EDA Website Information Publication Guideline

Year 2026

Code: EDREX.GL.CEO.002

Version No:1.0

Issue Date: 02/08/2026

Effective date:04/08/2026

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1 Introduction

The Egyptian Drug Authority (EDA) is committed to ensuring transparency, accessibility, and effective communication with stakeholders through its official website. The website serves as the primary digital platform for publishing regulatory information, official announcements, guidance documents, reports, databases, and other public communications related to pharmaceutical regulation in Egypt.

This guideline defines the structure, content types, and navigation approach of the EDA website. It also explains how users can efficiently access its various sections and outlines the principles applied to ensure that all published information is accurate, validated, reliable, and regularly maintained in accordance with regulatory requirements and international best practices.

2 Scope

The purpose of this guideline is to define the types of information available on the EDA website and provide a clear structure for its navigation and content organization. It aims to ensure consistency, transparency, and accessibility of published regulatory information, while supporting users in efficiently accessing services, regulatory references, and official publications. In addition, it establishes principles for the validation, review, and maintenance of website content to ensure accuracy, reliability, and data integrity.

3 Abbreviations

3.1 API: Active Pharmaceutical Ingredient
3.2 CPD: Continuing Professional Development
3.3 DDB: Drug Database
3.4 EDA: Egyptian Drug Authority
3.5 GBT: Global Benchmarking Tool
3.6 GCP: Good Clinical Practice
3.7 GMP: Good Manufacturing Practice
3.8 PAR: Public Assessment report
3.9 WHO: World Health Organization.

4 Definitions

4.1 EDA Website: The official electronic platform of the Egyptian Drug Authority used for publishing regulatory information, services, announcements, databases, guidance documents, and official communications

4.2 Validation: The documented process of reviewing, verifying, and approving information prior to publication to ensure accuracy, completeness, consistency, and compliance with applicable regulatory requirements.

4.3 PAR (Public Assessment Report): A structured regulatory report that summarizes the scientific evaluation and assessment process of a medicinal product, including the basis for its regulatory decision and approval.

4.4 GMP (Good Manufacturing Practice): International quality standards ensuring that pharmaceutical products are consistently produced and controlled according to quality requirements.

4.5 **Egyptian Drug Regulatory Index (EDREX):** The official repository of the Egyptian Drug Authority's legal provisions, guidelines, guidance, national drug list, and notice to applicants prepared to inform EDA stakeholders with the most recent EDA's legal, regulatory requirements, or interpretation of any regulatory requirement about medical products and medical devices regulated and marketed by the EDA.

4.6 **Legal provisions:** Laws, regulations, decrees issued by any Egyptian governmental entity, including the Egyptian Parliament, Egyptian President, Egyptian Prime Minister, Egyptian Ministers, or EDA chairman.

4.7 **Guideline:** is a systematically developed evidence-based statement which assists providers, recipients, and other stakeholders to make informed decisions about medical products and medical devices marketed in Egypt and regulated by EDA.

4.8 **Guidance:** A non-binding (non-obligatory) document issued by the Egyptian Drug Authority to provide best practices, recommendations, and practical direction about a certain disease or condition without establishing new legal requirements.

4.9 **National Drug List:** National Drug Lists are structured compilations of medications grouped according to shared characteristics, established to standardize and harmonize pharmacy practice across various settings. For example: Essential Medicine List, Non-Prescription Medication List, etc.

4.10 **Notice to Applicant**: Statutory document intended to assist relevant stakeholders affected by legislation to interpret any regulatory requirements. It may be in several formats, such as (but not limited to) Q&A, flow charts, plans, statements, etc.

5 Main Topics

5.1 Principles of Publication:

5.1.1 **Accuracy**: All published data is reviewed, verified, and validated by the responsible departments prior to publication to ensure it is accurate and complete.

5.1.2 **Reliability**: The EDA website is an official source of regulatory information. Published content is formally approved and can be relied upon as authentic and verified information.

5.1.3 **Transparency**: EDA ensures that relevant regulatory information, including decisions, announcements, reports, and public consultations, is made publicly available in a clear and transparent manner, where applicable.

5.1.4 **Accessibility**: Information is organized and presented to enable users to easily access, navigate, and understand website content.

5.1.5 **Timeliness**: Published content is regularly reviewed and updated to ensure users have access to the most current and relevant information.

5.1.6 **Consistency**: Standardized formats, terminology, and structures are applied across all website content to ensure clarity and uniformity.

5.1.7 **Accountability**: Each published item has a designated responsible owner accountable for its preparation, review, approval, and maintenance.

5.1.8 **Data Integrity**: assurance that EDA's data is accurate, complete and consistent at any point in its lifecycle

5.2 Types of Information Available on the EDA Website:

The website provides access to a comprehensive range of information, services, and regulatory content, including but not limited to:

5.2.1 Regulatory Framework and Legal References.

5.2.1.1 **EDA Chairman Decrees, Laws and Executive Regulations:** Official decrees issued by the Chairman of the Egyptian Drug Authority, national laws, and executive regulations that establish legally binding requirements governing pharmaceutical products, regulatory activities, healthcare-related practices, and the organizational framework of the Authority.

5.2.1.2 **Regulatory Reference of the EDA:** A centralized repository providing access to regulatory references, guidelines, circulars, policies, and other regulatory documents issued or adopted by the Authority to support compliance and regulatory decision-making.

5.2.1.3 **Regulatory Guidelines, Guidance Documents, and Notices to Applicants:** Official documents issued by the Authority that provide regulatory guidance, technical requirements, procedural instructions, and notices to support applicants and stakeholders in meeting applicable submission and compliance requirements.

5.2.1.4 **Egyptian Drug Formulary:** A national reference containing approved medicines, therapeutic standards, and clinical guidance for rational drug use.

5.2.2 Public Communication and Media Hub

5.2.2.1 **News, Events, Video Gallery, and Announcements:** Official communication content including news highlighting EDA achievements, and regulatory collaborations; events covering workshops, scientific seminars, conferences, and regulatory meetings.

5.2.3 Regulatory Digital Services

5.2.3.1 **Electronic Services Portal, Forms & Applications:** Digital platforms and standardized templates enabling stakeholders to complete EDA regulatory processes online, manage file processing, and submit required documentation for product registration, variations, license updates, clinical trial applications, and stability studies……etc.

5.2.4 Pharmaceutical Database and GMP information

5.2.4.1 **Drug Database and Registered Products:** A public database covering registered human and veterinary pharmaceuticals, medical devices, and herbal products, including APIs, strengths, approved indications, and marketing authorization status……. etc.

5.2.4.2 Good Manufacturing Practice (GMP): Includes inspection reports, operational guidance documents, certification and licensing records, validation frameworks, compliance monitoring information, and other regulatory materials related to the assessment and oversight of local and international manufacturing facilities.

5.2.5 EDA Reports

5.2.5.1 Reports: Includes annual reports, achievement reports, clinical reports, inspection reports, GCP inspection findings, regulatory updates, Public Assessment Reports (PARs), and other official publications related to the Authority's regulatory activities and performance.

5.2.6 Pharmacovigilance and Public Health Safety

5.2.6.1 Pharmacovigilance Framework: Includes WHO Safety Alerts, Drug Recall and pharmaceutical Fraud and pharmaceutical safety monitoring activities.

5.2.7 EDA Learning and Professional Development

5.2.7.1 Continuing Education and Development (CPD): Provides access to training programs, workshops, and scheduled courses designed to support professional development and capacity building for healthcare professionals and stakeholders.

5.3 Website Navigation and Access Tools

The EDA website provides multiple navigation tools designed to ensure easy access to regulatory information and services. These tools include:

5.3.1 Website Main Bar:

For easy navigation on the EDA website, the primary website main bar is used to access different sections of the website, as presented in the main bar screen **(Figure 1)**

It represents the main navigation structure of the portal and is designed as a top horizontal menu, as shown in the next image, providing quick access to all areas of the website. Items marked with a downward arrow (V) indicate the presence of a dropdown menu containing additional sub-items

The main bar includes the following sections:

5.3.1.1 Home Page

5.3.1.2 About Us

5.3.1.3 Service

5.3.1.4 The Regulatory Reference of the Egyptian Drug Authority (EDA)

5.3.1.5 Publications Reports &EDA in number

5.3.1.6 Media Center

5.3.1.7 Egyptian Pharmacopoeia

5.3.1.8 Awareness

5.3.1.9 Localization of Industry

5.3.1.10 Center for Continuing Professional Development (CPD)

Figure 1: Main bar screen

5.3.2 Search Engine / Search Function:

A search bar is available to enable users to quickly locate specific services, documents, and regulatory information across the EDA website. As presented in Search Engine screen (**Figure 2)** the search function is located at the top-right corner of the page.

Figure 2: Search Engine screen

5.3.3 Electronic Services

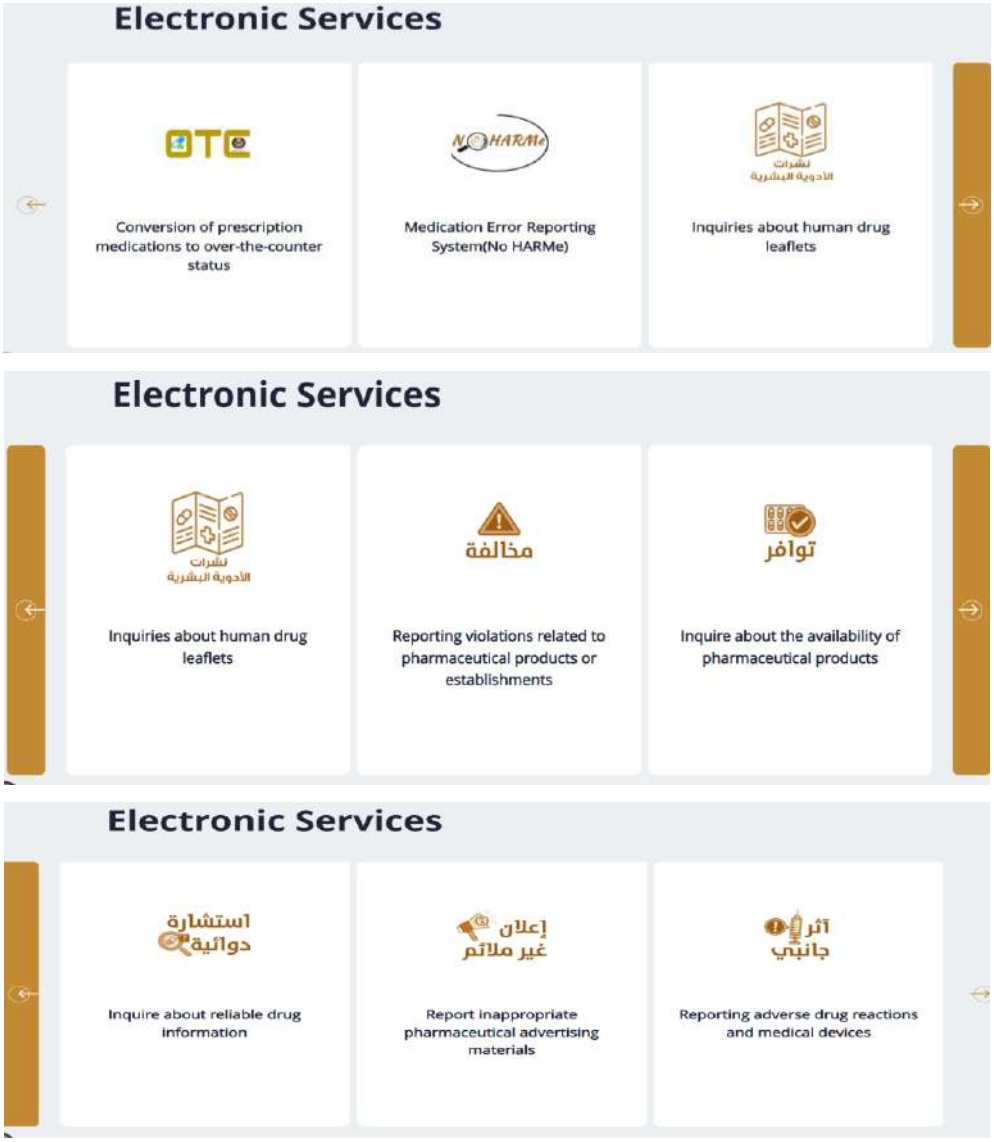
Provides access to the electronic services offered by the Egyptian Drug Authority (EDA), enabling users to submit applications, track requests, and complete various procedures through the online platform. As shown in the Electronic Servies screen (**Figure 3)**

, this section includes the following services:

5.3.3.1 Conversion of Prescription Medications to Over-the-Counter (OTC) Status
5.3.3.2 Medication Error Reporting System
5.3.3.3 Inquiries About Human Drug Leaflets
5.3.3.4 Reporting Violations Related to Pharmaceutical Products or Establishments
5.3.3.5 Inquire About the Availability of Pharmaceutical Products
5.3.3.6 Inquire About Reliable Drug Information
5.3.3.7 Report Inappropriate Pharmaceutical Advertising Materials
5.3.3.8 Reporting Adverse Drug Reactions and Medical Device Incidents

These services support communication between stakeholders and the EDA while facilitating access to regulatory information and reporting mechanisms through a centralized electronic platform.

Figure 3: Electronic Servies screen



5.3.4 Electronic programs and applications links

Provides direct access to a range of electronic programs, databases, inquiry tools, and regulatory applications developed by the Egyptian Drug Authority (EDA) to support regulatory activities, pharmaceutical registration, product inquiries, and access to drug-related information. **As shown**

in the Electronic programs and applications links (Figure 4), this section includes various electronic tools and applications, such as:

5.3.4.1 EDA Herbal Monograph
5.3.4.2 EDA Similars
5.3.4.3 BOX Inquiries
5.3.4.4 Naming Inquiries
5.3.4.5 Company Profile
5.3.4.6 Batch Production
5.3.4.7 Pricing Inquiries
5.3.4.8 API Searching Tool
5.3.4.9 DDB Egyptian Drug Database
5.3.4.10 EDA Inspection Reports

These examples illustrate the types of electronic programs and applications available through the EDA website, providing stakeholders with access to regulatory data, pharmaceutical information, inquiry services, and specialized regulatory tools.

Figure 4: Electronic programs and applications links

Electronic programs and applications links

Electronic programs and applications links

Electronic programs and applications links

Electronic programs and applications links

5.4 Website Content Structure

The EDA website is structured into several main sections to facilitate access to regulatory information, services, and official communications. These sections include:

5.4.1 Home page

Provides the main landing page with key updates, announcements, and quick access to essential regulatory information.

5.4.2 About EDA

Provides general information about the Egyptian Drug Authority (EDA), its governance structure, strategic direction, and international standards.**When clicked, it includes the following sections**:

5.4.2.1 Vision and Mission of the Egyptian Drug Authority

The Egyptian Drug Authority aims to become a leading national regulatory authority that ensures the quality, safety, efficacy, and availability of medical products and devices, while enhancing public health and stakeholder satisfaction in alignment with international standards and innovation.

5.4.2.2 Board of Directors of the Egyptian Drug Authority

Includes the formation of the EDA Board of Directors as per Republican Decree No. (4) of 2025 issued on January 12, 2025. The Board is headed by the Chairman of the Egyptian Drug Authority, with the Vice President and other appointed members, responsible for overseeing the Authority's governance, policies, and strategic direction.

5.4.2.3 Organizational structure

The EDA organizational structure is composed of two principal components: the EDA Central Administrations and the Supporting Functions. These organizational entities are established to deliver the Authority's regulatory, technical, administrative, and strategic responsibilities. Each component operates within clearly defined roles, responsibilities, and reporting lines to support effective governance and regulatory oversight.

5.4.2.4 Chairman's Speech

Includes speeches of the EDA Chairman highlighting the Authority's vision for advancing health through innovation and sustainable development. It emphasizes the safety, efficacy, and accessibility of medical products, alignment with Egypt Vision 2030.

5.4.2.5 Strategic Plan of the Egyptian Drug Authority (EDA)

It is a document and strategic framework used to achieve the long-term goals of the Authority. It serves as a roadmap that guides efforts, defines priorities, and supports informed decision-making to ensure sustainable development.

5.4.2.6 Quality Policy and Accreditations

The EDA demonstrates a strong commitment to regulatory excellence, quality assurance, and international alignment in the control of medical products. Through achieving internationally recognized accreditations such as WHO GBT (Maturity Level 3), ISO 9001:2015……etc.

5.4.2.7 Foreign Affairs and International Memberships:

The EDA's Foreign Affairs and International Memberships function strengthens the Authority's global and regional engagement through international memberships, strategic partnerships, memoranda of understanding (MoUs), and collaborative initiatives with regulatory authorities and international organizations. These activities support regulatory convergence, capacity building, knowledge exchange, and the advancement of the EDA's regulatory excellence

5.4.2.8 EDA Experts

Provides a list of the professors and subject matter experts serving as members of the EDA's scientific and technical expert network, who support the Authority by providing specialized scientific and technical expertise to inform regulatory evaluation and decision-making

5.4.3 Services

Provides electronic regulatory services and digital tools to support stakeholders in interacting with the Egyptian Drug Authority across all regulated product categories, including human pharmaceuticals, medical devices, complementary medicines…..etc.

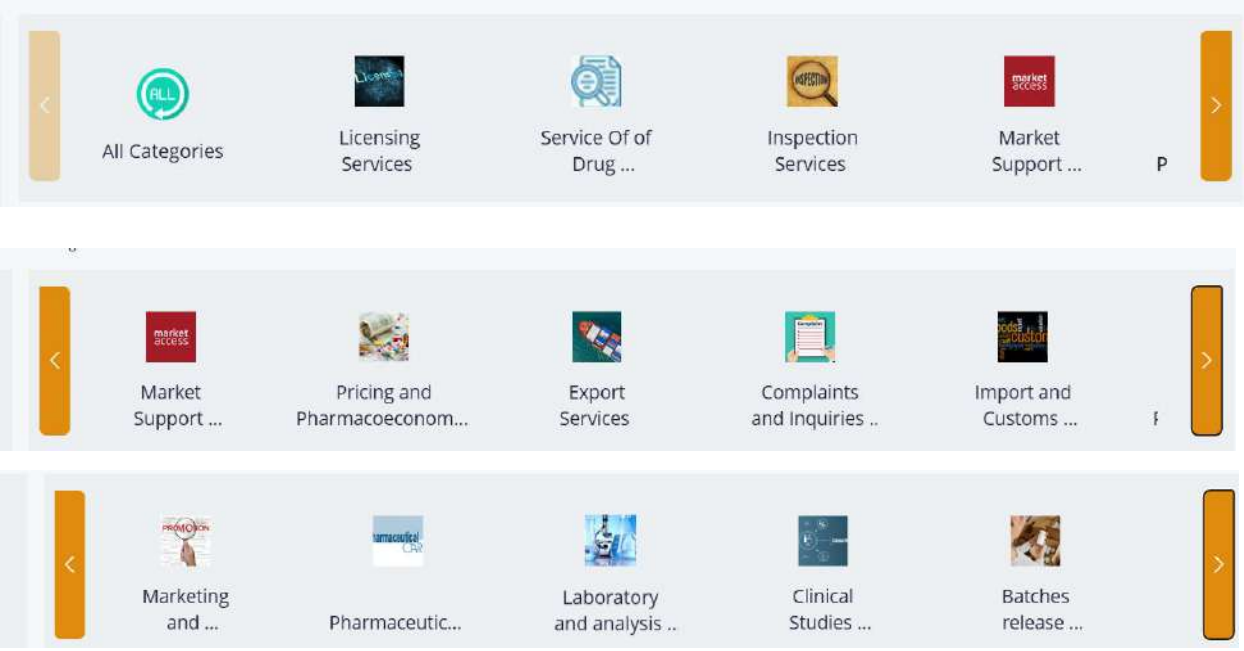
When clicked, the tab expands to display main items:

5.4.3.1 Services

Provides all electronic regulatory services by the Egyptian Drug Authority (EDA) covering as shown in the accompanying (**Figure 5)** for example:

- Updating the validity of the Toll Manufacturer License
- Technical support service for clinical trials
- Submission of variation files.
- Re-registration request for imported herbal products

Figure 5: Services



5.4.3.2 Pharmaceutical, Biological Products and Medical Device

This section includes the items listed below **as shown in the Figure (6)**:

5.4.3.3 Roadmap

Presents the roadmap for all EDA central administrations and their subordinate general administrations.

5.4.3.4 Rules and Regulations

Includes official regulatory procedures, decrees, and technical committee decisions issued by the Egyptian Drug Authority (EDA) governing pharmaceutical registration and re-registration, clinical research, herbal and veterinary products, and other regulatory activities. It provides the regulatory framework and procedural requirements that support compliance with national regulations and international best practices.

5.4.3.5 Announcements

Provides stakeholders with important updates regarding regulatory procedures, service availability, applications, public consultations, and other official notifications issued by the Egyptian Drug Authority

Figure (6): **Pharmaceutical, Biological Products and Medical Device**

5.4.3.2 Track and Trace:

Provides comprehensive documentation related to the Egyptian Pharmaceutical Track and Trace System (EPTTS), including implementation guides, technical requirements, user guides, market guidelines, identifier issuance guidance, XML messaging specifications, EPCIS event standards, and technical FAQs to support the commissioning, packaging, shipping, and traceability of pharmaceutical products throughout the supply chain.

5.4.3.3 Quick Links:

Provides direct access to the EDA's key electronic services, digital platforms, and inquiry systems, enabling users to efficiently access regulatory services, product information, company records, and other online resources

5.4.4 The Regulatory Reference of the Egyptian Drug Authority (EDA)

Provides structured access to regulatory guidelines, requirements, and centralized regulatory content issued by EDA.

When clicked, the tab expands to include:

5.4.4.1 Laws and Executive Regulations

Includes the laws, executive regulations, and official decisions governing the pharmaceutical sector, medical products, pharmacy practice, drug control, clinical research, and the regulatory functions of the Egyptian Drug Authority. It serves as an official legal reference for regulatory requirements and compliance

5.4.4.2 EDA Chairman Decrees

Includes official decrees and decisions issued by the Chairman of the Egyptian Drug Authority.

5.4.4.3 Egypt's National Drug Policy:

Provides the national strategic framework for strengthening the pharmaceutical sector by promoting access to safe, effective, and quality medical products, supporting their rational use, enhancing the pharmaceutical regulatory system, and advancing the EDA's regulatory maturity in alignment with national priorities and WHO Global Benchmarking Tool (WHO GBT) requirements.

5.4.4.4 The Regulatory Reference of the Egyptian Drug Authority (EDA)

Includes a comprehensive repository of regulatory references, decisions, guidelines, circulars, and official documents issued by the Egyptian Drug Authority. .

5.4.4.5 Regulatory Guidelines

Includes official guidelines issued by the Egyptian Drug Authority (EDA) to regulate pharmaceutical activities, ensure compliance, and support consistent regulatory decision-making across all sectors. It provides links to guidelines issued by the following central administrations, **as shown in the Figure (7)**

Figure (7): Guidelines Tab

5.4.4.6 Notice to Applicants

Includes official notices and regulatory updates issued by the Egyptian Drug Authority (EDA) to guide applicants on requirements, procedures, and compliance updates related to regulatory submissions **as shown in the Figure (8)**:

Figure (8): Notice to Applicants Tab

First: Notice to applicant of Central Administration of Pharmaceutical Policies and Market Access

Second: Notice to applicant of Central Administration for Biological Products, Innovative Products, and Clinical Studies

Third: Notice to applicant of Central Administration of Pharmaceutical Products

Fourth: Notice to applicant of Central Administration of Medical Devices

Fifth: Notice to applicant of Central Administration for Pharmaceutical Care

Sixth: Notice to applicant of Central Administration for Inspection of Pharmaceutical Establishments

Seventh: Notice to applicant of Central Administration of Drug Control

Eighth: Notice to applicant for Central Administration of Pharmaceutical Institutions Licensing

5.4.4.7 Guidance

Includes official EDA guidance documents that promote rational drug use, patient safety, and standardized pharmacy practice, with focus on antimicrobial stewardship, oncology pharmacy, and medication safety

5.4.4.8 Committees' Decisions:

Provides official decisions and resolutions issued by the EDA's technical and specialized committees, including the Technical Committee for Drug Control (TCDC), to support regulatory decision-making and pharmaceutical oversight.

5.4.4.9 The Egyptian Drug Formulary

Includes official (EDA) national formulary publications for 2023, 2024, and 2025, which support the rational use of medicines across major therapeutic areas. These publications provide evidence-based prescribing guidance covering key drug classes, including antimicrobial therapy, cardiovascular….etc .

5.4.4.10 Adopted References

Includes WHO technical guidelines and regulatory reference documents adopted by the EDA to support GMP, storage and distribution, stability, inspections, regulatory

review, and safe disposal of pharmaceuticals, ensuring compliance with international standards and promoting safe and effective pharmaceutical regulation.

5.4.5 Publications Reports &EDA in numbers

Includes official publications, regulatory reports, and documented outputs issued by the Egyptian Drug Authority (EDA). **When clicked, the tab expands to include:**

5.4.5.1 EDA in Numbers:

Presents key performance indicators, statistical reports, and operational metrics that highlight the Egyptian Drug Authority's regulatory activities and achievements. This section includes:

- Bio Inn Laboratory Evaluation Administration Activities
- GCP Inspection Metrics
- Pharmacovigilance Inspection Metrics
- Laboratory Testing Activities Metrics of the Central Administration of Drug Control (CADC)

5.4.5.2 Regulatory Reports

Provides access to official regulatory reports by the Egyptian Drug Authority (EDA) to promote transparency and communicate regulatory outcomes. This section includes inspection reports, licensing reports, registration-related reports, Public Assessment Reports (PARs) for pharmaceutical and biological products, Clinical Trial Application (CTA) Public Assessment Reports, Good Clinical Practice (GCP) Public Inspection Summary Reports as shown in the **Figure (9)**

Figure (9): regulatory reports

Regulatory Reports

Function	Report
Inspection	Summary of inspection reports for vaccine manufacturers
License	Summary of Factory License Reports
License	Summary of Warehouse Licensing Reports
Regestration Public assesment Reports (PAR)	C.A of pharmaceutical product G.A of Biological Products

5.4.5.3 EDA publications

5.4.5.3.1 Forms

Includes official regulatory and administrative forms required for applications, submissions, and other EDA-related procedures across all central administrations.

When the tab is clicked, it expands into sub-items to display the relevant categories under each central administration as shown in the form Figure (10), including:

- **Central Administration of Biological and Innovative Products, and Clinical Studies**
  Includes official regulatory forms used for the evaluation, registration, clinical trials, scientific support, and post-approval monitoring of biological and innovative medicinal products, as well as clinical research activities
- **Central Administration of Pharmaceutical Products**
  Includes official regulatory forms used for the application and evaluation of pharmaceutical-related products to ensure safety, quality, and regulatory compliance.
- **Central Administration of Medical Devices**

Includes official regulatory forms related to the regulation, registration, and market authorization of medical devices in Egypt.

- **Central Administration of Pharmaceutical Care**

  Includes official regulatory forms related to pharmaceutical care activities, marketing materials, and awareness or educational submissions.

- **Central Administration of Drug Control (CADC)**

  Includes official regulatory forms required for drug control procedures, submissions, and compliance processes.

Figure (10): Form tab

5.4.5.3.2 Periodic Lists

Includes official regulatory lists and updates issued by the Egyptian Drug Authority (EDA) to support pharmaceutical governance, safety, and quality assurance. These lists include key national references such as:

- CT Protocols Registry
- GCP Inspection Registry
- Bioequivalence & Stability Centers List
- Clinical Trials Registry

- National Essential Medicines List
- High Alert Medications List

5.4.5.3.3 EDA FAQs

Includes frequently asked questions and answers designed to provide clear guidance on EDA services. It is structured as a set of FAQs intended to help users understand key regulatory workflows and compliance requirements.

5.4.5.3.4 Monographs

Includes official pharmaceutical monographs that define standards, specifications, and quality requirements for medicinal substances and products, and includes the Egyptian Herbal Monograph.

5.4.6 Media Centre

Provides official media content, updates, and communications from the Egyptian Drug Authority (EDA), including news, events, videos, and regulatory announcements to support transparency and public awareness.

When clicked, the tab expands to include:

5.4.6.1 Events

Includes all conferences, workshops, seminars, and official events in which the Egyptian Drug Authority participates or organizes, highlighting national and international engagement activities.

5.4.6.2 Video Gallery

Includes official videos covering awareness campaigns, training activities, interviews, and documentation of EDA initiatives, programs, and public health messages.

5.4.6.3 News

Includes official press releases and updates on the Egyptian Drug Authority's activities, achievements, regulatory decisions, and public health initiatives.

5.4.6.4 Announcements

Includes official regulatory announcements, circulars, guidelines, and urgent communications issued by the Egyptian Drug Authority for stakeholders and the public.

5.4.7 Egyptian Pharmacopoeia

Provides official pharmaceutical standards, specifications, and reference information in the Egyptian Pharmacopoeia, aligned with international quality standards.

When clicked, the section expands to include:

5.4.7.1 Vision and Mission:

- **Vision:** To provide safe and effective medicines with the highest quality standards according to international specifications.
- **Mission:** To enhance and protect public health by setting standard criteria and specifications for controlling the quality of pharmaceutical raw materials, pharmaceutical and biological products to ensure their safety and efficacy, in coordination and cooperation with the pharmaceutical industry sector and international health authorities through the exchange of expertise and knowledge.

5.4.7.2 Commission Constitution

The Main Committee for the Egyptian Pharmacopoeia was formed by decision of the Chairman of the Egyptian Drug Authority, No. 198 for the year 2025.

5.4.7.3 News and Events

Includes all updates and news related to the pharmacopoeia

5.4.7.4 Participation Form

Anyone wishing to participate in the work of the Egyptian Pharmacopoeia should complete the participation form and send it to: ***pharmacopoeia@edaegypt.gov.eg***

5.4.7.5 Frequently Asked Questions (FAQ)

Contains the most frequently asked questions related to the Egyptian Pharmacopoeia.

5.4.7.6 Digital Content

To access the complete digital content of the Egyptian Pharmacopoeia, users may view the official database directly on the Egyptian Drug Authority website. For mobile accessibility, users can download the official Android application by scanning the QR code

5.4.7.7 Contact

For any inquiries related to the pharmacopoeia send it to: **pharmacopoeia@edaegypt.gov.eg**

5.4.8 Awareness

Provides awareness materials and public information to support the safe and effective use of medical products and promote public health awareness.

When clicked, the section expands to include the following main items:

5.4.8.1 Pharmaceutical Care Initiatives:

Presents awareness campaigns, initiatives, and activities related to pharmaceutical care and patient safety.

5.4.8.2 CA of pharmaceutical care publication that contain subitems:

- Pharmacovigilance publications
- Pharmacy practise newsletter

5.4.8.3 Recalls, Alers and Awareness Letters

When selected, this section expands to display the following sub-items:

- Recall and Alert Notice Letters, as presented in **Figure 11.**
- Awareness Letters, as presented in Figure 12

Figure 11: **Recall and Alert Notice Letters**

Recall Classification Recommendation Based on EDA Guidelines

Class	Definition	Level of recall
CLASS I Recall	For defective products that may cause serious health problems or lead to death	From distributor, retail and consumer levels.
CLASS II Recall	For A product that may cause a temporary health problem or pose a minor threat of a serious nature	From distributor and retail levels.
CLASS III Recall	For A product that is not likely to cause a health problem but violates labeling or manufacturing laws and guidelines	From distributor levels.

Figure 12: Awareness Letters

5.4.8.4 WHO Alerts

Provides safety warnings, alerts, and communications issued by the World Health Organization regarding medical products and public health concerns as shown on the **Figure 13.**

Figure 13: WHO Alerts

5.4.9 Localization of industry

Provides information on the Egyptian Drug Authority's initiatives, programs, and strategic efforts to support and promote the localization of the pharmaceutical industry in Egypt. This section includes the **Modern Pharmaceutical Industry Localization** subsection, which provides access to:

- Human Pharmaceutical Products Localization Roadmap.
- Biological Localization Roadmap.
- Medical devices Localization Roadmap.

5.4.10 Center for Continuing Professional Development (CPD)

it provides training programs, and professional development initiatives for healthcare and regulatory professionals. This section provides access to the activities, services, and initiatives of the EDA Center for Continuous Professional Development (CPD) and includes the following subsections as shown in **Figure 14**:

5.4.10.1 About the Center

Provides general information about the CPD Center, including its objectives, role, and scope of activities.

5.4.10.2 Upcoming Events

Includes the Training Programs Guide presented by the EDA Center for Continuous Professional Development. The Egyptian Drug Authority (EDA) announces its training plan and guide through this section. Company representatives interested in registering for training programs or workshops are encouraged to complete early registration by scanning the QR code associated with each program. The section also provides a contact list included in the guidance manual to facilitate inquiries and ensure effective communication regarding training programs.

5.4.10.3 Cooperation Protocols

Includes cooperation agreements between the Egyptian Drug Authority and various partners, such as pharmaceutical companies, healthcare institutions, and academic entities.

5.4.10.4 Achievements

Highlights the key accomplishments, milestones, and outputs of the CPD Center in supporting continuous professional development activities.

Figure 14: **CPD Screen**

5.5 Quick Navigation Examples

The EDA website provides practical navigation paths to help users quickly access key regulatory information and services. The following examples illustrate how users can locate commonly requested content:

5.5.1 Example 1: Registered pharmaceutical product

Step 1: From the Home Page, scroll down to the bottom of the page. Under the Electronic Programs and Applications section, select The Egyptian Drug Database (DDB), as shown in **Figure 15.**

Figure 15: Electronic Programs and Applications section

Step 2: The system will display the Egyptian Drug Database (DDB) page, as shown in **Figure 16.** Select the desired product category (Human Pharmaceutical, Biological, Herbal Medicine, Veterinary, Biocides, Cosmetics, or Complementary), then enter the Generic Name or Trade Name, type the displayed verification code, and click Search.

Figure 16: Egyptian Drug Database

Step 3: To search for a specific drug, select either the **Trade Name** or **Generic Name** search option. For example, enter **Panadol** as the **Trade Name** or **Paracetamol** as the **Generic Name**, enter the displayed verification code, and click **Search**, as shown in the next **Figure No. 17**.

Figure 17: **Search Tool for a Specific Drug**

5.5.1 Example 2: Public assessment Reports (PAR)

Step 1: On the home page of publication Reports and EDA in Numbers, select Regulatory Reports from the drop-down menu, click Public Assessment Reports (PAR).

Publication Reports and EDA in numbers as shown in the Figure 18.

Figure 18: Publication Reports and EDA in numbers tab:

Step 2: Once the Public Assessment Reports (PAR) page appears (Figure 19), select CA of Biological Product as an example.

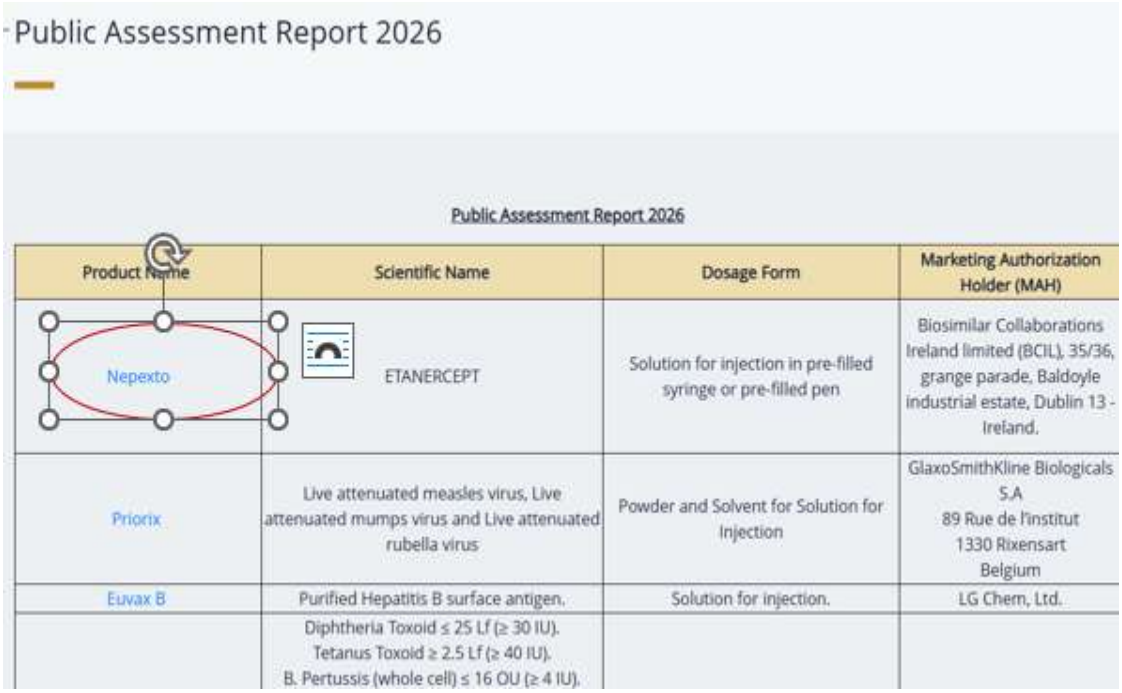
Figure 19: PAR page

Step 3: Once C Click CA of Biological Product. A list of Public Assessment Reports (PARs), arranged by publication year, will appear. For example, select the Public Assessment Report (PAR) for 2026, as shown in **Figure 20**

Figure 20: list of Public Assessment Reports

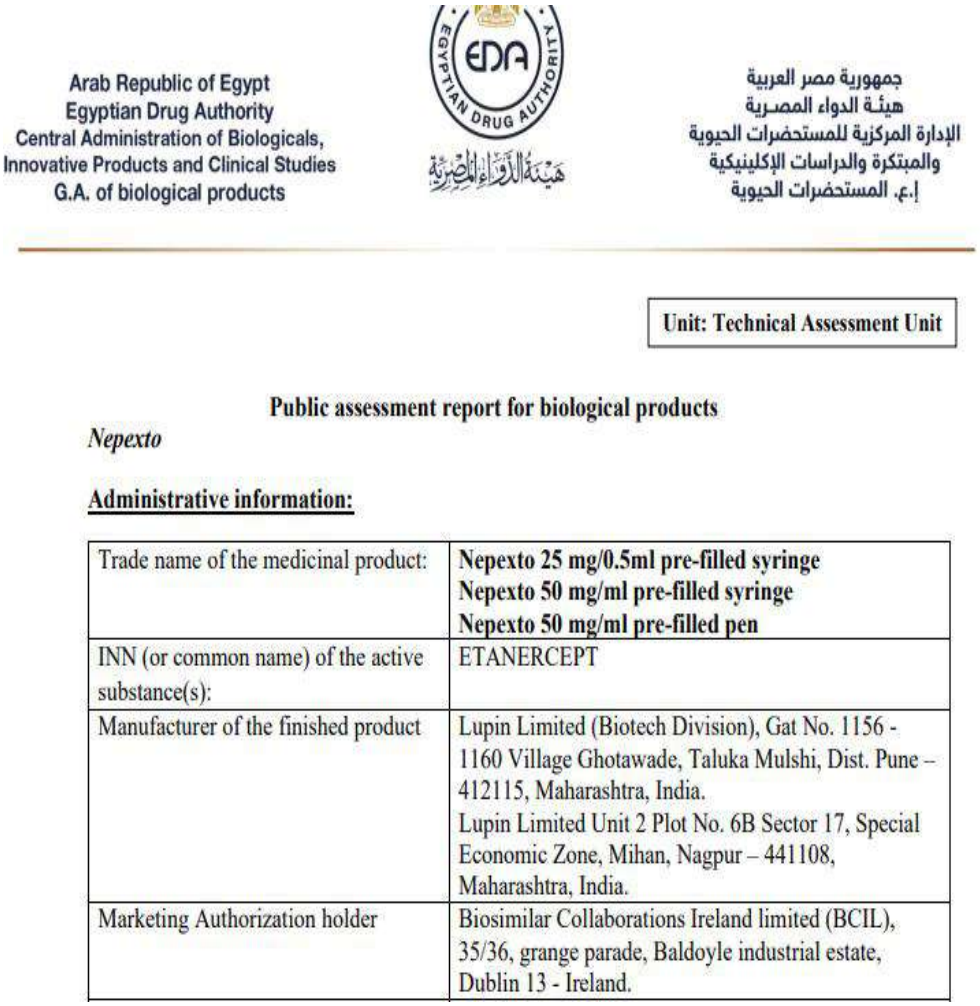
Step4: once click The Public Assessment Report 2026 page will appear, displaying the list of approved biological products for 2026, as shown in **Figure 21.** Select any product (e.g., Nepexto) to view its Public Assessment Report (PAR)

Figure 21: Approved PAR



Step 5: Once Click Nepexto. The corresponding Public Assessment Report (PAR) will open, as shown in **Figure 22**

Figure 22: Nepexto PAR



Arab Republic of Egypt
Egyptian Drug Authority
Central Administration of Biologicals, Innovative Products and Clinical Studies
G.A. of biological products

جمهورية مصر العربية
هيئة الدواء المصرية
الإدارة المركزية للمستحضرات الحيوية والمبتكرة والدراسات الإكلينيكية
إ.ع. المستحضرات الحيوية

Unit: Technical Assessment Unit

Public assessment report for biological products

Nepexto

Administrative information:

Trade name of the medicinal product:	**Nepexto 25 mg/0.5ml pre-filled syringe** **Nepexto 50 mg/ml pre-filled syringe** **Nepexto 50 mg/ml pre-filled pen**
INN (or common name) of the active substance(s):	ETANERCEPT
Manufacturer of the finished product	Lupin Limited (Biotech Division), Gat No. 1156 - 1160 Village Ghotawade, Taluka Mulshi, Dist. Pune – 412115, Maharashtra, India. Lupin Limited Unit 2 Plot No. 6B Sector 17, Special Economic Zone, Mihan, Nagpur – 441108, Maharashtra, India.
Marketing Authorization holder	Biosimilar Collaborations Ireland limited (BCIL), 35/36, grange parade, Baldoyle industrial estate, Dublin 13 - Ireland.

5.5.3 Example 3: Annual report

Step 1: From the Home Page, go to the Main Bar and select Publication Reports and EDA in numbers

Step 2: From the side menu, select Pharmacovigilance Inspection Metrics, as shown in **Figure 23**

Figure 23: Publication reports bar

Step 3: The system will display the available Annual Reports, organized by year, click on pharmacovigilance inspection metrics report for 2024 as shown in the next **Figure (24)**

Figure 24: Pharmacovigilance Inspection Metrics

Step 4: The system will display the corresponding Annual Report on pharmacovigilance inspection metrics for 2024 as shown in the **Figure 25**

Figure 25: pharmacovigilance inspection metrics for 2024

5.5.4 Example 4: GMP Licensing Inspection Report

Step 1: From the Home Page, go to the Main Bar and select Publication Reports EDA in numbers.

Step 2: From the side menu, select Regulatory Reports, then click Summary of Inspection Reports for Vaccine Manufacturers from the sub-menu, as shown in **Figure 26**

Figure 26: Summary of inspection reports for vaccine manufacturers

Step 3: A table containing the names of the vaccine manufacturers will be displayed. Select the desired manufacturer from the table (e.g., Zydus Life Sciences Limited – Vaccine Technology Center), as shown in **Figure 27**

Figure 27: Published Public Inspection Report

public inspection report	#
Zydus life sciences limited vaccine technology center	1
VACSERA, EGYVAC - Building 2	2
Biological E limited India	3
Beijing Minhai Biotechnology Co., Ltd	4
CanSino Biologics Inc- China	5

Step 4: The official EDA GMP Public inspection report document will open as shown in the next **Figure 28**

Figure 28: Example on EDA GMP Public Inspection Report

Arab Republic of Egypt
Egyptian Drug Authority
Central Administration of Inspection on Pharmaceutical Institutions
G.A. of factories inspection

جمهورية مصر العربية
هيئة الدواء المصرية
الإدارة المركزية للتفتيش على المؤسسات الصيدلية
إ.ع. التفتيش على المصانع

EDA GMP public inspection report

Part 1	***General information***
Manufacturers details	
Company information	
Name of manufacturer	*Zydus life sciences limited vaccine technology center*
Inspected site	
Address of inspected manufacturing site	*Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, 49 & 50* *Sarkhej- Bavla N.H. No. 8A, Opp. Ramdev Masala, Village - Chandar, Tai: Sanand, Dist.- Ahmedabad - 382 213* *Telephone number: +91-2717-664600* *Fax: +91-2717-664600* *Email address: Kapil.Maithal@zyduslife.com*
Inspection details	
Dates of inspection	*From 03 to 07 February 2025*
Type of inspection	*Overseas inspection prior registration of MMR vaccine* ***(drug substance - drug product)***
Introduction	
General information about the company and site	• *Live Viral Vaccine Plant (Plant-4) For manufacturing of drug substance of Live Viral Vaccines (Mump, Measles, Rubella)* • *3 laboratories for handling each of Measles, Mumps, Rubella virus separately. Formulation and filling are carried out in dedicated facility.* • *Fill finish facility (Plant-5/SVP 2) For filling of Live Virus Vaccines*
Brief report of inspection activities undertaken	
Scope and limitations	
Areas inspected	*Live Viral Vaccine Plant (Plant-4) is designed to manufacture and store concentrated bulk (single harvest) of Measles, Mumps, Rubell and varicella virus in dedicated blocks of Live Virus Production section. The facility is segregated based on the process activity such as media*

5.6 Update and Validation of website information

All published information on the EDA website is regularly reviewed, validated, and updated by the responsible departments to ensure accuracy, currency, and compliance with applicable regulatory requirements. Content is periodically assessed and revised, when necessary, with outdated information updated, archived, or removed, and significant changes managed under version control to ensure information integrity

6 References

6.1 WHO Global Benchmarking Tool (GBT) - RS09 for regulatory transparency and public access to information.

7 Annex:

- **N/A**

8 History Table

Version No.	Issue date	Summary of Changes
1/0	**New Issue**	NA