management and Tracking of Processes.
Employees	Providing Tools and Technology to Support Operations and Problem Solving.	Enhancing Skills and Continuous Training According to Best Practices.	Providing a Supportive Work Environment with Clear Administrative Systems.
Technical, Scientific, and Advisory Committees	Accurate Data and Reports for Effective Decision-Making.	Clear Roles for Collaboration with EDA and Ongoing Support.	Regular Communication Channels.
Consumers (Patients and Public)	Providing High-Quality, Safe, and Effective Pharmaceuticals and Medical Devices.	Raising Community Awareness and Health Education.	Effective Communication Channels for Receiving Inquiries and Feedback.
Pharmaceuticals and Medical Devices Companies (Marketing License Holders, Agents, Scientific Offices, and Industrial Chambers)	Clear and Transparent Mechanisms with Specific Guidelines.	Channels for Supporting Inquiries and Providing Feedback.	Enhancing Services and Delivering Them on Time.
Healthcare Providers (Hospitals, Health Units, Pharmacies, Syndicates)	Updated Information and Specific Guidelines.	Support for Delivering High-Quality Care.	A System for Receiving and Responding to Feedback.
Governmental Entities (The Council of Ministers, Relevant Ministries, Authorities, and Agencies)	Accurate Data and Reports to Support Decision-Making.	Clear Roles and Strengthening Governmental Collaboration.	Organized Processes for Information Exchange and Policy Improvement.
Academic and Research Institutions	Up-to-Date Data and Clear Collaboration Frameworks to Support Research.	Continuous Support for Research and Innovation.	Channels for Knowledge Exchange and Feedback.
International Authorities & Organizations	Data and Reports to Support Evaluation and Decision-Making.	Clear Roles for Cooperation with EDA and Adoption of Directions and Guidelines.	A System for Exchanging Experiences and Feedback.
NRAs in Other Countries	Clear Roles and Exchange of Information and Data to Support Mutual Cooperation.	Strengthening International Cooperation and Exchange of Expertise.	Periodic Communication Channels and Mechanisms to Support Market Access.

PESTEL Analysis

PESTEL Analysis

P — POLITICAL

- Internal political stability and international cooperation with other countries and international organizations.
- External political crises and strategic challenges.

E — ECONOMIC

- The drive toward localizing the manufacturing of medical products and devices.
- Economic challenges, heavy reliance on imports, and limited resources.

S — SOCIAL

- Public awareness and general interest in health and pharmaceutical issues amid crises and changes.
- Inadequate reporting in some scopes affects the accuracy of available data, and the decisions based on them.

T — TECHNOLOGICAL

- Digital transformation to keep pace with technological and information developments.
- Rapid pace of technological change and constant pressure to adapt.

E — ENVIRONMENTAL

- Commitment to Environmental Sustainability in line with Sustainable Development Goals (SDGs).
- The need to adapt to new local and global environmental and climate requirements and health crises.

L — LEGAL

- Existing supportive legislation and updated governance requirements.
- Monopolistic practices and legal challenges associated with non-compliant medicinal products and devices.

SWOT Analysis

SWOT Analysis

Internal Factors

Strengths

- EDA is the sole authority responsible for the regulatory, executive, and supervisory functions over medical products and devices, and the raw materials used in their manufacture.
- Strategic alliances at local and global levels that enhance capacity development and drive organizational excellence.
- International accreditations and standards adoption to enhance leadership, competitiveness, and service quality.
- Multi-channel stakeholders' communication to foster trust.
- Robust, stable & scalable infrastructure that supports continuous development.
- Highly skilled and adaptive workforce proficient in addressing challenges and delivering innovative, forward-looking solutions.

Areas for Improvement

- Delays in implementing automation and connectivity projects across EDA's premises and departments affect information management integration, operating costs, and the speed of decision-making and execution.
- Limited resources that may hinder the EDA’s ability to innovate and enhance operational capabilities.
- Process redundancy and overlap may limit communication efficiency and affect the quality of decision-making.
- Limited institutional frameworks for knowledge sustainability weaken organizational memory and pose risks to effective succession planning.
- Immature organizational culture limits reinforcement of institutional values and hinders behavioral alignment across the organization.

External Factors

Opportunities

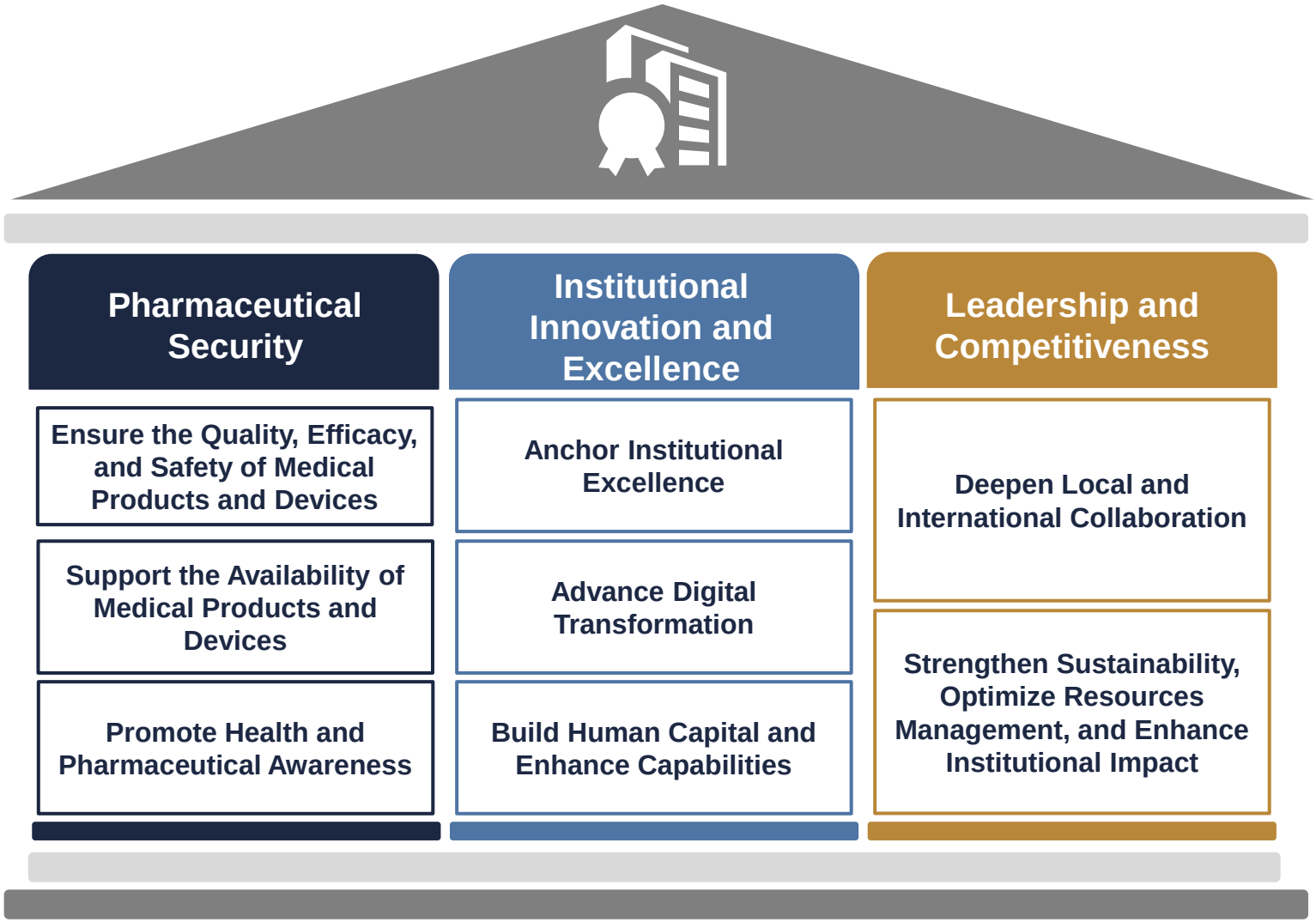
- National commitment to SDGs and Egypt’s Vision 2030 empowers EDA’s role in advancing the pharmaceutical sector.
- Government support for institutional excellence fosters performance enhancement in line with quality standards and best practices.
- National policy to localize industries, including medical products and devices.
- Expansion of cooperation and memberships enhances access to global markets.
- Government digitalization initiative ‘Digital Egypt’ supports technological progress.
- Rising public awareness of health and pharmaceuticals driven by crises and evolving challenges.

Threats

- Political crises, strategic challenges, global competition, and health emergencies disrupt supply chains and compromise the availability of medical products and devices.
- Economic pressures and import dependency increase vulnerability to price volatility, shipment delays, and market uncertainty.
- Rapid technological evolution challenges the ability to continuously update regulatory systems, infrastructure, and workforce capabilities.
- Non-compliant medical products and devices, along with monopolistic market practices, pose a threat to the healthcare system.
- Insufficient reporting in some areas affects the accuracy of available data, which may impact the effectiveness of regulatory analysis and the decisions based on it.

Strategic Priorities & Objectives

Strategic Priorities & Objectives



Aligning the Authority's Strategic Objectives with the State Plan

#	Strategic Objective of the Authority	United Nations Sustainable Development Goals	The National Agenda for Sustainable Development and Egypt's Vision2030	Egyptian government work program
1	**Ensure the Quality, Efficacy, and Safety of Medical Products and Devices**	- **Goal 3:** Good Health and Well-being	- **Goal 1 :** Quality of Life and Living Standards	- **Axis 2: Strategic goal 1 :** An inclusive healthcare system
2	**Support the Availability of Medical Products and Devices**	- **Goal 3:** Good health and well-being - **Goal 8:** Decent work and economic growth	- **Goal 1:** Quality of Life and Living Standards - **Goal 4:** Diversified, Knowledge-based, and Competitive Economy	- **Axis 1: Strategic goal 1:** Protecting national security - **Axis 2: Strategic goal 1:** An inclusive Healthcare system - **Axis 3: Strategic goal 2:** Private sector empowerment and enhancement of local and foreign investments - **Axis 3: Strategic goal 3:** Price regulation and inflation control
3	**Promote Health and Pharmaceutical Awareness**	- **Goal 3:** Good health and well-being - **Goal 12:** Responsible consumption and production	- **Goal 1:** Quality of Life and Living Standards	- **Axis 3: The third strategic goal:** Price regulation and inflation control.
4	**Anchor Institutional Excellence**	- **Goal 9:** Industry, innovation and infrastructure - **Goal 16:** Peace, justice and strong institutions	- **Goal 6:** Governance and partnerships	- **Axis 3: The first strategic goal:** Strengthening economic foundations and enhancing national capacities - **Axis 3: The second strategic goal:** Empowering the private sector and promoting local and foreign investments
5	**Advance Digital Transformation**	- **Goal 9:** Industry, innovation and infrastructure	- **Goal 5:** Well-Developed Infrastructure	- **Axis 2: The first strategic goal:** An inclusive Healthcare system
6	**Build Human Capital and Enhance Capabilities**	- **Goal 16:** Peace, justice and strong institutions	- **Goal 6:** Governance and partnerships	- **Axis 2: The first strategic goal:** An inclusive Healthcare system
7	**Deepening Local and International Cooperation**	- **Goal 17:** Establish partnerships to achieve the goals	- **Goal 6:** Governance and partnerships	- **Axis 3: The first strategic goal:** Strengthen economic foundations and enhancing national capacities
8	**Strengthen Sustainability, Optimize Resources Management, and Enhance Institutional Impact**	- **Goal 12:** Responsible consumption and production	- **Goal 4:** Diversified, Knowledge-based, and Competitive Economy	- **Axis 3: The first strategic goal:** Strengthen economic foundations and enhancing national capacities

Strategic Plan (January 2025 - June 2027)

Vision

A world-leading national drug authority advancing pharmaceutical security and integrated pharmaceutical care

Mission

To ensure the quality, safety, efficacy, and availability of medical products and devices; to enhance quality of life and stakeholder satisfaction through qualified personnel, in alignment with international standards and innovative frameworks

Strategic Priorities

- Pharmaceutical Security
- Institutional Innovation and Excellence
- Leadership and Competitiveness

Strategic Objectives

Strategic Objectives (Customer and Stakeholder Perspective)

Ensure the Quality, Efficacy, and Safety of Medical Products and Devices

- Encourage ADRs reporting by raising awareness and fostering motivation
- Enhance compliance with GMP standards, inspection mechanisms, and market surveillance
- Strengthen the efficiency of the registration system

Support the Availability of Medical Products and Devices

- Enhance pharmaceutical availability through strengthening localization and promoting investment

Promote Health and Pharmaceutical Awareness

- Launch comprehensive awareness programs for all segments of society
- Surveillance of pharmaceuticals susceptible to misuse
- Promote effective engagement via social media platforms

Internal Operations (Internal Operations Perspective)

Anchor Institutional Excellence

- Develop institutional culture and build trust and satisfaction of stakeholders through awareness, training, and institutional communication
- Enhance the effectiveness of the regulatory system by supporting decision-making
- Achieve international accreditations and recognitions

Advance Digital Transformation

- Expand the automation of the Authority's operations and services and update the website and electronic platforms
- Develop digital infrastructure and integrated databases

Competencies and Capabilities (Learning and Growth Perspective)

Build Human Capital and Enhance Capabilities

- Foster productive work environment by supporting professional development

Deepen Local and International Cooperation

- Expand cooperation agreements, local and international memberships and mutual recognition to support alignment with global standards, and exports
- Strengthen the role of the CPD to transfer and exchange of regulatory and pharmaceutical industry expertise at the local and regional levels

Efficient Resource Utilization (Financial perspective)

Strengthen Sustainability, Optimize Resource Management, and Enhance Institutional Impact

- Financial planning to support strategic development priorities

Institutional Values

- Integrity and impartiality
- Health and Safety
- Excellence and Innovation
- Collaboration and Responsiveness
- Sustainability and Professionalism

First Strategic Priority	**Pharmaceutical Security**
Strategic Goal One	**Ensure the Quality, Efficacy, and Safety of Medical Products and Devices**

Desired Strategic Impact	**Improve the quality and safety of medical products and devices and reduce the prevalence of falsified and substandard products**

KPIs

- Percentage of annual increase in Adverse Drug Reaction (ADR) reports
- Percentage of Good Manufacturing Practice (GMP) certified manufacturing facilities
- Annual percentage of regulatory decisions based on non-compliance with Good Clinical Practices (GCP)
- Percentage of market surveillance non-compliance cases resolved within the specified timeframe
- Percentage of final reports issued for sample analysis within the specified timeframe
- Percentage of compliance with the unified system for human medicinal product registration (CTD)

Programs

Encourage ADRs reporting by raising awareness and fostering motivation	**Enhance compliance with GMP standards, inspection mechanisms, and market surveillance**	**Strengthen the efficiency of the registration system**

First Strategic Priority	**Pharmaceutical Security**
Strategic Goal Two	**Support the Availability of Medical Products and Devices**

Desired Strategic Impact	**Access to medical products and devices, and increasing pharmaceutical contribution to country's economic revenues**
KPIs	Percentage of Availability of essential medicines Total number of human medicinal products registered as the first locally manufactured generic equivalent Number of newly established production lines in medical products and devices manufacturing facilities Number of analysis reports issued according to the reliance pathway with reference regulatory authorities Percentage coverage of locally manufactured and packaged medicinal products for market needs

Programs

Enhance pharmaceutical availability through strengthening localization and promoting investment

First Strategic Priority	**Pharmaceutical Security**
Strategic Goal Three	**Promote Health and Pharmaceutical Awareness**

Desired Strategic Impact	**Rational use of medicines and reduction of medication errors**
KPIs	Annual number of participants enrolled in health and pharmaceutical education programs Percentage of corrective actions taken following inspections of controlled substances Annual percentage increase in public reach via social media platforms

Programs

Launch comprehensive awareness programs for all segments of society	**Surveillance of pharmaceuticals susceptible to misuse**	**Promote effective engagement via social media platforms**

Second Strategic Priority	**Institutional Innovation and Excellence**
Strategic Goal Four	**Anchor Institutional Excellence**

Desired Strategic Impact	**Achieve institutional sustainability and enhance governance** **Promote international recognition and enhance the effectiveness of the regulatory system**
KPIs	Customer Satisfaction Rate (External Customers) Total internal training programs for capacity building in support of institutional culture and professional practices Percentage of observations from external audits resolved within the specified timeframe Percentage of observations in the Accountability State Authority (ASA)'s report resolved within the specified timeframe Total accreditations granted by local and international entities

Programs

Develop institutional culture & build trust & satisfaction of stakeholders through awareness, training, & institutional communication	**Enhance the effectiveness of the regulatory system by supporting decision-making**	**Achieve international accreditations and recognitions**

Second Strategic Priority	**Institutional Innovation and Excellence**
Strategic Goal Five	**Advance Digital Transformation**

Desired Strategic Impact	**Develop a Data-Driven Regulatory System**

KPIs

- Percentage of automated operations
- Total number of smart applications deployed on the website
- Percentage of completion of internal server infrastructure
- Total number of external hosting environments

Programs

Expand the automation of the Authority's operations and services and update the website and electronic platforms	**Develop digital infrastructure and integrated databases**

Second Strategic Priority	**Institutional Innovation and Excellence**
Strategic Goal Six	**Build Human Capital and Enhance Capabilities**

Desired Strategic Impact	**Establish a Robust Regulatory Environment for Pharmaceuticals and Medical Devices**
KPIs	Number of training programs for EDA's employees and the pharmaceutical sector implemented annually Annual Employee Turnover Rate

Programs

Foster productive work environment by supporting professional development

Third Strategic Priority — **Leadership and Competitiveness**

Strategic Goal Seven — **Deepen Local and International Cooperation**

Desired Strategic Impact

Ensure compliance of local medical products & devices with standards and facilitate global market access

Exchange regulatory expertise with neighboring regulatory authorities and enhance the health system's resilience and adaptability in the region

KPIs

- Total number of executed international cooperation and mutual recognition agreements
- Total number of seats acquired in international organizations
- Annual export revenues of medical products and devices
- Total number of implemented mutual international cooperation trainings
- Annual Skills Improvement Rate after international cooperation trainings

Programs

Expand cooperation agreements, local and international memberships and mutual recognition to support alignment with global standards, and exports

Strengthen the role of the CPD to transfer and exchange of regulatory and pharmaceutical industry expertise at the local and regional levels

Third Strategic Priority	**Leadership and Competitiveness**
Strategic Goal Eight	**Strengthen Sustainability, Optimize Resources Management, and Enhance Institutional Impact**
Desired Strategic Impact	**Achieve Institutional Stability and Resilience to Support the Long-Term Advancement of the Authority's Regulatory Framework**
KPIs	Percentage of annual financial support allocated for development

Programs

Financial planning to support strategic development priorities

Thank You